



State of Tennessee
Health Services and Development Agency
Andrew Jackson, 9th Floor, 502 Deaderick Street, Nashville, TN 37243

www.tn.gov/hsda Phone: 615-741-2364 Fax: 615-741-9884

Date: April 13, 2016

To: HSDA Members

From: *MNH*
Melanie M. Hill, Executive Director

Re: CONSENT CALENDAR JUSTIFICATION

Vanderbilt University Medical Center, Nashville (Davidson County), TN - CN1602-010

Modification of a hospital requiring a capital expenditure greater than 5 million dollars. The relocation of the Clinical Research Center (CRC) from the 3rd floor of Medical Center North to the 2nd floor of the Round Wing also in Medical Center North. The proposed new space will house 5 relocated inpatient medical/surgical licensed beds and 6 exam and outpatient rooms. Ancillary and administrative space will be added to support these programs. The estimated project cost is \$10,579,159.00.

As permitted by Statute and further explained by Agency Rule on the last page of this memo, I have placed this application on the consent calendar based upon my determination that the application appears to meet the established criteria for granting a certificate of need. If Agency Members determine that the criteria have been met, a member may move to approve the application by adopting the criteria set forth in this justification or develop another motion for approval that addresses each of the three criteria required for approval of a certificate of need. If you find one or more of the criteria have not been met, then a motion to deny is in order.

At the time the application entered the review cycle, it was not opposed. If the application is opposed prior to being heard, it will move to the bottom of the regular April agenda and the applicant will make a full presentation.

Summary—

The applicant, VUMC, is seeking approval for a major construction project with expenditures greater than 5 million dollars that involves the renovation and relocation of the Clinical Research Center (CRC).

VUMC is a non-profit hospital with 1,025 licensed beds and 134 CON approved but unimplemented beds. It operates a Level 1 Trauma Center, comprehensive Regional Burn Center, Level 4 NICU, Vanderbilt-Eskind Diabetes Center, Vanderbilt Ingram-Cancer Center, and the only National Cancer Institute designated comprehensive cancer center in Tennessee to treat both adult and pediatric cancer patients.

Please see the application for a description of the project.

Executive Director Justification -

Need- The need to renovate is evident based upon needing to meet current health facility guidelines including those for rare or unknown, highly communicable disease, such as the Ebola Virus Disease. The proposed project will promote a state of the art design that aligns with cutting edge patient-oriented research. The growth and expansion in both numbers of patients and types of research support this expansion with approximately 400 investigators conducting 500 unique research projects just in the last five years.

Economic Feasibility- The project will be funded by the cash reserves of Vanderbilt University Medical Center. A letter dated February 3, 2016 from Cecelia Moore, Vice Chancellor for Finance, confirmed that that VUMC as an operating unit of Vanderbilt University held cash and unrestricted investments with a fair market value of \$827 million.

Contribution to the Orderly Development of Health Care- The project does contribute to the orderly development of health care since this construction project will promote a state of the art design that aligns with cutting edge patient-oriented research. If VUMC is to maintain its top 10 ranking in terms of public and private research funding, the CRC must continue to it grow and expand, as well and meet stringent communicable disease requirements.

Statutory Citation -TCA 68-11-1608. Review of applications -- Report

(d) The executive director may establish a date of less than sixty (60) days for reports on applications that are to be considered for a consent or emergency calendar established in accordance with agency rule. Any such rule shall provide that, in order to qualify for the consent calendar, an application must not be opposed by any person with legal standing to oppose and the application must appear to meet the established criteria for the issuance of a certificate of need. If opposition is stated in writing prior to the application being formally considered by the agency, it shall be taken off the consent calendar and placed on the next regular agenda, unless waived by the parties.

Rules of the Health Services and Development Agency - 0720-10-.05 CONSENT CALENDAR

- (1) Each monthly meeting's agenda will be available for both a consent calendar and a regular calendar.
- (2) In order to be placed on the consent calendar, the application must not be opposed by anyone

having legal standing to oppose the application, and the executive director must determine that the application appears to meet the established criteria for granting a certificate of need. Public notice of all applications intended to be placed on the consent calendar will be given.

(3) As to all applications which are placed on the consent calendar, the reviewing agency shall file its official report with The Agency within thirty (30) days of the beginning of the applicable review cycle.

(4) If opposition by anyone having legal standing to oppose the application is stated in writing prior to the application being formally considered by The Agency, it will be taken off the consent calendar and placed on the next regular agenda. Any member of The Agency may state opposition to the application being heard on the consent calendar, and if reasonable grounds for such opposition are given, the application will be removed from the consent calendar and placed on the next regular agenda.

(a) For purposes of this rule, the "next regular agenda" means the next regular calendar to be considered at the same monthly meeting.

(5) Any application which remains on the consent calendar will be individually considered and voted upon by The Agency.

HEALTH SERVICES AND DEVELOPMENT AGENCY MEETING
APRIL 27, 2016
APPLICATION SUMMARY

NAME OF PROJECT: Vanderbilt University Medical Center

PROJECT NUMBER: CN1602-010

ADDRESS: 1211 Medical Center Drive
Nashville (Davidson County), Tennessee 37232

LEGAL OWNER: Vanderbilt University Medical Center
1211 Medical Center Drive
Nashville (Davidson County), Tennessee 37232

OPERATING ENTITY: Not Applicable

CONTACT PERSON: Ginna Felts
(615) 936-6005

DATE FILED: February 12, 2016

PROJECT COST: \$10,579,159

FINANCING: Cash Reserves

PURPOSE OF REVIEW: Modification of a hospital requiring a capital expenditure greater than \$5 million

DESCRIPTION:

Vanderbilt University Medical Center , a 1,025 licensed bed hospital with 134 CON approved but unimplemented beds has a Clinical Research Center (CRC) that has been providing a full-service hospital based clinical research center since 1967. Over the past five years the CRC has been used by 400 investigators to conduct 500 unique research projects. In the last year the CRC supported 210 active protocols serving all stages and types of research, with approximately 294 inpatients and 5,328 outpatient visits. The applicant proposes to relocate the CRC from the third floor of the Medical Center North Building to the second floor of the Round Wing also part of the Medical Center North building. The relocated CRC will house 5 relocated inpatient licensed beds and 6 exam/outpatient rooms. In addition, ancillary and administration space will be

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added to support these programs. The total licensed bed complement of the medical center will not change due to this project.

The applicant has been placed under **CONSENT CALENDAR REVIEW** in accordance with TCA 68-11-1608(d) and Agency Rule 0720-10-.05.

CRITERIA AND STANDARDS REVIEW

CONSTRUCTION, RENOVATION, EXPANSION, AND REPLACEMENT OF HEALTH CARE INSTITUTIONS

2. **For renovation or expansions of an existing licensed health care institution:**
 - a. **The applicant should demonstrate that there is an acceptable existing demand for the proposed project.**

Over the past five years the CRC has been used by 400 investigators to conduct 500 unique research projects. In the last year the CRC supported 210 active protocols serving all stages and types of research, with approximately 294 inpatients and 5,328 outpatient visits.

It appears that the application meets this criterion.

- b. **The applicant should demonstrate that the existing physical plant's condition warrants major renovation or expansion.**

The existing space for the CRC was last renovated in 1971. Various work-flow adaptations, changes in equipment, shifts to private patient rooms, and increases in outpatient services have made the existing space inefficient.

It appears that the application meets this criterion.

STAFF SUMMARY

Note to Agency members: This staff summary is a synopsis of the original application and supplemental responses submitted by the applicant. Any HSDA Staff comments will be presented as a "Note to Agency members" in bold italics.

The applicant is proposing to relocate its Clinical Research Center (CRC) from the 3rd floor of the Medical Center North building to the 2nd floor of the Round Wing, which is an extension of Medical Center North. The relocated space will include 5 relocated inpatient licensed beds and 6 exam rooms. Two of the inpatient rooms will be designed to meet requirements established by the Vanderbilt Communicable Disease Response Team (CDRT) for the Communicable Disease Response Unit (CDRU). The CDRU is a state of the art facility designed for the care of a patient with a rare or unknown, highly communicable disease, such as the Ebola Virus Disease.

The second floor of the Round Wing was previously used as an Education and Learning Center. These functions were moved to alternative locations on the medical center campus. The CDRU is currently located in a small area of the second floor space and will be incorporated within the renovated CRC as a multi-use space.

After relocation of the CRC the existing space on the 3rd floor will be temporarily utilized by other Vanderbilt University Hospitals (VUH) nursing units while cosmetic upgrades are completed. A final use of the space has not been determined.

Some of the programs that have used the CRC include Vaccine Development, Alzheimer's Research, Cancer Clinical Trials, Kidney Diseases and Diabetes Research, Clinical Pharmacology Research, Special Populations-Prader Willi Syndrome, and Undiagnosed Disease Research. For more information regarding the programs utilizing the CRC, see pages 7-10 and pages 16-110 of Supplemental #1.

Need

The need for this project is based on the following:

- Space for the CRC has not been renovated since 1971. Various work-flow adaptations, changes in equipment, shifts to private patient rooms, and increases in outpatient services have made the existing space inefficient.
- The relocation will promote a state of the art design that aligns with the cutting edge patient oriented research and place the center closer to the clinical core of the medical center.

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- The current space for the CRC on the third floor of Medical Center North utilizes 20,325 SF. The proposed location for the CRC on the second floor of the Round Wing will be a more efficient layout reducing square footage of the CRC by 6,654 SF.
- Relocating to a different location will allow a single move, rather than a phased renovation within the existing third floor space.
- The proposed 2nd floor location provides a grade level drop-off and entry for ambulatory patients, a connection to the hospital via a patient-transport tunnel and close proximity to parking and shuttle services.
- The proposed CRC is also directly below 6 floors of inpatient beds and located at the center of the clinical enterprise.

An overview of the project is provided on pages 4-5 of the original application.

The proposed project is scheduled to take approximately 13 months with an expected completion by September 2017.

Ownership

- Vanderbilt University (VU), by and through its Vanderbilt University Medical Center (VUMC), owns Vanderbilt University Hospital (VUH), the Monroe Carell Jr. Children's Hospital at Vanderbilt (MCJCHV), and the Psychiatric Hospital at Vanderbilt (VPH). All three facilities are operated under one license as Vanderbilt University Hospitals and are known collectively as Vanderbilt University Medical Center.
- It is anticipated during the first half of 2016 that VU will sell substantially all the clinical assets used in the operation of VUMC to a newly formed not-for-profit, tax-exempt Tennessee corporation. The new corporation will also be named Vanderbilt University Medical Center and will operate independently of VU.

Facility Information

- A floor plan drawing of the proposed space for the CRC is included in Attachment B. IV.
- The project includes approximately 13,672 square feet (SF) of space: 11,183 renovated SF and 2,489 SF of new construction. The space for the proposed project includes 5 inpatient rooms and 6 exam/outpatient rooms.
- VUMC is currently licensed as a 1,025 bed acute care hospital. The Joint Annual Report for 2014 indicates VUMC staffs 1,004 beds. Licensed bed occupancy was 80.9% and staffed bed occupancy was 82.6%.

The following provides the Department of Health's definition of the two bed categories pertaining to occupancy information provided in the Joint Annual Reports:

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- *Licensed Beds* - The maximum number of beds authorized by the appropriate state licensing (certifying) agency or regulated by a federal agency. This figure is broken down into adult and pediatric beds and licensed bassinets (neonatal intensive or intermediate care bassinets).
- *Staffed Beds* - The total number of adult and pediatric beds set up, staffed and in use at the end of the reporting period. This number should be less than or equal to the number of licensed beds.

Service Area Demographics

The applicant's declared service area includes all Tennessee Counties and 30 counties in western Kentucky.

- Using information from Truven Health Analytics, the applicant reports a total population of Tennessee in 2015 was 6,562,534 and is expected to increase 3.5% to 6,794,943 by 2020. The Kentucky counties reported 841,116 population increasing 1.1% to 850,139 in 2020.
- The total 65+ age population in Tennessee is estimated at 1,003,750 in 2015 and projected to grow 18.6% to 1,190,490 in 2020. The Kentucky counties estimated Age 65+ population is 137,803 in 2015 projected to grow 13.3% to 156,174 in 2020.
- As of March 2016, approximately 22.4% of Tennessee residents were enrolled in the TennCare program.

Source: Truven Health Analytics; TennCare; 2000-2020 Population Projections, Tennessee Department of Health, Division of Policy, Planning and Assessment, Office of Health Statistics.

Service Area Historical Utilization

The applicant reports that there are no other programs comparable to the CRC in Tennessee.

Applicant's Historical and Projected Utilization

Vanderbilt University Medical Center Clinical Research Historical Utilization

Variable	2013	2014	2015	'13-'15 % change
Inpatient Admissions	463	390	299	-35.4%
Inpatient Days	1,119	772	597	-46.6%
Occupancy %	22%	15%	12%	-45.5%
ALOS	3.0	2.0	2.0	-33.3%
Outpatient Visits	5,710	6,415	5,374	-5.9%

Source: CN1602-010

- The previous table indicates inpatient volumes in the CRC declined by over 46% between 2013 and 2015.
- Outpatient visits in the CRC declined by almost 6% between 2013 and 2015.
- The applicant states that it is extremely difficult to project patient census in the CRC for several reasons: types of projects open for recruitment, patient eligibility to a current open trial and patient retention and completion in a clinical trial. Additionally the type of patient (inpatient, observation, outpatient) is difficult to project as well and varies depending on the course of treatment. The applicant assumes that future volumes will be comparable to 2015 volumes.

Project Cost

Major costs are:

- Construction Costs plus contingencies-\$9,240,000 or 87.3% of total cost.
- Architectural and Engineering Fees-\$1,270,500 or 12.0% of the total cost.
- For other details on Project Cost, see the Project Cost Chart in the original application.
- The total renovation construction cost is \$523 per square foot (/SF), and the new construction cost per square foot is \$1,025/SF.
- As reflected in the table below, the proposed project's new construction and renovated construction cost are both above the third quartile cost of statewide hospital construction projects from 2012 to 2014. In fact the proposed renovation costs are 75% higher than the third quartile and new construction costs are 245% above the third quartile.
- Factors contributing to estimated constructed costs being significantly higher than those in the table below include the large amount of infrastructure required. In addition to replacing two existing air handling units, with a replacement cost of approximately \$2,000,000, a new emergency power feed will be added to replace an existing emergency generator. The new construction component of the project represents an extension of the existing façade, and includes new footings, site work, structure, and canopy that are not clearly captured when comparing projects on a square-foot basis.

**Statewide Hospital Construction Cost per Square Foot
2012-2014**

	Renovated Construction	New Construction	Total Construction
1st Quartile	\$110.98/sq. ft.	\$224.09/sq. ft.	\$156.78/sq. ft.
Median	\$192.46/sq. ft.	\$259.66/sq. ft.	\$227.88/sq. ft.
3rd Quartile	\$297.82/sq. ft.	\$296.52/sq. ft.	\$298.66/sq. ft.

Source: HSDA Applicant's Toolbox

Historical Data Chart

- According to the Historical Data Chart VUMC reported a net operating loss after capital expenditures of \$23,201,130 in 2013; however reported net operating incomes of \$102,579,776 in 2014 and \$215,576,897 in 2015.
- The applicant provided a Historical Data Chart for the CRC in Supplemental #1. For years 2013-2015, the CRC broke even since the operation of the unit is totally dependent on grant monies.

Projected Data Chart

The applicant provided a Projected Data Chart for the CRC

- The applicant projects \$1,822,183 of revenue in both FY2017 and FY 2018 and \$1,822,183 in operating expenses resulting in \$0 net income. This is based on a combination of inpatients discharges and outpatient visits totaling 5,672.
- The CRC has historically been funded by a variety of funding sources to include federal and non-federal grants, industry pharmaceutical clinical trial funds, and other research funds. The cost of operating the CRC has been covered by a combination of these sources (largely grant funds) for the past 9 years and will continue through the current grant period that ends May 31, 2017. The applicant expects to submit a renewal application that would extend the support period at least 5 years beyond 2017. Neither the patient nor third-party payors will be billed for services.

Charges

Dividing gross revenue by the number of patients projected to be seen at the CRC calculates to an average gross charge of \$325; however as stated previously neither patient nor third-party payor will be charged as the funding is essentially all grant monies.

Medicare/TennCare Payor Mix

- Neither the patient nor third-party payors will be billed for services.

Financing

The proposed project will be funded from cash reserves. A February 3, 2016 letter from Cecelia Moore, Associate Vice Chancellor for Finance, Vanderbilt University confirms that Vanderbilt University Medical Center as an operating unit of Vanderbilt University held cash and unrestricted investments with a fair market value of \$827 million.

According to the 2015 Financial Report, Vanderbilt University has working capital cash and investments of \$1,230 million.

Staffing

The applicant's proposed direct patient care staffing includes the following:

Position	Current	Proposed	Difference
Outpatient RN	14	12	-2
Inpatient RN	4	4	0
Ultrasound Technician	1	1	0
Metabolic Technician	1	0	-1
Total	20	17	-3

Source: CN1502-022

Licensure/Accreditation

Vanderbilt University Hospitals is licensed by the Tennessee Department of Health, Division of Health Care Facilities and accredited by The Joint Commission.

Corporate documentation, real estate deed information, and list of contracts are on file at the Agency office and will be available at the Agency meeting.

Should the Agency vote to approve this project, the CON would expire in **three** years.

CERTIFICATE OF NEED INFORMATION FOR THE APPLICANT

There are no other Letters of Intent, denied or pending applications for this applicant.

Vanderbilt University Hospitals, CN1406-021A, has an outstanding Certificate of Need that will expire on November 1, 2020. The CON was approved at the September 24, 2014 Agency meeting for the relocation of the obstetrical program, the newborn nursery, and the neonatal unit from Vanderbilt University Hospital to Monroe Carell Jr. Children's Hospital, the addition of 23 obstetrical beds and 24 neonatal/pediatric critical care beds, the addition of 61 adult acute care beds,

Vanderbilt University Medical Center

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the renovation of 79,873 square feet and new construction of 126,686 square feet. The estimated total project cost is **\$118,276,950.00**. *Project status update: Based on an Annual Progress Report dated 10/29/15, the plans for two observation units were approved by the Department of Health for construction. These units will open in two phases and are expected to be completed by late 2016. Construction on the other remaining components of this project will not begin until CN0710-075AE, Monroe Carell Jr. Children's Hospital at Vanderbilt, is completed.*

Monroe Carell Jr. Children's Hospital at Vanderbilt, CN0710-075AE, has an outstanding Certificate of Need that will expire on March 1, 2018. The Certificate of Need was approved at the January 23, 2008 Agency meeting to expand the existing Monroe Carell Jr. Children's Hospital (MCJCHV) through an adjacent building connected to the existing hospital. The expansion will provide 90 additional pediatric acute critical care beds, 26 neonatal intensive care beds (16 relocated), and an expanded obstetrical service including 36 relocated postpartum beds, 12 new antepartum beds, 16 labor and delivery suites (12 relocated), 2 relocated operating rooms and 1 new obstetric operating room. Five pediatric operating rooms are proposed on the third floor which will also contain 5 additional shelled operating rooms to accommodate continued growth. MCJCHV is not licensed separately from Vanderbilt University Hospital (VUH). VUH's licensed bed capacity will increase from 946 to 1,051. The estimated project cost is **\$120,000,000.00**. *Project Status: During the January 22, 2014 meeting the following was approved: request for modification in the floor plan which resulted in a decrease in square footage from 372,140 SF to 210,000 SF and decreasing the project cost from \$248,326,286 to \$120,000,000. The project was granted a 4 year extension to March 1, 2018. According to the Annual Progress Report submitted 2/25/2016, construction documents were to be issued on March 18, 2016. Preconstruction work has been authorized including scanning existing structure and testing of concrete. A crane has been reserved and will be in place in July 2016.*

CERTIFICATE OF NEED INFORMATION FOR OTHER SERVICE AREA FACILITIES:

There are no other Letters of Intent, denied or pending applications, or outstanding Certificates of Need for other health care organizations in the service area proposing this type of service.

PLEASE REFER TO THE REPORT BY THE DEPARTMENT OF HEALTH, DIVISION OF HEALTH STATISTICS, FOR A DETAILED ANALYSIS OF THE STATUTORY CRITERIA OF NEED, ECONOMIC FEASIBILITY, AND CONTRIBUTION TO THE ORDERLY DEVELOPMENT OF HEALTH CARE IN THE AREA FOR THIS PROJECT. THAT REPORT IS ATTACHED TO THIS SUMMARY IMMEDIATELY FOLLOWING THE COLOR DIVIDER PAGE.

MAF
(04/12/2016)

LETTER OF INTENT



State of Tennessee
Health Services and Development Agency

Andrew Jackson Building, 9th Floor
 502 Deaderick Street
 Nashville, TN 37243

www.tn.gov/hsda Phone: 615-741-2364 Fax: 615-741-9884

LETTER OF INTENT

The Publication of Intent is to be published in the Tennessean which is a newspaper
 of general circulation in Davidson, Tennessee, on or before February 10, 2016,
 for one day.
(Name of Newspaper)
(County) (Month / day) (Year)

This is to provide official notice to the Health Services and Development Agency and all interested parties, in accordance with T.C.A. § 68-11-1601 *et seq.*, and the Rules of the Health Services and Development Agency, that:

Vanderbilt University Hospitals an existing acute care hospital
(Name of Applicant) (Facility Type-Existing)

owned by: Vanderbilt University with an ownership type of not-for-profit

and to be managed by: Vanderbilt University Hospitals intends to file an application for a Certificate of Need for [PROJECT DESCRIPTION BEGINS HERE]: the renovation and the relocation of the inpatient unit operated as the Clinical Research Center on the campus of Vanderbilt University Hospitals at 1211 Medical Center Drive, Nashville, Tennessee. The project will require approximately 13,672 square feet of renovation. The project does not involve the initiation of new health care services for which a certificate of need is required or the acquisition of major medical equipment. The project will not change the number of licensed beds at Vanderbilt University Hospitals. The estimated project cost is \$10,579,159.

The anticipated date of filing the application is: February 12, 2016

The contact person for this project is Ginna Felts Vice President, Business Development
(Contact Name) (Title)

who may be reached at: Vanderbilt University Medical Center 3319 West End Avenue, Suite 920
(Company Name) (Address)

Nashville TN 37203 615/936-6005
(City) (State) (Zip Code) (Area Code / Phone Number)

Ginna Felts 2.10.16 ginna.rader@vanderbilt.edu
(Signature) (Date) (E-mail Address)

**ORIGINAL
APPLICATION**

FEB 12 '16 4:40:27

Name of Facility, Agency, or Institution

14

1.

Vanderbilt University Hospitals
Name

1211 Medical Center Drive
Street or Route

Nashville
City

TN
State

Davidson
County

37232
Zip Code

2. Contact Person Available for Responses to Questions

Ginna Felts
Name

Vice President, Business Development
Title

Vanderbilt University Medical Center
Company Name

ginna.rader@vanderbilt.edu
Email address

3319 West End Ave. Suite 920
Street or Route

Nashville
City

TN
State

37203
Zip Code

Employee
Association with Owner

615-936-6005
Phone Number

615-936-5310
Fax Number

3. Owner of the Facility, Agency or Institution: Attachment A.3

Vanderbilt University Medical Center
Name

615-322-3454
Phone Number

1211 Medical Center Drive
Street or Route

Davidson
County

Nashville
City

TN
State

37232
Zip Code

4. Type of Ownership of Control (Check One): Attachment A.4

- A. Sole Proprietorship _____
- B. Partnership _____
- C. Limited Partnership _____
- D. Corporation (For Profit) _____
- E. Corporation (Not-for-Profit) X

- F. Government (State of TN or Political Subdivision) _____
- G. Joint Venture _____
- H. Limited Liability Company _____
- I. Other (Specify) _____

5.	<u>Name of Management/Operating Entity (If Applicable)</u>		

	Name		
	_____	_____	_____
	Street or Route		County
	_____	_____	_____
	City	State	Zip Code
6.	<u>Legal Interest in the Site of the Institution (Check One): Attachment A.6</u>		
	A. Ownership	<u> X </u>	D. Option to Lease
	B. Option to Purchase	_____	E. Other (Specify) _____
	C. Lease of _____ Years	_____	_____
7.	<u>Type of Institution (Check as appropriate--more than one response may apply)</u>		
	A. Hospital (Specify) _____	<u> X </u>	I. Nursing Home
	B. Ambulatory Surgical Treatment Center (ASTC), Multi-Specialty	_____	J. Outpatient Diagnostic Center
	C. ASTC, Single Specialty	_____	K. Recuperation Center
	D. Home Health Agency	_____	L. Rehabilitation Facility
	E. Hospice	_____	M. Residential Hospice
	F. Mental Health Hospital	_____	N. Non-Residential Methadone Facility
	G. Mental Health Residential Treatment Facility	_____	O. Birthing Center
	H. Mental Retardation Institutional Habilitation Facility (ICF/MR)	_____	P. Other Outpatient Facility (Specify) _____
			Q. Other (Specify) _____
8.	<u>Purpose of Review (Check) as appropriate--more than one response may apply)</u>		
	A. New Institution	_____	G. Change in Bed Complement
	B. Replacement/Existing Facility	_____	[Please note the type of change by underlining the appropriate response: Increase, Decrease, Designation, Distribution, Conversion, <u>Relocation</u>]
	C. Modification/Existing Facility	<u> X </u>	
	D. Initiation of Health Care Service as defined in TCA § 68-11-1607(4) (Specify) Ambulatory Surgery	_____	H. Change of Location
	E. Treatment Center	_____	I. Other (Specify) _____
	F. Discontinuance of OB Services	_____	
	G. Acquisition of Equipment	_____	

9. Bed Complement Data

Please indicate current and proposed distribution and certification of facility beds.

RESPONSE: Please see the completed bed chart below.

	Current Beds Licensed	CON Approved Bed Projects (Unimplemented)	Staffed Beds	Beds Proposed (in this CON)	Total Beds at Completion (of all Projects)
A. Medical	235	(10)	210	-	225
B. Surgical	222	61	222	-	283
C. Long-Term Care Hospital	-	-	-	-	-
D. Obstetrical	50	23	50	-	73
E. ICU/CCU (+PICU)	205	60	205	-	265
F. Neonatal	96	-	100	-	96
G. Pediatric	129	-	129	-	129
H. Adult Psychiatric	88	-	88	-	88
I. Geriatric Psychiatric	-	-	-	-	-
J. Child/Adolescent Psychiatric	-	-	-	-	-
K. Rehabilitation	-	-	-	-	-
L. Nursing Facility (non-Medicaid Certified)	-	-	-	-	-
M. Nursing Facility Level 1 (Medicaid only)	-	-	-	-	-
N. Nursing Facility Level 2 (Medicare only)	-	-	-	-	-
O. Nursing Facility Level 2 (dually certified Medicaid/Medicare)	-	-	-	-	-
P. ICF/MR	-	-	-	-	-
Q. Adult Chemical Dependency	-	-	-	-	-
R. Child and Adolescent Chemical Dependency	-	-	-	-	-
S. Swing Beds	-	-	-	-	-
T. Mental Health Residential Treatment	-	-	-	-	-
U. Residential Hospice	-	-	-	-	-
TOTAL	1,025	134	1,004	-	1,159

10 Medicare Provider Number 440039: Acute Care
 Certification Type Inpatient facility

11. Medicaid Provider Number 440039: Acute Care
 Certification Type Inpatient facility

12. If this is a new facility, will certification be sought for Medicare and/or Medicaid?
 RESPONSE: Not Applicable

13. Identify all TennCare Managed Care Organizations/Behavioral Health Organizations (MCOs/BHOs) operating in the proposed service area. Will this project involve the treatment of TennCare participants? YES If the response to this item is yes, please identify all MCOs/BHOs with which the applicant has contracted or plans to contract.
 RESPONSE: Not applicable to this project; the payers are not billed for services provided to patients. However, please see Attachment A.13 for existing MCO contracts with Vanderbilt University Medical Center.

- I. Provide a brief executive summary of the project not to exceed two pages. Topics to be included in the executive summary are a brief description of proposed services and equipment, ownership structure, service area, need, existing resources, project cost, funding, financial feasibility and staffing.

RESPONSE: Vanderbilt University (VU), by and through its Vanderbilt University Medical Center, owns the Vanderbilt University Hospital (VUH), the Monroe Carell Jr. Children's Hospital at Vanderbilt (MCJCHV), and Vanderbilt Psychiatric Hospital (VPH). These facilities operate under one hospital license as Vanderbilt University Hospitals, and they as well as their associated clinics are collectively known as Vanderbilt University Medical Center (VUMC). It is anticipated that during the first half of 2016, VU will sell substantially all the clinical assets used in the operation of Vanderbilt University Medical Center to a newly formed not-for-profit, tax-exempt Tennessee corporation, which similarly will be named "Vanderbilt University Medical Center." This new entity will operate independently of VU. (Please see Attachment Section B.1 for pre- and post-Closing organizational charts.)

VUMC provides a number of clinical services unique to its region including: a Level 1 Trauma Center, a comprehensive Regional Burn Center, a Level 4 Neonatal Intensive Care Unit, the Vanderbilt-Eskind Diabetes Center and the Vanderbilt-Ingram Cancer Center, the only National Cancer Institute-designated comprehensive cancer center in Tennessee to treat both adult and pediatric cancer patients.

Both the Vanderbilt University School of Medicine and the Vanderbilt University School of Nursing are recognized by *U.S. News & World Report's* Best Graduate Schools rankings as among the nation's best with the School of Medicine currently ranking 14th and the School of Nursing 11th.

Vanderbilt University Hospital and the Monroe Carell Jr. Children's Hospital at Vanderbilt were recognized again this year by *U.S. News & World Report* magazine's Best Hospitals rankings as being among the nation's best with a combined 18 nationally ranked specialty programs.

Vanderbilt University School of Medicine's biomedical research program has earned its place among the nation's top 10 academic medical centers in terms of public and private research funding, receiving more than \$500 million in total funding during the current fiscal year.

The Clinical Research Center (CRC) is the core physical research hub within the Vanderbilt Institute for Clinical and Translational Research (Vanderbilt CTSA) that has been providing a full-service, hospital-based, clinical research center since 1967. Growth and expansion in both numbers of patients and types of research have been extensive over the past decades. Over the past five years, the CRC has been used by 400 investigators to conduct 500 unique research projects. In the last year, the CRC supported 210 active protocols serving all stages and types of research, with approximately 294 inpatients and 5,328 outpatient visits. These research efforts are supported by both federal and non-federal sources.

The current CRC is located on the third floor of Medical Center North. Although the current CRC has been well-utilized and has supported tremendous research accomplishments, the proposed new space will add convenience to patients and researchers as well as promote a state of the art design that aligns with the cutting edge patient oriented research. The CRC brings value to the Vanderbilt research enterprise and can grow in significance with a more prominent and well-designed space and configuration. The proposed new space, which will be located on the second floor of the Round Wing, will house five (5) relocated inpatient licensed beds and six (6) exam and outpatient rooms. Two of the five inpatient rooms will be designed to meet requirements established by the Vanderbilt Communicable Disease Response Team (CDRT) for the Communicable Disease Response Unit (CDRU). The CDRU is a state-of-the-art facility designed for the care of a

patient with a rare or unknown, highly communicable disease, such as the Ebola Virus Disease (EVD). The unit consists of three distinct areas: patient room, anteroom, and nurse station. It provides a safe environment to care for patients while protecting staff, other patients, and the local community. Patient care is provided by the CDRT. This team consists of volunteers from the following disciplines: nurses, physicians, paramedics, and educators from the adult and pediatric enterprise. Each team member possesses knowledge and/or skills necessary to care for patients who require intensive medical care. Each volunteer also receives intensive training in the care of patients with highly communicable, serious infectious diseases. Initial and ongoing training are key principles to maintaining staff competencies. These training efforts include specific disease pathology, personal protective equipment (PPE), and infection control measures.

The project is for the renovation of a hospital in excess of \$5 million. No major medical equipment will be involved. The total licensed bed compliment at the medical center will not be changed.

The scope of renovation is approximately 13,672 GSF and is projected to cost \$10,579,159. Funding will be provided through cash reserves.

- ii. Provide a detailed narrative of the project by addressing the following items as they relate to the proposal
- A. Describe the construction, modification and/or renovation of the facility (exclusive of major medical equipment covered by T.C.A. § 68-11-1601 et seq.) including square footage, major operational areas, room configuration, etc. Applicants with hospital projects (construction cost in excess of \$5 million) and other facility projects (construction cost in excess of \$2 million) should complete the Square Footage and Cost per Square Footage Chart. Other facility projects need only complete Parts B.-E. Please also discuss and justify the cost per square foot for this project.

If the project involves none of the above, describe the development of the proposal.

RESPONSE: The Clinical Research Center (CRC) is a full-service, hospital-based, clinical research center. The center is currently located on the third floor of Medical Center North and will be relocated to the second floor of the Round Wing. This relocation will promote a state of the art design that aligns with the cutting edge patient oriented research and place the center closer to the clinical core of the medical center. The proposed new space will house five (5) relocated inpatient medical/ surgical licensed beds and six (6) exam and outpatient rooms. In addition, ancillary and administration space will be added to support these programs.

The scope of renovation is approximately 13,672 GSF. This includes expansion and renovation of the second floor footprint. A dedicated entry to the CDRU will be required. In addition, the renovation will convert the second floor of the Round Wing from business occupancy to institutional occupancy, requiring existing infrastructure including emergency power and HVAC to be upgraded to current code requirements. The project is scheduled to take approximately 13 months and is projected to cost \$10,579,159.

- B. Identify the number and type of beds increased, decreased, converted, relocated, designated, and/or redistributed by this application. Describe the reasons for change in bed allocations and describe the impact the bed change will have on the existing services.

RESPONSE: The chart below portrays the bed assignments at the medical center. Five licensed medical/ surgical beds will be relocated from the current CRC to the new proposed location. The total licensed bed compliment at the medical center will not be changed.

	Current Beds Assignment *	Proposed Bed Assignment	+/-
Medical/ Surgical	508	508	-
Obstetrical	73	73	-
ICU/CCU (+PICU)	265	265	-
Neonatal	96	96	-
Pediatric	129	129	-
Psychiatry	88	88	-
TOTAL	1,159	1,159	-

*Includes remaining approved but unimplemented bed projects

- C. As the applicant, describe your need to provide the following health care services (if applicable to this application):

RESPONSE: Not Applicable.

1. Adult Psychiatric Services
2. Alcohol and Drug Treatment for Adolescents (exceeding 28 days)
3. Birthing Center
4. Burn Units
5. Cardiac Catheterization Services
6. Child and Adolescent Psychiatric Services
7. Extracorporeal Lithotripsy
8. Home Health Services
9. Hospice Services
10. Residential Hospice
11. ICF/MR Services
12. Long-term Care Services
13. Magnetic Resonance Imaging (MRI)
14. Mental Health Residential Treatment
15. Neonatal Intensive Care Unit
16. Non-Residential Methadone Treatment Centers
17. Open Heart Surgery
18. Positron Emission Tomography
19. Radiation Therapy/Linear Accelerator
20. Rehabilitation Services
21. Swing Beds

- D. Describe the need to change location or replace an existing facility.

RESPONSE: This project does not include change in location or replacement of an existing facility.

- E. Describe the acquisition of any item of major medical equipment (as defined by the Agency Rules and the Statute) which exceeds a cost of \$2.0 million; and/or is a magnetic resonance imaging (MRI) scanner, positron emission tomography (PET) scanner, extracorporeal lithotripter and/or linear accelerator by responding to the following:

RESPONSE: Not Applicable. No major medical equipment will be involved.

1. For fixed-site major medical equipment:
 - a. Describe the new equipment, including:
 1. Total cost; (As defined by Agency Rule).
 2. Expected useful life;
 3. List of clinical applications to be provided; and
 - b. Documentation of FDA approval.
 - c. Provide current and proposed schedules of operations

2. For mobile major medical equipment:
 - a. List all sites that will be served;
 - b. Provide current and/or proposed schedule of operations;
 - c. Provide the lease or contract cost;
 - d. Provide the fair market value of the equipment; and
 - e. List the owner for the equipment.
3. Indicate applicant's legal interest in equipment (i.e., purchase, lease, etc.) In the case of equipment purchase include a quote and/or proposal from an equipment vendor, or in the case of an equipment lease provide a draft lease or contract that at least includes the term of the lease and the anticipated lease payments.

III. (A) Attach a copy of the plot plan of the site on an 8 1/2" x 11" sheet of white paper which must include:

1. Size of site (in acres);
2. Location of structure on the site; and
3. Location of the proposed construction;
4. Names of streets, roads or highway that cross or border the site.

RESPONSE: The medical center campus is approximately of 16.5 acres, with the hospitals comprising of 6.5 acres. Please see Attachment B.Project Description.III.A

(B) 1. Describe the relationship of the site to public transportation routes, if any, and to any highway or major road developments in the area. Describe the accessibility of the proposed site to patients/clients.

RESPONSE: VUMC is accessible from most major transportation routes including Highways I-65, I-440, and I-40. Public transportation access includes bus stops near the hospital on 21st Avenue South.

IV. Attach a floor plan drawing for the facility which includes legible labeling of patient care rooms (noting private or semi-private), ancillary areas, equipment areas, etc. on an 8 1/2" x 11" sheet of white paper.

RESPONSE: Please see Attachment B.Project Description.IV – Floor Plan

V. For a Home Health Agency or Hospice, identify:

RESPONSE: Not Applicable

1. Existing service area by County;
2. Proposed service area by County;
3. A parent or primary service provider;
4. Existing branches; and
5. Proposed branches.

SECTION C: GENERAL CRITERIA FOR CERTIFICATE OF NEED

The following questions are listed according to the three (3) criteria: (I) Need, (II) Economic Feasibility, and (III) Contribution to the Orderly Development of Health Care.

NEED

1. Describe the relationship of this proposal toward the implementation of the State Health Plan and Tennessee's Health: Guidelines for Growth.

- a. Please provide a response to each criterion and standard in Certificate of Need Categories that are applicable to the proposed project.

RESPONSE: Not applicable.

- b. Applications that include a Change of Site for a health care institution, provide a response to General Criterion and Standards (4)(a-c)

RESPONSE: Specific responses to the Tennessee's Health: Guidelines for Growth are provided below.

The following Five Principles for Achieving Better Health serve as the basic framework for the State Health Plan. After each principle, the applicant states how the CON application supports the principle.

RESPONSE: Vanderbilt's plans are also similar to the Five Principals for Achieving Better Health as articulated in the State Health Plan.

- A. **Healthy Lives: Growth and expansion in diverse research areas has been extensive over the last several years in the CRC. With the recent addition of the CDRU, a unit designed for the care of a patient with a rare or unknown, highly communicable disease, this proposed project will continue to allow this type of research to be performed. And, as a result, more treatment options will be discovered and better patient care will be delivered.**
- B. **Access to Care: The proposed relocation will improve access to care and will add convenience to patients and researchers. The CRC will be able to grow in significance with a more prominent and well-designed space and configuration. The CRC is broadly utilized, and last year, investigators from 56 divisions (specialties) utilized the resources available in the CRC.**
- C. **Economic Efficiencies: The proposed project will achieve economic efficiencies through increase in number of patients and types of research available.**
- D. **Quality of Care: The proposed project will achieve the highest standards of quality through quality metrics and best practices. To ensure that all studies utilizing CRC resources meet the highest standards for quality, science, and safety, a Scientific Review Committee (SRC) evaluates the quality of science, feasibility of the study design and statistical plan, data and safety monitoring plans, and prioritizes requests for support. The centrality of prioritization by one robust SRC with experienced investigators drawn from many disciplines, with a common mandate for rigorous scientific evaluation, ensures equivalent treatment of all proposals.**
- E. **Health Care Workforce: Vanderbilt is committed to providing world-class care at the medical center, and thus, recruiting and retaining the best employee workforce for patient care, research and biomedical education.**

2. Describe the relationship of this project to the applicant facility's long-range development plans, if any.

RESPONSE: VUMC is a comprehensive healthcare facility dedicated to patient care, research, and biomedical education. The medical center's reputation for excellence in each of these areas has made VUMC a major patient referral center for the Mid-South. As a result, this project promotes the researchers that are at the forefront of posing innovative solutions in a state of the art facility, which will add convenience to their patients and to them. The proposed project will continue to allow this type of research to be performed, thus allowing more treatment options to be discovered and better patient care delivered.

3. Identify the proposed service area and justify the reasonableness of that proposed area. Submit a county level map including the State of Tennessee clearly marked to reflect the service area. Please submit the map on 8 1/2" x 11" sheet of white paper marked only with ink detectable by a standard photocopier (i.e., no highlighters, pencils, etc.).

RESPONSE: The medical center primary service area is represented in the attached Service Area map (Attachment C.Need.3). However, for this particular project, patients come from across the United States to receive the trials available at the CRC.

4. A. Describe the demographics of the population to be served by this proposal.

RESPONSE: The demographics provided represent the medical center's service area. Please see Attachment C.Need.4.A. As previously mentioned, for this particular project, patients come from across the United States to receive the trials available at the CRC.

- B. Describe the special needs of the service area population, including health disparities, the accessibility to consumers, particularly the elderly, women, racial and ethnic minorities, and low-income groups. Document how the business plans of the facility will take into consideration the special needs of the service area population.

RESPONSE: The medical center provides services to all consumers irrespective of gender, race, ethnicity or income. For this particular project, males and females of most racial categories volunteer to be involved in clinical research that may bring about advances in science and health care.

5. Describe the existing or certified services, including approved but unimplemented CONs, of similar institutions in the service area. Include utilization and/or occupancy trends for each of the most recent three years of data available for this type of project. Be certain to list each institution and its utilization and/or occupancy individually. Other projects should use the most appropriate measures, e.g., cases, procedures, visits, admissions, etc.

RESPONSE: Not applicable. The CRC is the core physical research hub within the Vanderbilt CTSA. There are no comparable programs in Tennessee.

6. Provide applicable utilization and/or occupancy statistics for your institution for each of the past three (3) years and the projected annual utilization for each of the two (2) years following completion of the project. Additionally, provide the details regarding the methodology used to project utilization. The methodology must include detailed calculations or documentation from referral sources, and identification of all assumptions.

RESPONSE: Please find the medical center's inpatient utilization for FY13-FY15 provided below. Due to the variability in clinical research, it is extremely difficult to project patient census in the CRC unit for several reasons, including types of projects that are open for recruitment, patient eligibility to a currently open trial and patient retention and completion in a clinical trial. In addition, the type of patient, inpatient, observation, and/ outpatient is difficult to project as well and varies depending on the course of treatment.

	FY13	FY14	FY15	Y1	Y2
Beds	1,019	1,025	1,025	5	5
Discharges	53,957	55,422	55,346	-	-
Days	298,894	301,655	305,953	-	-
Occupancy	80%	81%	82%	-	-

ECONOMIC FEASIBILITY

1. Provide the cost of the project by completing the Project Costs Chart on the following page. Justify the cost of the project.
 - For projects that include new construction, modification, and/or renovation; documentation must be provided from a contractor and/or architect that support the estimated construction costs.

RESPONSE: See Attachment C. Economic Feasibility.1

PROJECT COSTS CHART

201901271001
 10012190000

A.	Construction and equipment acquired by purchase:	
1.	Architectural and Engineering Fees	\$1,270,500
2.	Legal, Administrative, Consultant Fees	\$15,000
3.	Acquisition of Site	
4.	Preparation of Site	
5.	Construction Costs	\$8,400,000
6.	Contingency Fund	\$840,000
7.	Fixed Equipment	\$29,910
8.	Moveable Equipment (List all equipment over \$50,000)	\$-
9.	Other (Specify) _____	\$-
B.	Acquisition by gift, donation, or lease:	\$-
1.	Facility	
2.	Building only	
3.	Land only	
4.	Equipment (Specify) _____	
5.	Other (Specify) _____	
C.	Financing Costs and Fees	\$-
1.	Interim Financing	
2.	Underwriting Costs	
3.	Reserve for One Year's Debt Service	
4.	Other (Specify) _____	
D.	Estimated Project Cost (A+B+C)	\$10,555,410
E.	CON Filing Fee	\$23,749
F.	Total Estimated Project Cost(D+E)	
	TOTAL	\$10,579,159

2. Identify the funding sources for this project.

Please check the applicable item(s) below and briefly summarize how the project will be financed. (Documentation for the type of funding MUST be inserted at the end of the application, in the correct alpha/numeric order and identified as Attachment C, Economic Feasibility-2.)

- A. Commercial loan--Letter from lending institution or guarantor stating favorable initial contact, proposed loan amount, expected interest rates, anticipated term of the loan, and any restrictions or conditions;
- B. Tax-exempt bonds--Copy of preliminary resolution or a letter from the issuing authority stating favorable initial contact and a conditional agreement from an underwriter or investment banker to proceed with the issuance;
- C. General obligation bonds—Copy of resolution from issuing authority or minutes from the appropriate meeting.
- D. Grants--Notification of intent form for grant application or notice of grant award; or
- E. Cash Reserves--Appropriate documentation from Chief Financial Officer.
- F. Other—Identify and document funding from all other sources.

RESPONSE: Vanderbilt expects to finance the project with cash reserves. Please see Attachment C, Economic Feasibility.2.

3. Discuss and document the reasonableness of the proposed project costs. If applicable, compare the cost per square foot of construction to similar projects recently approved by the Health Services and Development Agency.

RESPONSE: The chart provided below shows the average hospital construction cost per square foot for all CON-approved applications between 2012 and 2014; source is Tennessee HSDA. VUMC costs for this project are much higher when compared to the other recently approved Tennessee CON projects due to the higher construction costs of mechanical requirements involved in creating appropriate space for this high specialized unit.

Hospital Construction Cost per Square Foot
Approved Projects, 2012-2014

	Renovated Construction	New Construction	Total Construction
1 st Quartile	\$110.98/sq ft	\$224.09/sq ft	\$156.78/sq ft
Median	\$192.46/sq ft	\$259.66/sq ft	\$227.88/sq ft
3 rd Quartile	\$297.82/sq ft	\$296.52/sq ft	\$298.66/sq ft

Complete Historical and Projected Data Charts on the following two pages--Do not modify the Charts provided or submit Chart substitutions! Historical Data Chart represents revenue and expense information for the last three (3) years for which complete data is available for the institution. Projected Data Chart requests information for the two (2) years following the completion of this proposal. Projected Data Chart should reflect revenue and expense projections for the Proposal Only (i.e., if the application is for additional beds, include anticipated revenue from the proposed beds only, not from all beds in the facility).

4. Please identify the project's average gross charge, average deduction from operating revenue, and average net charge.

RESPONSE:

Average Gross Charge	\$325
Average Deduction from Operating Revenue	\$-
Average Net Charge	\$325

HISTORICAL DATA CHART

Give information for the last three (3) years for which complete data are available for the facility or agency. The fiscal year begins in July (Month).

	2013	2014	2015
A. Utilization Data	80%	81%	82%
B. <u>Revenues from Services to Patients</u>			
1. Inpatient Services	\$ 3,521,619,463	\$ 3,117,433,787	\$ 3,357,544,947
2. Outpatient Services	\$ 1,878,519,498	\$ 2,657,364,290	\$ 3,043,106,365
3. Emergency Services	\$ 236,435,402	\$ 251,984,557	\$ 271,179,568
4. Other Operating Revenue	\$ 8,789,242	\$ 10,265,765	\$ 13,934,130
Gross Operating Revenue	\$ 5,645,363,605	\$ 6,037,048,399	\$ 6,685,765,010
C. <u>Deductions from Revenue</u>			
1. Contractual Adjustments	\$ (3,409,755,679)	\$ (3,596,062,670)	\$ (4,143,680,213)
2. Provision for Charity Care	\$ (374,555,880)	\$ (343,156,255)	\$ (297,840,450)
3. Provisions for Bad Debt	\$ (51,130,366)	\$ (77,107,701)	\$ (28,094,171)
Total Deductions	\$ (3,835,441,925)	\$ (4,016,326,626)	\$ (4,469,614,834)
Net Operating Revenue	\$ 1,809,921,680	\$ 2,020,721,773	\$ 2,216,150,176
D. <u>Operating Expenses</u>			
1. Salaries and Wages	\$ 585,448,338	\$ 562,674,483	\$ 582,932,925
2. Physician's Salaries and Wages	\$ 103,731,792	\$ 111,531,564	\$ 124,674,900
3. Supplies and Drug Costs	\$ 408,462,877	\$ 469,442,062	\$ 537,997,860
4. Taxes	\$ 155,380	\$ 511,012	\$ 1,398,512
5. Depreciation	\$ 68,679,764	\$ 66,387,238	\$ 63,755,020
6. Rent	\$ 19,070,567	\$ 18,999,735	\$ 23,365,060
7. Interest, other than Capital	\$ -	\$ -	\$ -
8. Management Fees:	\$ -	\$ -	\$ -
a. Fees to Affiliates	\$ -	\$ -	\$ -
b. Fees to Non-Affiliates	\$ -	\$ -	\$ -
9. Other Expenses	\$ 579,195,462	\$ 612,785,261	\$ 622,311,499
Total Operating Expenses	\$ 1,764,744,180	\$ 1,842,331,355	\$ 1,956,435,776
E. <u>Other Revenue - Net</u>	\$ 3,066,166	\$ 1,108,599	\$ 30,269,068
Net Operating Income (loss)	\$ 48,243,666	\$ 179,499,017	\$ 289,983,468
F. Capital Expenditures			
1. Retirement of Principal	\$ 23,544,334	\$ 25,848,241	\$ 21,659,698
2. Interest Expense	\$ 47,900,462	\$ 51,071,000	\$ 52,746,873
Total Capital Expenditures	\$ 71,444,796	\$ 76,919,241	\$ 74,406,571
Net Operating Income (Loss)			
Less Capital Expenditures	\$ (23,201,130)	\$ 102,579,776	\$ 215,576,897

* The FY13 financial statements include a onetime reduction in net revenue of \$126M attributable to a change in the estimated net realizable value of patient accounts receivable. The change in estimate was applied in FY13 and is consistent with Generally Accepted Accounting Principles (GAAP) that requires such a change in estimate be recognized in the fiscal year during which the change in estimate was applied. Excluding the change in estimate noted above, the FY13 net operating income less capital expenditures would have been \$ 103.3M.

PROJECTED DATA CHART

Give information for the two (2) years following the completion of this proposal. The fiscal year begins in July (Month).

	FY17	FY18
A. Utilization Data (Discharges)	5,672	5,672
B. Revenue from Services to Patients		
1. Inpatient Services	\$	\$
2. Outpatient Services	\$	\$
3. Emergency Services		
4. Other Operating Revenue	\$1,822,183	\$1,822,183
Gross Operating Revenue	\$1,822,183	\$1,822,183
C. Deductions for Operating Revenue		
1. Contractual Adjustments		
2. Provision for Charity Care		
3. Provisions for Bad Debt		
Total Deductions	\$0	\$0
NET OPERATING REVENUE	\$1,822,183	\$1,822,183
D. Operating Expenses		
1. Salaries and Wages	\$1,530,416	\$1,530,416
2. Physician's Salaries and Wages		
3. Supplies (Medical Supplies & Services)	\$291,767	\$291,767
4. Taxes		
5. Depreciation		
6. Rent		
7. Interest, other than Capital		
8. Other Expenses		
Total Operating Expenses	\$1,822,183	\$1,822,183
E. Other Revenue (Expenses) -- Net (Specify)		
NET OPERATING INCOME (LOSS)	\$0	\$0
F. Capital Expenditures		
1. Retirement of Principal		
2. Interest		
Total Capital Expenditures		
NET OPERATING INCOME (LOSS) LESS CAPITAL EXPENDITURES	\$0	\$0

6. A. Please provide the current and proposed charge schedules for the proposal. Discuss any adjustment to current charges that will result from the implementation of the proposal. Additionally, describe the anticipated revenue from the proposed project and the impact on existing patient charges.

RESPONSE: Not applicable to this project; patients and third-party payers are not billed for services provided to patients.

- B. Compare the proposed charges to those of similar facilities in the service area/adjoining service areas, or to proposed charges of projects recently approved by the Health Services and Development Agency. If applicable, compare the proposed charges of the project to the current Medicare allowable fee schedule by common procedure terminology (CPT) code(s).

RESPONSE: Not applicable to this project; patients and third-party payers are not billed for services provided to patients.

7. Discuss how projected utilization rates will be sufficient to maintain cost-effectiveness.

RESPONSE: These research efforts are supported by both federal and non-federal sources.

8. Discuss how financial viability will be ensured within two years; and demonstrate the availability of sufficient cash flow until financial viability is achieved

RESPONSE: These research efforts are supported by both federal and non-federal sources.

9. Discuss the project's participation in state and federal revenue programs including a description of the extent to which Medicare, TennCare/Medicaid, and medically indigent patients will be served by the project. In addition, report the estimated dollar amount of revenue and percentage of total project revenue anticipated from each of TennCare, Medicare, or other state and federal sources for the proposal's first year of operation.

RESPONSE: Not applicable to this project; patients and third-party payers are not billed for services provided to patients.

10. Provide copies of the balance sheet and income statement from the most recent reporting period of the institution and the most recent audited financial statements with accompanying notes, if applicable. For new projects, provide financial information for the corporation, partnership, or principal parties involved with the project. Copies must be inserted at the end of the application, in the correct alpha-numeric order and labeled as Attachment C, Economic Feasibility.10.

RESPONSE: See Attachment C, Economic Feasibility.10.

11. Describe all alternatives to this project which were considered and discuss the advantages and disadvantages of each alternative including but not limited to:

- a. A discussion regarding the availability of less costly, more effective, and/or more efficient alternative methods of providing the benefits intended by the proposal. If development of such alternatives is not practicable, the applicant should justify why not; including reasons as to why they were rejected.

RESPONSE: The relocation of the CRC to a location that is proximate to the clinical core, and is more convenient and identifiable for outpatient visitors has been a long-standing goal of VUMC. Several relocation options have been studied, all of which involved building new space, as there is no identifiable area of adequate size near VUMC's clinical core. The most developed study involved a new addition above The

Vanderbilt Clinic (TVC). This scheme was proposed as part of an NIH grant application in 2004, but was significantly more expensive than the current proposed renovation, and was not funded. In addition to relocation options, renovating the current CRC in-place was investigated. This option was ruled out due to the lack of a suitable temporary location for the CRC, negative impact on CRC operations with phased construction, and the lack of improved proximity to the clinical core to improve safety for higher acuity patients, and proximity to parking for outpatients. Additionally, a renovation of the existing space would yield minimal to no cost-savings.

- b. The applicant should document that consideration has been given to alternatives to new construction, e.g., modernization or sharing arrangements. It should be documented that superior alternatives have been implemented to the maximum extent practicable.

RESPONSE: The proposed CRC relocation includes 11,183 SF of existing renovation, and 2,489 SF of new construction. The project is primarily renovation, with a minor extension of the existing façade. The location identified is the only available space adjacent to the existing clinical core with the ability to accommodate the CRC program. The building addition provides the necessary area for the CRC program, and is used to create a new entry for outpatient and ambulance drop-off and pick-up. By relocating to an area more proximate to the clinical core, and developing a more efficient layout, the square footage of the CRC was reduced by approximately 6,654 SF.

CONTRIBUTION TO THE ORDERLY DEVELOPMENT OF HEALTH CARE

1. List all existing health care providers (e.g., hospitals, nursing homes, home care organizations, etc.), managed care organizations, alliances, and/or networks with which the applicant currently has or plans to have contractual and/or working relationships, e.g., transfer agreements, contractual agreements for health services.

RESPONSE: Please see Attachment C. Contribution to the Orderly Development of Healthcare.1

2. Describe the positive and/or negative effects of the proposal on the health care system. Please be sure to discuss any instances of duplication or competition arising from your proposal including a description of the effect the proposal will have on the utilization rates of existing providers in the service area of the project.

RESPONSE: The proposed relocation will improve access to care and will add immeasurable convenience to patients and researchers. The CRC will be able to grow in significance with a more prominent and well-designed space and configuration. The CRC is broadly utilized, and last year, investigators from 56 divisions (specialties) utilized the resources available in the CRC. The CRC is unique in the region and thus does not duplicate or compete with any other facility in the region.

3. Provide the current and/or anticipated staffing pattern for all employees providing patient care for the project. This can be reported using FTEs for these positions. Additionally, please compare the clinical staff salaries in the proposal to prevailing wage patterns in the service area as published by the Tennessee Department of Labor & Workforce Development and/or other documented sources.

RESPONSE: The staffing for this project and salary comparisons are provided below.

Staff Position	Current Staffing Model	Future Staffing Model
Outpatient RN	14	12
Inpatient RN	4	4
Ultrasound Technician	1	1
Metabolic Technician	1	-
Administrative Unit Support	1	1
Visit Schedule	1	1
Medical Receptionist	1	1
Housekeeping	2	1

Staff Position	VUMC	Entry	Median	Experienced
Registered Nurse	\$ 32.91	\$ 22.07	\$ 28.30	\$ 31.74
Ultrasound Technician	\$ 32.91	\$ 24.89	\$ 31.77	\$ 34.73
Metabolic Technician*	\$ 45.79	\$ 22.25	\$ 28.36	\$ 32.18
Administrative Unit Support**	\$ 20.79	\$ 10.94	\$ 16.96	\$ 20.00
Visit Scheduler**	\$ 24.75	\$ 10.94	\$ 16.96	\$ 20.00
Medical Receptionist**	\$ 18.74	\$ 10.94	\$ 16.96	\$ 20.00
Housekeeping	\$ 17.34	\$ 8.13	\$ 9.83	\$ 12.08

Hourly Rate - Occupational Employment Statistics Survey Data for 2014 in Nashville-Davidson--Murfreesboro, TN MSA

*Rates compared with Medical and Clinical Laboratory Technologists

**Rates compared with Healthcare Support Workers, All Other

- Discuss the availability of and accessibility to human resources required by the proposal, including adequate professional staff, as per the Department of Health, the Department of Mental Health and Developmental Disabilities, and/or the Division of Mental Retardation Services licensing requirements.

RESPONSE: VUMC will staff the project. VUMC provides a dynamic recruitment and retention program for employees. As one of the largest employers, VUMC actively searches for the most appropriate candidates and seeks to place them in career successful positions.

- Verify that the applicant has reviewed and understands all licensing certification as required by the State of Tennessee for medical/clinical staff. These include, without limitation, regulations concerning physician supervision, credentialing, admission privileges, quality assurance policies and programs, utilization review policies and programs, record keeping, and staff education

RESPONSE: Vanderbilt University Medical Center will be responsible for credentialing, quality assurance, and staff education.

Credentialing

The Provider Support Services department credentials all providers that will admit patients to VUMC or attend to patients at VUMC and its satellite locations. Documents are verified from the primary source and include medical or professional licenses, DEA status (if applicable), malpractice insurance and claims history, appropriate

schooling, board certification and faculty status. Once all documents have been verified, they are presented to the Credentials Committee for review and recommendation to the Medical Center Medical Board. The Medical Center Medical Board then recommends approval to the Board of Trust, which makes the final decision.

Quality Assurance

VUMC's Performance Improvement and Safety Plan is framed around the Institute of Medicine's (IOM) Quality Chasm Report. It incorporates the IOM Six Aims for Improvement (i.e. care that is safe, timely, efficient, effective, equitable, and patient-centered).

Staff Education

VUMC devotes a variety of resources to the development of staff at all levels of the organization. VUMC's Learning Center provides comprehensive orientation and role specific training to help new staff become successful in their jobs.

6. Discuss your health care institution's participation in the training of students in the areas of medicine, nursing, social work, etc. (e.g., internships, residencies, etc.).

RESPONSE: VUMC has accredited training programs in medicine, radiation oncology (residents), medical physicists and dosimetrists, nursing, pharmacy, respiratory therapy, dietetics, medical technology, radiation therapy technology, cardiovascular perfusion technology and nuclear medicine technology. VUMC is also a major clinical training facility for Vanderbilt University Medical and Nursing Schools. VUMC supports a total house staff training program of 711 residents and 267 fellows.

7. (a) Please verify, as applicable, that the applicant has reviewed and understands the licensure requirements of the Department of Health, the Department of Mental Health and Developmental Disabilities, the Division of Mental Retardation Services, and/or any applicable Medicare requirements.

RESPONSE: The proposed facility will be constructed and operated to comply with all existing codes and license requirements.

- (b) Provide the name of the entity from which the applicant has received or will receive licensure, certification, and/or accreditation.

RESPONSE: Licensure: State of Tennessee, Department of Health Facilities, Licensure Division

- (c) If an existing institution, please describe the current standing with any licensing, certifying, or accrediting agency. Provide a copy of the current license of the facility.

RESPONSE: Please see Attachment C. Contribution to the Orderly Development of Healthcare.7.c

- (d) For existing licensed providers, document that all deficiencies (if any) cited in the last licensure certification and inspection have been addressed through an approved plan of correction. Please include a copy of the most recent licensure/certification inspection with an approved plan of correction.

RESPONSE: Please see Attachment C. Contribution to the Orderly Development of Healthcare.7.d

8. Document and explain any final orders or judgments entered in any state or country by a licensing agency or court against professional licenses held by the applicant or any entities or persons with more than a 5% ownership interest in the applicant. Such information is to be provided for licenses regardless of whether such license is currently held.

RESPONSE: Not Applicable

9. Identify and explain any final civil or criminal judgments for fraud or theft against any person or entity with more than a 5% ownership interest in the project

RESPONSE: Not Applicable

10. If the proposal is approved, please discuss whether the applicant will provide the Tennessee Health Services and Development Agency and/or the reviewing agency information concerning the number of patients treated, the number and type of procedures performed, and other data as required.

RESPONSE: If this proposal is approved, VUMC will provide the Tennessee Health Services and Development Agency with requested data.

PROOF OF PUBLICATION

Attach the full page of the newspaper in which the notice of intent appeared with the mast and dateline intact or submit a publication affidavit from the newspaper as proof of the publication of the letter of intent.

DEVELOPMENT SCHEDULE

Tennessee Code Annotated § 68-11-1609(c) provides that a Certificate of Need is valid for a period not to exceed three (3) years (for hospital projects) or two (2) years (for all other projects) from the date of its issuance and after such time shall expire; provided, that the Agency may, in granting the Certificate of Need, allow longer periods of validity for Certificates of Need for good cause shown. Subsequent to granting the Certificate of Need, the Agency may extend a Certificate of Need for a period upon application and good cause shown, accompanied by a non-refundable reasonable filing fee, as prescribed by rule. A Certificate of Need which has been extended shall expire at the end of the extended time period. The decision whether to grant such an extension is within the sole discretion of the Agency, and is not subject to review, reconsideration, or appeal.

1. Please complete the Project Completion Forecast Chart on the next page. If the project will be completed in multiple phases, please identify the anticipated completion date for each phase.
2. If the response to the preceding question indicates that the applicant does not anticipate completing the project within the period of validity as defined in the preceding paragraph, please state below any request for an extended schedule and document the "good cause" for such an extension.

PROJECT COMPLETION FORECAST CHART

Enter the Agency projected Initial Decision date, as published in Rule 68-11-1609(c): May 2016
 Assuming the CON approval becomes the final agency action on that date; indicate the number of days from the above agency decision date to each phase of the completion forecast.

<u>Phase</u>	<u>DAYS REQUIRED</u>	<u>Anticipated Date (MONTH/YEAR)</u>
1. Architectural and engineering contract signed	30	April 2016
2. Construction documents approved by the Tennessee Department of Health	100	August 2016
3. Construction contract signed	100	August 2016
4. Building permit secured	130	September 2016
5. Building construction commenced	155	September 2016
6. Construction 40% complete	275	January 2017
7. Construction 80% complete	375	May 2017
8. Construction 100% complete-approved for occupancy	475	August 2017
9. *Issuance of license	505	September 2017
10. *Initiation of service	505	September 2017
11. Final Architectural Certification of Payment	535	October 2017
12. Final Project Report Form (HF0055)	535	October 2017

*For projects that do NOT involve construction or renovation: Please complete items 10 and 11 only.

Note: If litigation occurs, the completion forecast will be adjusted at the time of the final determination to reflect the actual issue date.

Form HF0004
 Revised 05/03/04
 Previous Forms are obsolete

FEB 12 11:16 PM '16

STATE OF TENNESSEE

COUNTY OF Davidson

Ginna Felts, being first duly sworn, says that he/she is the applicant named in this application or his/her/its lawful agent, that this project will be completed in accordance with the application, that the applicant has read the directions to this application, the Rules of the Health Services and Development Agency, and T.C.A. § 68-11-1601, et seq., and that the responses to this application or any other questions deemed appropriate by the Health Services and Development Agency are true and complete.

Ginna Felts

Business Development

Sworn to and subscribed before me this 12th day of February, 2016, a Notary
(Month)(Year)

Public in and for the County/State of Davidson County, Tennessee.

Jiff Hygell
NOTARY PUBLIC

My commission expires July 8, 2019.
(Month/Day) (Year)



Vanderbilt University Medical Center CON
Application Attachments
(in order of appearance)

Corporate Charter & Cert of Existence: Attachment A.3

Org Chart and Ownership List: Attachment A.4

Title/Deed: Attachment A.6

MCO Contracts and Networks: Attachment A.13

Pre/Post Closing Org Chart: Attachment B.1

Plot Plan: Attachment B.Project Description.III.A

Floor Plan: Attachment B.Project Description.IV

Service Area Map: Attachment C.Need.3

Primary Service Area Demographic Chart: Attachment C.Need.4.A

Estimated Construction Cost Letter: Attachment C.Economic Feasibility.1

Funding Documentation (proof of cash reserves): Attachment C.Economic Feasibility.2

VUMC Financial Statements: Attachment C.Economic Feasibility.10

Contracts: Attachment C.Contribution to the Orderly Development of Healthcare.1

Licensure & Accreditation: Attachment C.Contribution to the Orderly Development of Healthcare.7.c

Licensure Certification & Plan of Correction: Attachment C.Contribution to the Orderly Development of Healthcare.7.d

Proof of publication

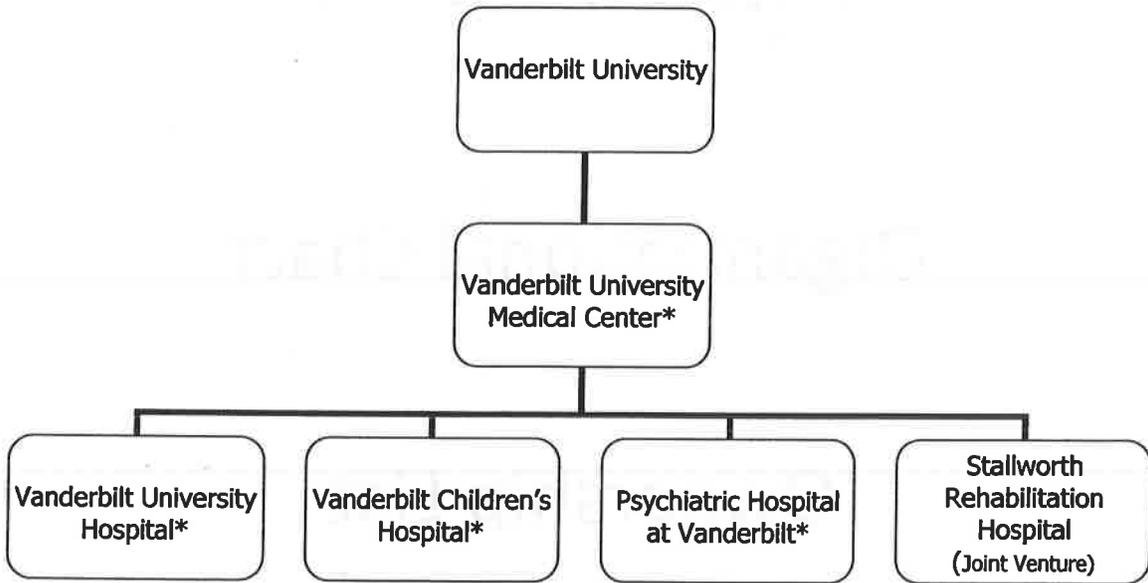
Attachment A.4

Organizational Chart

Ownership List

Attachment A.4

Vanderbilt University Hospital Organization Chart



*Not Separately Incorporated

Attachment A.4**Vanderbilt University Medical Center Ownership Participation****Ambulatory Surgery Center of Cool Springs, LLC**

2009 Mallory Lane, Suite 100
Franklin, TN 37067
Current License: Licensed/ASTC
% Ownership: 50%

One Hundred Oaks Imaging, LLC

719 Thompson Lane
Nashville, TN 37204
Current License: Outpatient Department
% Ownership: 80%

Spring Hill Imaging Center, LLC

5421 Main Street
Spring Hill, TN 37174
Current License: Outpatient Diagnostic Center
% Ownership: 24.5%

Vanderbilt-Gateway Cancer Center, GP

Alfred Thun Road
Clarksville, TN 37040
Current License: ASTC
% Ownership: 50%

Vanderbilt Imaging Services, LLC

1161 21st Avenue South
D-3300 Medical Center North
Nashville, TN 37232-2104
Current License: Medicare License since 10/01/1999; American College of Radiology Accredited
% Ownership: 67%

Vanderbilt-Maury Radiation Oncology, LLC

1003 Reserve Boulevard
Spring Hill, TN 37174
Current License: ASTC
% Ownership: 40%

Vanderbilt-Stallworth Rehabilitation Hospital, L.P.

2201 Children's Way
Nashville, TN 37212
Current License: Health Care Facility/Rehabilitation Hospital; JCAHO Accreditation
% Ownership: 50%

Vanderbilt Home Care Services, Inc

2120 Bellcourt Ave.
Nashville, TN 37232
Current License: Health Care Facility/Home Care Organization
% Ownership: 100%

Williamson Imaging, LLC

2009 Mallory Lane, Suite 150
Franklin, TN 37067
Current License: Medicare License since 10/10/2001; American College of Radiology Accredited
% Ownership: 80% ownership by Vanderbilt Imaging Services

Attachment A.13

Vanderbilt University Hospitals MCO Contracts and Networks

Attachment A.13
VUH/VCH Contracts & Networks

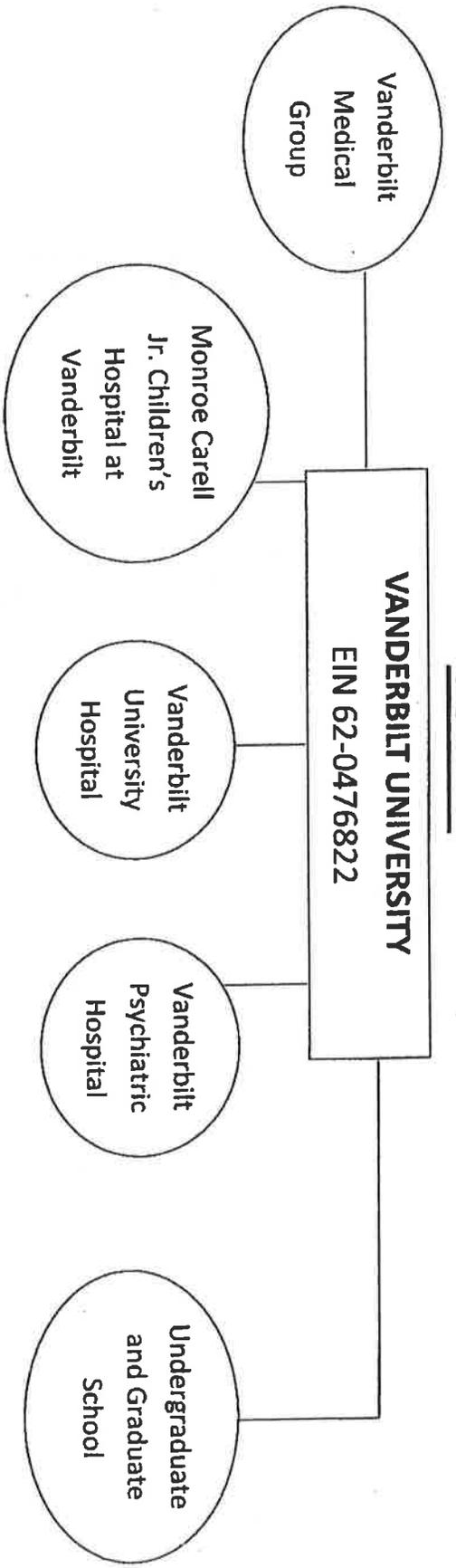
- Aetna/US Healthcare
- AmeriGroup Community Care*
- Best Doctor
- Blue Cross Blue Shield of Tennessee/Magellan
- Baptist Health Plan (KY)
- CIGNA Behavioral Health
- Center Care
- Community Care Network Methodist Hospital
- Cigna HealthCare/Great West
- Correct Care Solutions
- Corizon
- Corvel Workman's Comp
- Coventry Cares
- Coventry Health
- Health Partners
- HealthSpring
- HealthNet Federal Services (Tricare)
- Health One Alliance / Alliant Health Plan
- Humana, Inc.
- Humana Military
- CrestPoint ISHN
- Magellan Health
- Metro General Hospital
- Murray Calloway Hospital
- NAMCI (AL)
- NovaNet PPO
- Owensboro Community Health Network
- Private Healthcare Systems, Inc. (PHCS)
- Prime Health
- Signature Health Alliance
- TriWest Choice (VA)
- United Behavioral Health
- United BH/Community Plan*
- United Healthcare
- UnitedHealthCare Community Plan*
- USA MCO
- BlueCare/TennCare/Select*
- WellCare
- Windsor Health Group

Items noted with an * are TennCare MCOs

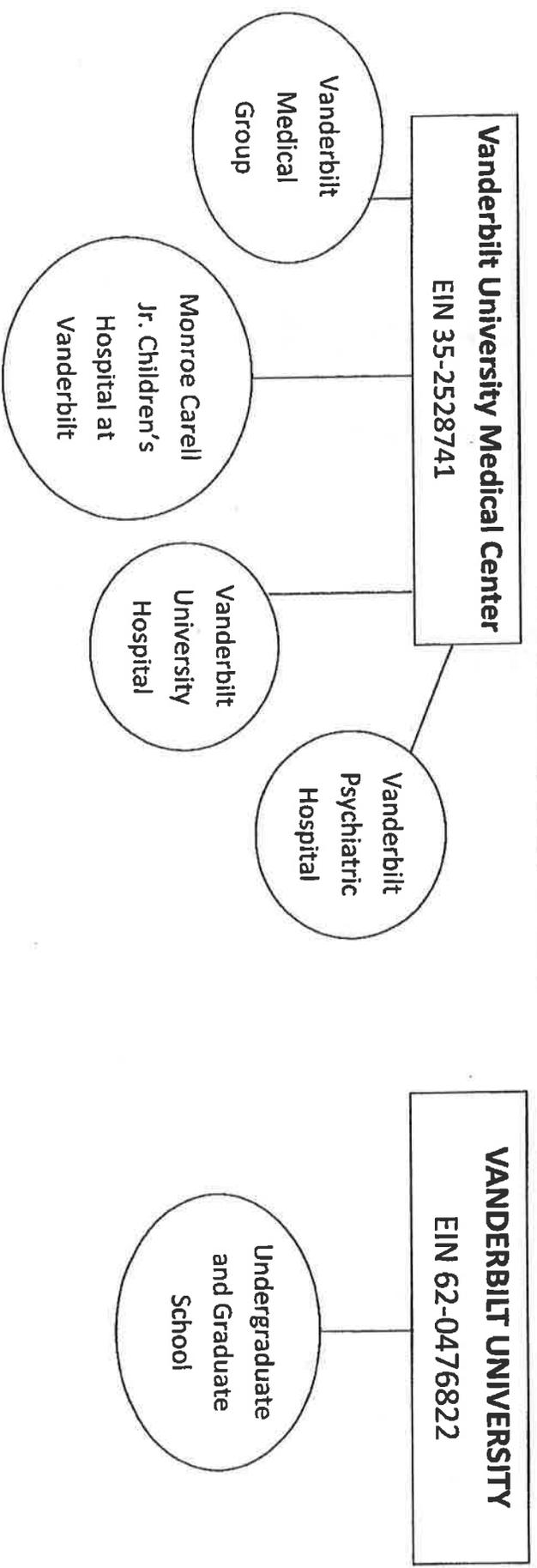
Attachment B.1

Pre/Post Closing Organizational Chart

TODAY



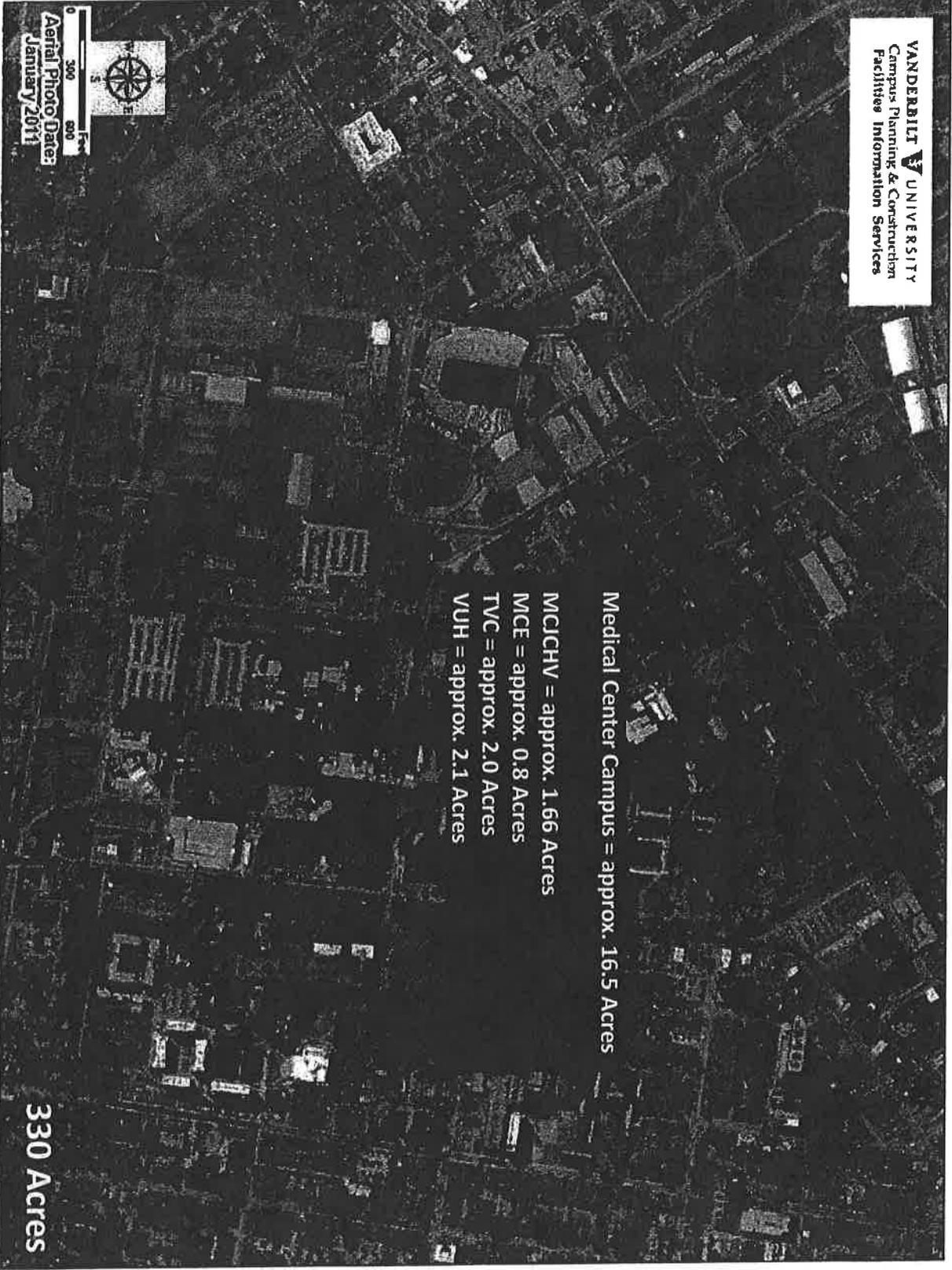
POST TRANSITION



Attachment B. Project Description. III.A

Plot Plan

VANDERBILT UNIVERSITY
Campus Planning & Construction
Facilities Information Services



Medical Center Campus = approx. 16.5 Acres

MC/CHV = approx. 1.66 Acres

MCE = approx. 0.8 Acres

TVC = approx. 2.0 Acres

VUH = approx. 2.1 Acres

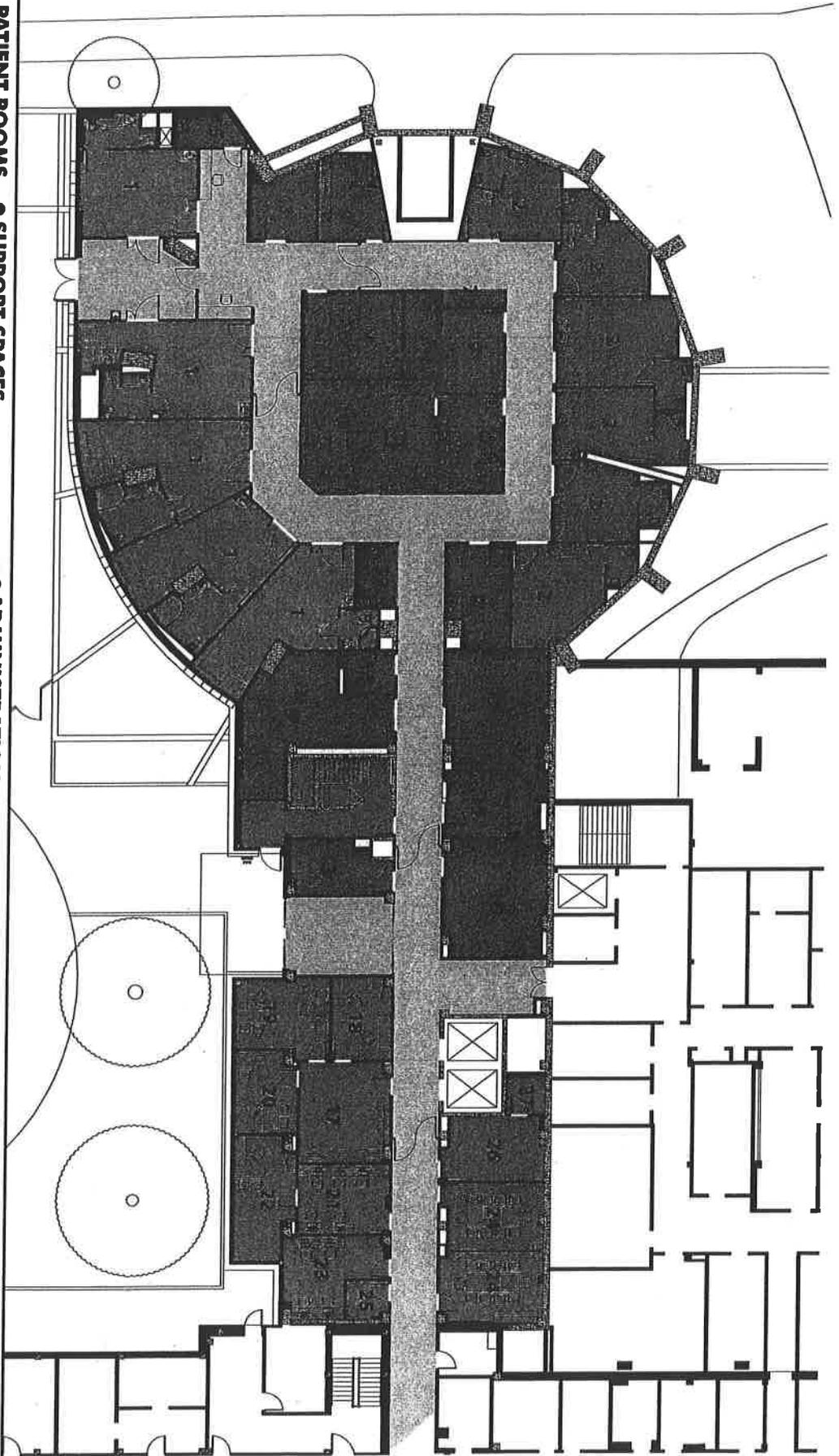
0 300 600 Feet
Aerial Photo Date:
January 2011



330 Acres

Attachment B. Project Description. IV

Floor Plan



● **PATIENT ROOMS**

- 1. PATIENT ROOM
- 2. EXAM ROOM

● **SUPPORT SPACES**

- 3. STORAGE
- 4. SMALL SPECIMEN PROCESSING
- 5. STAFF TOILET
- 6. STAFF BREAK ROOM
- 7. NOURISHMENT
- 8. CLEAN
- 9. SOILED
- 10. NURSE STATION
- 11. NURSE WORKROOM
- 12. WAITING
- 13. PUBLIC TOILET
- 14. ECHO ROOM
- 15. INFUSION
- 16. SPECIMEN PROCESSING

● **ADMINISTRATION**

- 17. CRC RECEPTIONIST
- 18. CRC NURSE ASST. MANAGER
- 19. MEDICAL DIRECTOR
- 20. NURSE MANAGER
- 21. CLINICAL TRIAL CENTER
- 22. CLINICAL TRIAL OFFICE
- 23. NUTRITION OFFICE
- 24. CONFERENCE

● **UTILITY**

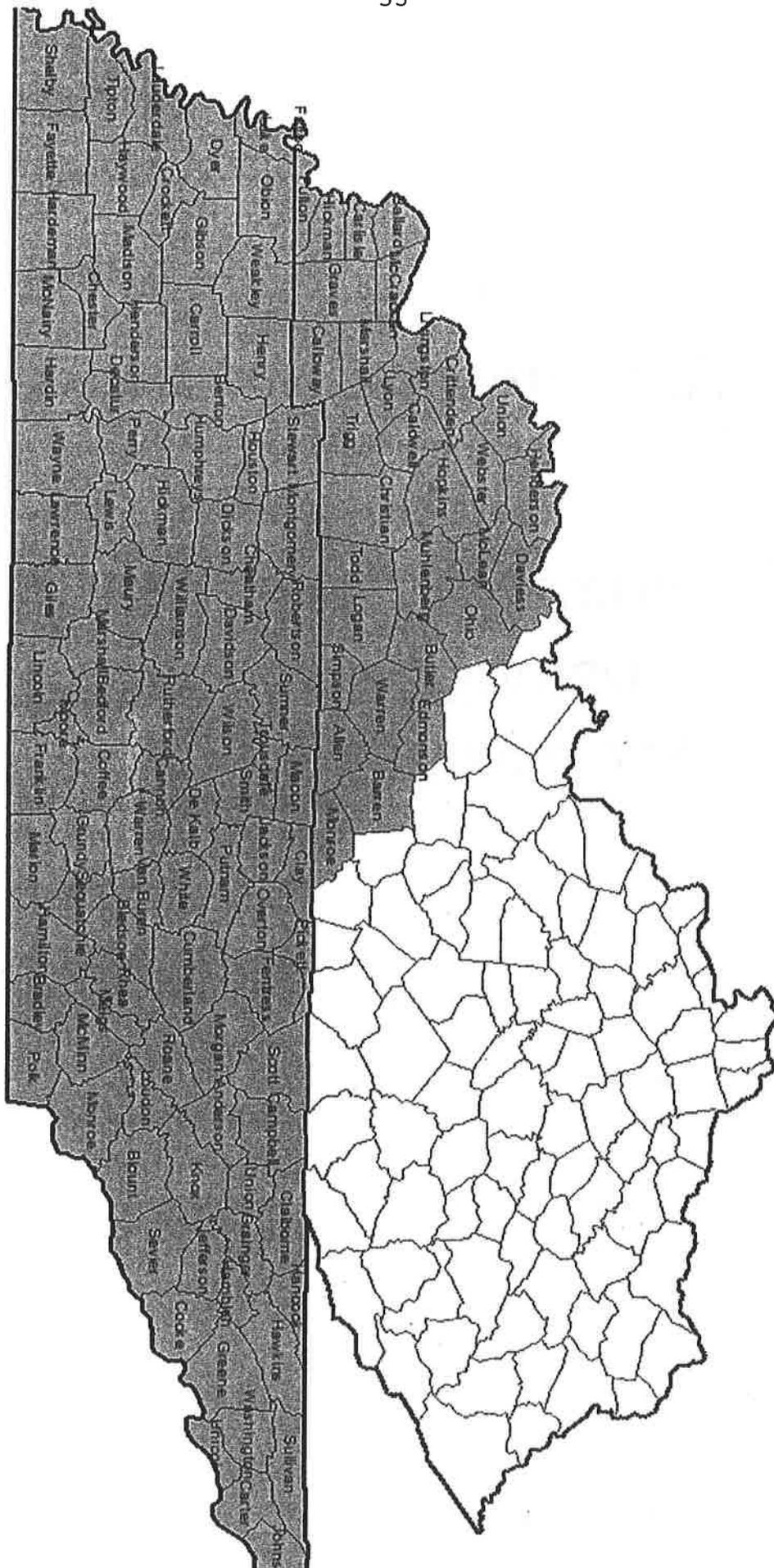
- 25. ENV. SVC.
- 26. COMPUTER LAB
- 27. DATA

YUMC - CLINICAL RESEARCH CENTER

BLAIR + MUI DOWD ARCHITECTS, PC
DONALD BLAIR ARCHITECTS

Attachment C.Need.3

Service Area Map



Service Area Map

Attachment C.Need.4.A

Primary Service Area Demographic and Socioeconomic Chart

Demographic Geographic Area	Total Population - 2015	Total Population - 2020	Total Population - % Change	Age 65+ Population - 2015	Age 65+ Population - 2020	Age 65+ Population - % Change	Age 65+ of Total Population	Age 65+ as % of Total Population	Median Household Income	TennCare Enrollees	TennCare Enrollees as % of Total	Persons Below Poverty Level (2014)	Persons Below Poverty Level as % of Total
Adrian	75,753	77,107	1.8%	14,611	16,722	14.4%	19.3%	19.3%	\$40,225	16,505	21.8%	12,659	17.1%
Beard	46,368	47,982	3.5%	6,869	7,909	15.1%	14.8%	14.8%	\$42,856	13,008	28.1%	9,508	21.1%
Berpan	16,190	16,129	-0.4%	3,622	4,004	10.5%	22.4%	22.4%	\$33,574	4,208	26.0%	3,521	21.8%
Bleas	12,856	13,025	1.3%	2,316	2,653	14.6%	18.0%	18.0%	\$34,760	3,321	25.8%	2,595	21.6%
Blount	126,285	130,458	3.3%	23,453	27,452	17.1%	18.6%	18.6%	\$45,880	22,588	17.9%	17,626	14.4%
Brewer	103,132	107,457	4.2%	16,507	19,502	18.1%	16.0%	16.0%	\$39,136	22,486	21.8%	19,263	19.8%
Camden	39,964	39,790	-0.4%	7,848	8,829	12.5%	19.6%	19.6%	\$31,554	13,432	33.6%	8,979	22.6%
Carroll	13,752	13,861	0.8%	2,538	2,905	14.5%	18.5%	18.5%	\$43,314	3,081	22.4%	2,462	18.1%
Carroll	28,459	28,698	0.8%	5,650	6,307	11.6%	19.9%	19.9%	\$35,631	7,858	27.6%	5,346	19.4%
Carter	57,270	57,784	0.9%	11,308	12,836	13.5%	19.7%	19.7%	\$35,160	13,340	23.3%	13,060	23.5%
Cheatham	39,772	40,833	2.7%	5,341	6,723	25.9%	13.4%	13.4%	\$51,563	7,537	19.0%	5,882	15.1%
Chester	17,440	17,911	2.7%	2,938	3,370	14.7%	16.8%	16.8%	\$46,992	3,986	22.9%	3,229	20.0%
Claborn	31,273	30,914	-1.1%	5,821	6,567	12.8%	18.6%	18.6%	\$36,570	9,435	30.2%	7,342	24.0%
Clay	7,730	7,709	-0.3%	1,798	1,971	9.6%	23.3%	23.3%	\$31,406	2,278	29.5%	1,684	21.8%
Coke	35,384	35,561	0.5%	6,862	7,830	14.1%	19.4%	19.4%	\$30,942	11,703	33.1%	9,747	27.8%
Coffee	53,632	54,918	2.4%	9,256	10,519	13.6%	17.3%	17.3%	\$35,756	13,620	25.4%	11,173	21.3%
Crockett	14,592	14,764	1.2%	2,610	2,910	11.5%	17.9%	17.9%	\$41,725	4,095	28.1%	2,549	17.9%
Cumberland	58,116	60,368	3.9%	16,875	19,012	12.7%	29.0%	29.0%	\$38,261	12,934	22.3%	9,206	16.4%
Davidson	674,005	717,220	6.4%	78,184	97,721	25.0%	11.6%	11.6%	\$45,284	147,971	22.1%	117,756	18.8%
Decatur	11,652	11,736	0.7%	2,702	2,994	10.8%	23.3%	23.3%	\$37,982	2,920	25.0%	2,496	21.8%
DeKalb	19,424	20,231	4.2%	3,476	4,122	18.6%	17.9%	17.9%	\$39,628	5,395	27.8%	3,673	19.7%
Dickson	50,415	51,469	2.1%	7,612	8,947	17.5%	15.1%	15.1%	\$45,019	11,281	22.4%	7,188	14.5%
Dyer	38,179	38,506	0.9%	6,337	7,231	14.1%	16.6%	16.6%	\$41,986	10,886	28.5%	5,988	16.0%
Fayette	38,842	39,643	2.1%	7,034	8,187	16.4%	18.1%	18.1%	\$41,381	7,061	18.2%	5,455	14.5%
Fentress	17,993	17,872	-0.7%	3,621	4,134	14.2%	20.3%	20.3%	\$29,582	6,186	34.6%	4,366	24.7%
Franklin	41,365	42,259	2.2%	8,085	9,267	14.6%	19.5%	19.5%	\$42,750	8,017	19.4%	6,201	15.9%
Gibson	49,193	49,236	0.1%	8,681	9,524	9.7%	17.6%	17.6%	\$38,601	13,461	27.4%	9,393	19.3%
Giles	28,398	27,880	-1.8%	5,435	5,991	10.2%	19.1%	19.1%	\$38,240	6,435	22.7%	5,049	17.8%
Grainger	22,731	23,060	1.4%	4,288	4,984	16.2%	18.9%	18.9%	\$35,544	6,081	26.8%	4,759	21.2%
Greene	67,823	67,642	-0.3%	13,524	15,188	12.3%	19.9%	19.9%	\$35,659	15,645	23.1%	14,780	22.1%
Grundy	13,356	13,195	-1.2%	2,733	3,014	10.3%	20.5%	20.5%	\$29,531	4,858	36.4%	3,858	29.1%
Hamblen	63,366	64,763	2.2%	11,349	12,854	13.3%	17.9%	17.9%	\$38,058	16,153	25.5%	13,594	22.0%
Hamilton	354,001	371,070	4.8%	57,942	69,258	19.5%	16.4%	16.4%	\$48,759	68,016	19.2%	53,698	27.8%
Hancock	6,632	6,577	-0.8%	1,267	1,421	12.2%	19.1%	19.1%	\$23,450	2,383	35.9%	1,816	17.8%
Hardeman	25,900	25,205	-2.7%	4,182	4,557	9.0%	16.1%	16.1%	\$30,505	7,251	28.0%	5,985	25.9%
Hardin	26,070	26,431	1.4%	5,492	6,213	13.1%	21.1%	21.1%	\$34,257	7,338	28.1%	5,673	22.2%
Hawkins	56,911	57,734	1.4%	11,021	12,693	15.2%	19.4%	19.4%	\$40,581	13,976	24.6%	9,511	17.0%
Haywood	18,031	17,711	-1.8%	2,924	3,314	13.3%	16.2%	16.2%	\$35,276	6,013	33.3%	4,297	23.7%
Henderson	28,084	28,559	1.7%	4,748	5,480	15.4%	16.9%	16.9%	\$38,990	7,298	26.0%	5,702	20.7%
Henry	32,091	32,211	0.4%	6,967	7,744	11.2%	21.7%	21.7%	\$39,302	8,210	25.6%	6,260	19.8%
Hickman	24,191	24,176	-0.1%	3,926	4,536	15.5%	16.2%	16.2%	\$42,974	6,401	26.5%	4,281	18.8%
Houston	8,191	8,074	-1.4%	1,624	1,805	11.1%	19.8%	19.8%	\$37,789	2,068	25.2%	1,771	21.8%
Humphreys	18,137	18,053	-0.5%	3,539	3,949	11.6%	19.5%	19.5%	\$45,342	4,276	23.6%	2,969	16.4%
Jackson	11,533	11,644	1.0%	2,399	2,739	14.2%	20.8%	20.8%	\$35,838	2,916	25.3%	2,735	24.1%
Jefferson	52,294	53,439	2.2%	9,954	11,555	16.1%	19.0%	19.0%	\$40,348	12,661	24.2%	8,357	16.6%
Johnson	17,805	17,633	-1.0%	3,647	4,014	10.1%	20.5%	20.5%	\$33,216	4,539	25.5%	3,785	23.3%
Knox	450,166	468,891	4.2%	66,255	79,091	19.4%	14.7%	14.7%	\$47,037	77,546	17.2%	65,635	15.3%

**Attachment C Need 4.A
Primary Service Area Demographic Chart**

Geographic Area	Total Population - 2015	Total Population - 2020	Total Population - % change	Age 65+ Population - 2015	Age 65+ Population - 2020	Age 65+ Population - % change	Age 65+ of Total Population	Median Household Income	TennCare Enrollees	TennCare Enrollees as % of Total	Persons Below Poverty Level (2014)	Persons Below Poverty Level as % of Total
Lawrence	27,802	28,129	1.2%	1,144	1,260	10.1%	14.9%	\$29,601	2,261	29.4%	1,495	29.7%
Lawrence	41,922	42,331	1.0%	7,433	8,242	10.9%	17.7%	\$33,162	8,093	29.1%	6,471	26.3%
Lawrence	11,908	11,880	-0.2%	2,240	2,527	12.8%	18.8%	\$38,814	10,743	25.6%	8,050	19.4%
Lawrence	33,808	34,584	2.3%	6,269	7,207	15.0%	18.5%	\$35,134	2,999	25.2%	3,333	19.8%
Lawrence	51,424	54,245	5.5%	12,570	14,577	16.0%	24.4%	\$42,487	7,664	22.7%	5,372	16.3%
Lawrence	23,909	23,676	-0.9%	3,671	4,297	17.1%	16.0%	\$50,370	9,187	17.9%	7,708	15.7%
Lawrence	99,066	100,925	1.9%	14,770	17,088	15.7%	14.9%	\$38,053	6,903	30.1%	9,472	18.5%
Lawrence	28,530	29,164	2.2%	5,293	6,186	16.9%	18.6%	\$44,389	25,084	25.3%	5,845	22.7%
Lawrence	31,337	32,229	2.8%	4,858	5,869	20.8%	15.5%	\$41,507	7,222	25.3%	4,697	20.1%
Lawrence	85,612	90,535	5.8%	13,024	16,046	23.2%	15.2%	\$41,327	6,776	21.6%	19,046	20.1%
Lawrence	52,294	52,840	1.0%	9,962	11,343	13.9%	19.0%	\$43,333	18,631	21.8%	5,663	20.3%
Lawrence	26,159	26,509	1.3%	5,153	5,856	13.6%	19.7%	\$39,682	12,500	23.9%	4,749	15.5%
Lawrence	11,607	11,630	0.2%	2,278	2,612	14.7%	19.4%	\$31,851	7,883	30.1%	13,103	16.1%
Lawrence	45,509	46,221	1.6%	8,851	10,301	16.4%	19.4%	\$36,188	3,277	28.2%	2,491	21.9%
Lawrence	187,213	198,331	5.9%	16,460	20,328	23.5%	8.8%	\$50,258	11,888	26.1%	8,413	19.0%
Lawrence	6,242	6,195	-0.8%	1,321	1,479	12.0%	21.2%	\$46,324	33,421	17.9%	28,961	16.3%
Lawrence	21,805	21,856	0.2%	3,529	4,059	15.0%	16.2%	\$41,010	848	13.6%	755	12.3%
Lawrence	30,754	30,228	-1.7%	5,900	6,504	10.2%	19.2%	\$40,999	4,860	22.3%	4,117	22.0%
Lawrence	21,974	22,050	0.3%	4,266	4,830	13.2%	19.4%	\$32,730	8,096	26.3%	5,903	19.1%
Lawrence	7,885	7,986	1.3%	1,635	1,849	13.1%	20.7%	\$32,289	5,269	24.0%	4,887	22.4%
Lawrence	5,085	5,138	1.0%	1,301	1,450	11.5%	25.6%	\$38,421	2,111	26.8%	1,834	23.8%
Lawrence	16,668	16,817	0.9%	3,260	3,727	14.3%	19.5%	\$40,159	1,198	23.6%	837	16.7%
Lawrence	74,116	76,389	3.1%	12,049	13,715	13.8%	16.3%	\$34,293	4,211	25.2%	3,104	18.9%
Lawrence	32,844	34,030	3.6%	5,855	6,907	18.0%	17.8%	\$39,013	17,412	23.5%	17,687	25.2%
Lawrence	52,459	51,662	-1.5%	11,159	12,315	10.4%	21.3%	\$45,392	9,161	27.9%	7,148	23.0%
Lawrence	68,004	70,201	3.2%	9,303	11,215	20.6%	13.7%	\$58,832	11,789	22.5%	9,064	17.2%
Lawrence	290,264	313,883	8.1%	28,591	37,271	30.4%	9.8%	\$56,604	13,837	20.3%	8,149	12.3%
Lawrence	21,863	21,781	-0.4%	3,441	3,897	13.3%	15.7%	\$30,148	48,633	16.8%	35,710	13.3%
Lawrence	14,990	15,852	5.8%	2,825	3,398	20.3%	18.8%	\$35,211	8,102	37.1%	5,981	27.7%
Lawrence	95,271	100,387	5.4%	17,089	20,613	20.6%	17.9%	\$42,676	4,061	27.1%	2,636	21.3%
Lawrence	942,266	962,213	2.1%	111,579	136,234	22.1%	11.8%	\$46,117	268,819	22.7%	195,530	15.9%
Lawrence	19,016	19,100	0.4%	3,034	3,566	17.5%	16.0%	\$47,089	4,324	22.5%	2,984	22.5%
Lawrence	13,401	13,624	1.7%	2,553	2,965	16.1%	19.1%	\$44,360	3,011	22.5%	2,520	19.1%
Lawrence	156,415	157,787	0.9%	32,495	36,683	12.9%	20.8%	\$40,457	33,584	21.5%	27,716	18.0%
Lawrence	172,896	184,056	6.5%	25,758	31,658	22.9%	14.9%	\$55,152	29,378	11.0%	16,818	10.2%
Lawrence	61,699	62,797	1.8%	8,132	9,700	19.3%	13.2%	\$55,152	13,759	22.3%	7,976	13.1%
Lawrence	7,833	7,911	1.0%	1,261	1,488	18.0%	16.1%	\$43,806	2,044	26.1%	1,233	15.9%
Lawrence	17,908	17,742	-0.9%	3,925	4,343	10.6%	21.9%	\$36,910	4,116	23.0%	3,683	20.7%
Lawrence	19,023	19,101	0.4%	3,188	3,708	16.3%	16.8%	\$35,138	5,190	27.3%	4,279	22.7%
Lawrence	5,583	5,661	1.4%	1,154	1,327	15.0%	20.7%	\$33,443	1,400	25.1%	1,181	21.6%
Lawrence	40,048	40,695	1.6%	6,823	7,745	13.5%	17.0%	\$35,732	11,340	28.3%	8,455	21.5%
Lawrence	126,612	130,783	3.3%	21,799	25,698	17.9%	17.2%	\$43,416	24,206	19.1%	21,605	17.9%
Lawrence	16,875	16,938	0.4%	3,123	3,511	12.4%	18.5%	\$37,645	3,473	20.6%	3,158	21.3%
Lawrence	34,090	33,677	-1.2%	5,833	6,417	10.0%	19.6%	\$38,431	7,543	22.1%	6,900	21.5%
Lawrence	26,449	27,241	3.0%	5,189	5,983	15.3%	19.6%	\$36,067	7,232	27.3%	5,640	22.1%
Lawrence	206,864	226,191	9.3%	24,715	33,674	36.2%	11.9%	\$94,539	11,979	5.8%	10,742	5.6%

Attachment C, Need 4.A
Primary Service Area Demographic Chart

Geographic Area	Total Population - 2015	Total Population - 2020	Total Population - % change	Age 65+ Population - 2015	Age 65+ Population - 2020	Age 65+ Population - % change	Age 65+ Population as % of Total	Median Household Income	TennCare Enrollees	TennCare Enrollees as % of Total	Persons Below Poverty Level (2014)	Persons Below Poverty Level as % of Total
Alton	125,884	136,018	8.1%	18,648	23,846	27.9%	14.8%	\$58,564	18,746	14.9%	12,308	10.4%
Amessee	6,562,534	6,794,943	3.5%	1,003,750	1,190,490	18.6%	15.3%	\$45,998	1,481,270	22.6%	1,121,944	17.8%
Appleton	20,415	20,846	2.1%	3,433	3,972	15.7%	16.8%	\$40,068				
Barlow	8,356	8,481	1.5%	1,645	1,869	13.6%	19.7%	\$46,502				
Battle	12,814	12,971	1.2%	2,273	2,586	13.8%	17.7%	\$38,532				
Bell	12,695	12,507	-1.5%	2,479	2,723	9.8%	19.5%	\$41,503				
Bellton	37,776	38,409	1.7%	6,212	7,000	12.7%	16.4%	\$42,753				
Carlisle	4,944	4,844	-2.0%	1,014	1,105	9.0%	20.5%	\$44,058				
Christian	73,668	73,417	-0.3%	8,128	8,941	10.0%	11.0%	\$38,470				
Crittenden	9,229	9,219	-0.1%	1,855	2,056	10.8%	20.1%	\$36,671				
Davess	98,931	101,304	2.4%	15,931	18,263	14.6%	16.1%	\$47,261				
Edmonson	11,972	11,861	-0.9%	2,351	2,622	11.5%	19.6%	\$37,872				
Fulton	6,163	5,718	-7.2%	1,203	1,221	1.5%	19.5%	\$40,045				
Graves	37,427	37,758	0.9%	6,611	7,354	11.2%	17.7%	\$39,894				
Henderson	46,283	46,500	0.5%	7,381	8,497	15.1%	15.9%	\$41,559				
Hickman	4,684	4,559	-2.7%	1,094	1,173	7.2%	23.4%	\$38,814				
Hopkins	46,472	46,387	-0.2%	8,131	9,239	13.6%	17.5%	\$43,668				
Livingston	9,248	9,068	-1.9%	1,898	2,098	10.5%	20.5%	\$41,327				
Logan	26,987	27,353	1.4%	4,743	5,399	13.8%	23.1%	\$38,433				
Marshall	8,481	8,635	1.8%	1,959	2,173	10.9%	21.2%	\$47,791				
McCracken	30,943	30,733	-0.7%	6,573	7,259	10.4%	18.5%	\$40,795				
McLean	65,085	64,949	-0.2%	12,070	13,528	12.1%	19.2%	\$45,333				
Monroe	9,473	9,475	0.0%	1,822	2,023	11.0%	19.0%	\$40,996				
Muhlenberg	10,502	10,174	-3.1%	1,992	2,187	9.8%	18.3%	\$30,286				
Ohio	30,971	30,715	-0.8%	5,676	6,308	11.1%	17.1%	\$41,890				
Simpsom	23,976	24,162	0.8%	4,093	4,630	13.1%	16.1%	\$42,112				
Todd	18,101	18,881	4.3%	2,911	3,424	17.6%	15.4%	\$41,837				
Trigg	12,443	12,436	-0.1%	1,918	2,074	8.1%	21.0%	\$40,833				
Union	14,261	14,289	0.2%	2,999	3,358	12.0%	15.4%	\$44,985				
Warren	14,941	14,901	-0.3%	2,298	2,600	13.1%	12.4%	\$38,942				
Webster	120,516	126,358	4.8%	14,919	18,030	20.9%	16.4%	\$44,091				
Kentucky	13,359	13,229	-1.0%	2,191	2,462	12.4%	16.4%	\$42,197				
	841,116	850,139	1.1%	137,803	156,174	13.3%	16.4%					

Source: Truven Health Analytics

Attachment C.Economic Feasibility.1

Estimated Construction Cost Letter



December 22, 2015

To whom It may concern

RE: **VUMC Clinical Research Center**
CON Application
Verification of Construction Cost Estimate

R.C. Mathews Contractor is a licensed General Contractor in Nashville, Tennessee. We have reviewed the Schematic Design Plans and construction program for the above referenced project.

Our review confirmed the size and scope of the project. We find the renovated area of the existing building to be approximately 11,700sf and the new (expansion) area to be 2,500sf. Based on our experience and historic cost data from similar work at VUMC the construction cost estimate would be \$8,400,000 for this size and type of project in this area.

Sincerely,

A handwritten signature in black ink, appearing to read "Doug Warren", written over a horizontal line.

Doug Warren
Project Manager
R.C. Mathews Contractor

Cc: Walker Mathews, file

Attachment C. Economic Feasibility.2

Funding Documentation



*Cecelia B. Moore
Associate Vice Chancellor for Finance
Vanderbilt University Medical Center*

February 3, 2016

Ms. Melanie M. Hill
Executive Director
Tennessee Health Services & Development Agency
Andrew Jackson State Office Bldg.
Suite 850
500 Deaderick St.
Nashville, TN 37243

Dear Ms. Hill:

This letter will confirm that Vanderbilt University by and through its Vanderbilt University Medical Center has resources sufficient to fund the project described in this Certificate of Need application. Funding of the project will be provided through cash reserves.

As evidence of Vanderbilt's ability to provide the necessary capital, the following information is offered.

1. As of June 30, 2016, Vanderbilt University Medical Center as an operating unit of Vanderbilt University, held cash and unrestricted investments with a fair market value of \$827 million
2. Vanderbilt University has current credit ratings of Aa2/AA+/AA by Moody's/Fitch/S&P.
3. For additional financial information regarding Vanderbilt, please visit the following website: www.vanderbilt.edu/divadm/finrprt

Sincerely,

A handwritten signature in cursive script that reads "Cecelia B. Moore".

Cecelia Moore
Associate Vice Chancellor for Finance
Vanderbilt University Medical Center

**Attachment C.Economic
Feasibility.10**

**Vanderbilt University
Medical Center Financial
Statements
2015**

2015 FINANCIAL REPORT

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Letter from the Chancellor

The heart of an academic research university beats in time with the creativity, productivity, and scholarly excellence of its faculty, physicians, and scientists. In turn, this vibrant environment of learning and discovery attracts the best and brightest students, as well as patients from around the corner and across the globe. Vanderbilt University's culture of service and caring combined with an incredible bandwidth of intellectual power has positioned the university among the world's best.

This is not a distinction that we take lightly or with complacency. Our success — which stems from a combination of vision, philanthropy, responsible stewardship, and prudent fiscal management — enables Vanderbilt to aspire boldly and invest in the people who breathe life into our mission. In FY 2015, we launched a \$50 million Trans-Institutional Initiative Program (TIPS) to support cross-disciplinary research and collaborative projects. The goal with this new funding is to support innovative and creative ideas that will help solve pressing problems facing society. As part of this effort, a new Engineering and Science Building, serves as a great visual marker of the progress of the program. As the building's construction takes shape, we are inspired to know that it will soon provide a place for students, faculty, staff, and visiting entrepreneurs to gather in an environment dedicated to discovery and innovation.

Vanderbilt's deep commitment to supporting research and scholarship is exemplified in a significant investment made this year in the inaugural class of 14 Chancellor Faculty Fellows, a diverse group of proven leaders and innovators in fields ranging from patent law and public policy - to astronomy - to mental health, to support their research and scholarship. And, Opportunity Vanderbilt, which remains one of the most generous financial aid programs in the country, has made a top-tier college education possible for thousands of deserving students.

To fully appreciate Vanderbilt University's tremendous financial and institutional strength, one must also consider the challenges facing healthcare across our nation and the broader state of discourse in higher education. Dwindling federal support for research; decreased reimbursements in funding for health care; uneven economic growth; intense scrutiny and criticism of the high cost of education; and ballooning student debt are serious concerns that we must contend with on a daily basis and throughout the year.

Vanderbilt could not achieve and maintain such a high level of excellence without continually looking ahead and creating strategies to manage impending challenges. Recent changes in the education and health care fields have led us to explore a restructure of the way we conduct the activities and endeavors of Vanderbilt University Medical Center. We are giving careful consideration to how we can best allow the clinical enterprise the flexibility required to remain competitive in today's rapidly changing health care environment while simultaneously buffering the University from the business risks inherent with today's health care landscape. Although legally and financially distinct, the two institutions will remain connected by our shared missions of research and education.

Our story, which began with Cornelius Vanderbilt's \$1 million gift and dream of founding a great university to reconnect a country torn apart by war, tells the tale of what can be achieved when vision, strategy, and philanthropy combine. Of all of the many inventions and investments made by the Commodore that helped build this great nation, I strongly believe if he visited his eponymous university today, he would declare this institution his greatest investment of all time. While his steamboats and railroads have gone the way of the passenger pigeon, Vanderbilt University thrives! We are honored and privileged to carry forward this legacy.

Sincerely,

Nicholas S. Zeppos
Chancellor

Vanderbilt University Statistics

	2014/2015	2013/2014	2012/2013	2011/2012	2010/2011
STUDENTS					
Undergraduate	6,851	6,835	6,796	6,817	6,879
Graduate and professional	5,835	5,922	5,914	6,019	5,835
Total fall enrollment	12,686	12,757	12,710	12,836	12,714
Undergraduate admissions					
Applied	29,518	31,099	28,348	24,837	21,811
Accepted	3,865	3,963	4,034	4,078	3,914
Enrolled	1,605	1,613	1,608	1,601	1,600
Selectivity	13.1%	12.7%	14.2%	16.4%	17.9%
Yield	41.5%	40.7%	39.9%	39.3%	40.9%
Degrees conferred					
Baccalaureate	1,644	1,663	1,675	1,673	1,735
Master's	1,497	1,416	1,421	1,432	1,252
M.D.	120	91	111	99	97
Other doctoral	598	580	551	516	556
Total degrees conferred	3,859	3,750	3,758	3,720	3,640
Undergraduate six-year graduation rate	92.0%	92.9%	92.5%	92.2%	91.9%
Undergraduate tuition	\$ 42,768	\$ 41,928	\$ 41,088	\$ 40,320	\$ 38,952
% increase over prior year	2.0%	2.0%	1.9%	3.5%	3.5%
HOSPITALS AND CLINICS					
Licensed beds	1,025	1,025	1,019	985	916
Inpatient days	314,288	310,119	307,292	285,270	282,547
Discharges	59,026	59,112	57,768	53,818	52,453
Average daily census	861	850	842	782	774
Average length of stay (days)	5.3	5.2	5.3	5.3	5.4
Average occupancy level (licensed beds)	84.0%	82.9%	83.3%	83.6%	84.5%
Hospital surgical operations - inpatient	21,573	22,601	22,396	22,183	22,246
Hospital surgical operations - outpatient	33,575	30,867	30,023	28,815	25,650
Ambulatory visits	1,885,068	1,834,856	1,833,337	1,725,901	1,586,395
Emergency visits	121,663	118,590	119,225	114,051	109,987
LifeFlight (helicopter) missions	1,547	2,313	2,359	2,550	2,203
Case mix index	1.96	1.90	1.93	1.90	1.93
FACULTY AND STAFF					
Full-time faculty	3,740	3,742	3,672	3,551	3,448
Full-time staff	19,305	19,671	19,967	20,119	19,192
Part-time faculty	439	405	430	439	396
Part-time staff	692	709	763	768	798
Total headcount	24,176	24,527	24,832	24,877	23,834
GRANT AND CONTRACT FUNDING					
(in thousands)					
Government sponsors	\$ 348,356	\$ 358,632	\$ 377,839	\$ 397,555	\$ 399,440
Private sponsors	74,142	69,466	61,714	54,768	53,494
Facilities and administrative costs recovery	137,626	140,051	142,609	147,806	145,295
Total grants and contracts	\$ 560,124	\$ 568,149	\$ 582,162	\$ 600,129	\$ 598,229
ENDOWMENT					
Market value (in thousands)	\$ 4,093,388	\$ 4,046,250	\$ 3,635,343	\$ 3,360,036	\$ 3,375,153
Endowment return	3.7%	13.3%	9.3%	1.3%	13.6%
Endowment per student	\$ 322,670	\$ 317,179	\$ 286,022	\$ 261,767	\$ 265,467
Endowment payout	4.1%	4.1%	4.3%	4.4%	4.8%

Financial Overview

In the face of continuing pressures on research funding and health care reimbursements, Vanderbilt experienced sustained financial success in the year ending June 30, 2015. The university's total net assets increased \$132 million to \$5,975 million, driven by overall positive operating results and favorable investment performance. While Vanderbilt's financial position continues to strengthen, our strategic metrics hold strong. Selectivity for the undergraduate schools remained steady and professional school application volumes reflected continued growth. Vanderbilt demonstrated its continued commitment to ensuring that students of every background can attend the university with increased scholarship support through Opportunity Vanderbilt.

Vanderbilt continues to address the ever-changing health care environment's challenges. The expansion of health care coverage through

enrollment in public insurance exchanges, private sector coverage, and Medicaid Expansion is expected to, over time, reduce the cost of uncompensated care provided by Vanderbilt to uninsured individuals. While providers in Medicaid expansion states benefited from a greater population of insured patients, Tennessee has not yet expanded its Medicaid program. Vanderbilt continues to focus on strategic initiatives to increase overall revenue realization and prudent management of expenses to ensure continued financial strength in times of uncertainty.

Given the challenges facing both higher education and health care, Vanderbilt remains increasingly committed to innovation and efficiency to preserve and strengthen the university's financial health in support of our mission.

Financial Position

As of June 30, 2015, Vanderbilt's financial position consisted of assets totaling \$8,271 million and liabilities totaling \$2,296 million, resulting in net assets of \$5,975 million.

Summary of Financial Position as of June 30, in millions

	2015	2014
ASSETS		
Working capital cash and investments	\$ 1,230	\$ 1,119
Endowment and other cash and investments	4,639	4,456
Accounts and contributions receivable	562	569
Property, plant, and equipment, net	1,748	1,765
Prepaid expenses and other assets	92	89
Total assets	\$ 8,271	\$ 7,998
LIABILITIES		
Payables and accrued liabilities	\$ 599	\$ 600
Deferred revenue	100	93
Interest rate exchange agreements	175	169
Securities sold short	187	-
Taxable debt for liquidity	250	250
Project and equipment-related debt	985	1,043
Total liabilities	2,296	2,155
NET ASSETS		
Unrestricted net assets	3,279	3,180
Temporarily restricted net assets	1,461	1,467
Permanently restricted net assets	1,235	1,196
Total net assets	5,975	5,843
Total liabilities and net assets	\$ 8,271	\$ 7,998

Vanderbilt's assets, totaling \$8,271 million as of June 30, 2015, increased \$273 million, or 3.4%, from the prior year. Total assets increased primarily due to positive net operating results. The endowment, net of securities sold short, earned a return of 3.7% and its value (after the impact of distributions in support of operations and the addition of new gifts and unrestricted quasi-endowments) increased to \$4,093 million at the end of fiscal 2015 from \$4,046 million at the end of fiscal 2014.

Total liabilities increased \$141 million, or 6.5%, to \$2,296 million as of June 30, 2015, from \$2,155 million as of June 30, 2014. This was attributable largely to the \$187 million of securities sold short, partially offset by the \$58 million decrease in long-term debt as a result of scheduled principal payments and net premium amortizations for the year. Interest rate exchange agreement liabilities increased \$6 million as a result of the mark-to-market adjustment offset in part by the termination of fixed-payer interest rate exchange agreements. Payables and other accrued liabilities remained consistent with the prior year.

Cash and Liquidity

Vanderbilt's working capital cash and investments, which include highly liquid operating accounts, amounts posted as collateral (related primarily to interest rate exchange agreements), and amounts invested in the long-term investment pool alongside the endowment, totaled \$1,230 million as of June 30, 2015.

Vanderbilt continues to invest operating assets in a conservative, diversified manner to ensure adequate security and liquidity under a variety of stress scenarios. During fiscal 2015, operating and endowment assets available within 30 days increased to \$2,247 million from \$2,158 million in fiscal 2014 (4.1% increase), while same day liquidity increased to \$1,375 million from \$1,133 million in fiscal 2014 (21.4% increase). A higher level of endowment assets with same day liquidity drove this increase as of June 30, 2015. Based largely on this very strong liquidity position, Vanderbilt maintains the highest short-term ratings from the major credit rating agencies.

To provide supplemental liquidity support, Vanderbilt maintains an agreement with one bank to provide a general operating line of credit with a maximum available commitment totaling \$100 million. In addition, Vanderbilt carries \$400 million of revolving credit facilities with two additional banks to provide dedicated self-liquidity support for the debt portfolio; one of these lines, totaling \$200 million, includes a general use provision.

Debt

Vanderbilt's debt portfolio includes fixed-rate debt, variable-rate debt, and commercial paper, along with interest rate exchange agreements used for hedging interest rate exposure within the university's debt portfolio.

For the sixth consecutive year, Vanderbilt did not issue new-money debt. Scheduled principal payments on long-term debt and elective reductions of commercial paper reduced total outstanding debt by \$58 million to a balance of \$1,235 million as of June 30, 2015. This

amount consisted of \$985 million of capital project-related debt and \$250 million of taxable debt for liquidity support.

During fiscal 2015, Vanderbilt terminated \$60 million notional of fixed-payer interest rate exchange agreements in order to reduce the university's aggregate collateral exposure and eliminate ongoing settlement costs. Over the past six fiscal years, Vanderbilt terminated \$510 million of fixed-payer interest rate exchange agreements and incurred net amortization of \$18 million, reducing its fixed-payer portfolio notional balance to \$483 million at the end of fiscal 2015 as compared to \$1,011 million at the end of fiscal 2009.

Statements of Activities

Vanderbilt's total operating and nonoperating activity resulted in a \$132 million increase in net assets in fiscal 2015, compared to a \$504 million increase in fiscal 2014.

Summary of Changes in Net Assets in millions

	2015	2014
Revenues and expenses:		
Unrestricted operating revenues	\$ 4,067	\$ 3,833
Unrestricted operating expenses	(3,933)	(3,754)
Unrestricted operating activity	134	79
Contribution activity in temporarily restricted and permanently restricted net assets	(22)	(4)
Investment income and endowment distributions in temporarily restricted and permanently restricted net assets	78	91
Other changes in net assets:		
Change in appreciation of endowment, net of distributions	(29)	322
Change in interest rate exchange agreements	(28)	6
Change in net assets related to noncontrolling interests	(39)	(37)
Contributions for plant	8	10
Other nonoperating activity	30	37
Increase in net assets	\$ 132	\$ 504
Ending balance of net assets	\$ 5,975	\$ 5,843

Vanderbilt University Net Assets fiscal 2011 - fiscal 2015 in millions



During fiscal 2015, total net assets increased due primarily to strong net operating results. In comparison, the increase in fiscal 2014 was due primarily to strong net operating results and endowment returns.

In fiscal 2015, permanently restricted net assets increased \$39 million, or 3.3%, to \$1,235 million, as compared to \$1,196 million in fiscal 2014, due primarily to new true endowment corpus additions. Temporarily restricted net assets decreased \$6 million, or 0.4%, to

\$1,461 million in fiscal 2015 as compared to \$1,467 million in fiscal 2014, primarily as a result of decreased market values of assets held in permanently restricted funds. All accumulated market gains on both permanently and temporarily restricted net assets are temporarily restricted until appropriated for use. Unrestricted net assets increased \$99 million, or 3.1%, to \$3,279 million in fiscal 2015 as compared to \$3,180 million in fiscal 2014, as a result of \$134 million in unrestricted operating results offset by a \$39 million decrease in net assets related to noncontrolling interests and \$4 million increase due to other changes in net assets.

Consolidated Operating Revenues

Consolidated operating revenues increased \$202 million, or 5.2%, to \$4,122 million in fiscal 2015, as compared to \$3,920 million in fiscal 2014. The primary driver of this increase was a \$203 million, or 7.8%, increase in health care services revenue to \$2,816 million in fiscal 2015 from \$2,613 million in fiscal 2014 due largely to increases in hospital acuity, realization rate, and increases in retail, specialty, and contract managed pharmacy revenues. The health care section of the financial overview includes further details of Vanderbilt's health care services.

To facilitate Vanderbilt's commitment to student access and affordability, the university provides significant financial aid to students and their families. In fiscal 2015, Vanderbilt provided \$250 million in support to its students for tuition and room and board as shown in the table below.

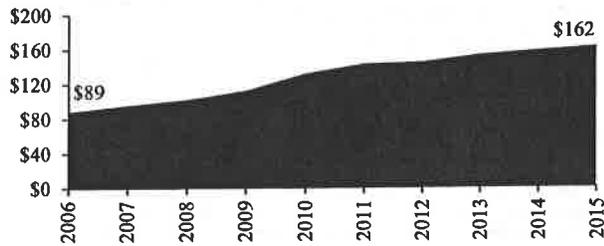
Tuition, Room and Board, and Financial Aid – Fiscal 2015 in millions

	Undergraduate (6,851 students)	Graduate and Professional (5,835 students)	Total
Tuition and fees	\$ 307	\$ 182	\$ 489
Financial aid	(129)	(88)	(217)
Tuition and fees, net	\$ 178	\$ 94	\$ 272
Room and board	\$ 78	\$ -	\$ 78
Financial aid	(33)	-	(33)
Room and board, net	\$ 45	\$ -	\$ 45
Total	\$ 223	\$ 94	\$ 317

The financial aid number above excludes Pell Grants of \$4 million. Generally Accepted Accounting Principles (GAAP) financial statements exclude Pell Grants, which are agency funds.

Over the past decade, Vanderbilt nearly doubled its level of support for undergraduate aid, as shown in the graph below.

Undergraduate Financial Aid
fiscal 2006 - 2015, in millions



For undergraduates, aid as a percentage of gross tuition, room and board, and educational fees in fiscal 2015 was 42%. A portion of operations (\$98 million), endowments (\$57 million), external agencies (\$4 million), working capital investments (\$2 million), and gifts (\$1 million) funded this aid. Critical to this support is the university's Opportunity Vanderbilt fundraising initiative that began in fiscal 2009 to support undergraduate financial aid. Through June 30, 2015, this initiative raised \$213 million.

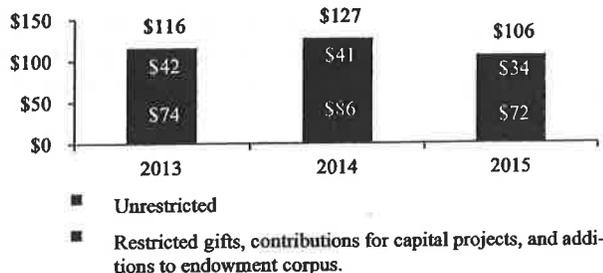
Vanderbilt reports contributions revenue within the consolidated financial statements based on GAAP. This basis for measurement differs from guidelines established by the Council for Advancement and Support of Education (CASE). CASE guidelines represent the development reporting standard for colleges and universities and focus on philanthropic distributions of private resources (primarily gifts and foundation grants) to benefit the public.

GAAP to CASE Reconciliation
in millions

	2015
Total consolidated GAAP contributions	\$ 106
Grants and similar agreements meeting CASE guidelines (gifts per CASE standards)	28
Net decrease in contributions receivable (fiscal 2014 to 2015)	(8)
Other	(3)
CASE reported gifts (cash basis)	\$ 123

On a GAAP basis, in fiscal 2015, Vanderbilt recorded \$106 million in contributions revenue, including pledges, a 16.5% decrease compared to the \$127 million recorded in fiscal 2014.

Contributions (GAAP basis)
in millions



Consolidated Operating Expenses

Consolidated operating expenses increased \$179 million, or 4.8%, to \$3,933 million in fiscal 2015, as compared to \$3,754 million in fiscal 2014. The primary driver of this increase was a \$123 million, or 9.9%, increase in supplies, services, and other expenses to \$1,364 million in fiscal 2015 from \$1,241 million in fiscal 2014. This increase was primarily due to hospital and clinic pharmaceutical expenses. Additionally, increased outpatient volumes drove increases in salaries, wages, and benefits.

Other Changes in Net Assets

Other changes in net assets included changes in appreciation of endowment, net of distributions totaling a decrease of \$29 million in fiscal 2015 and an increase of \$322 million in fiscal 2014. The change in appreciation for the endowment resulted from a 3.7% investment return offset by 4.1% of the endowment utilized for distributions during fiscal 2015, compared to a 13.3% investment return offset by 4.1% of the endowment utilized for distributions during fiscal 2014.

In fiscal 2015, Vanderbilt incurred net losses of \$28 million on interest rate exchange agreements compared to net gains of \$6 million in fiscal 2014. Included in these net losses and gains are costs associated with the termination of interest rate exchange agreements of \$22 million in fiscal 2015 compared to \$32 million in fiscal 2014. Further, Vanderbilt experienced unrealized gains of \$2 million in fiscal 2015 compared to \$25 million in fiscal 2014 as a result of mark-to-market valuation adjustments. These adjustments resulted from the positive effect of the termination of agreements in the respective periods, offset slightly by the negative effect of decreased long-term LIBOR rates. Additionally, fiscal 2015 results were impacted by an \$8 million unrealized loss resulting from a decreased discount rate to reflect counterparty risk (the risk that Vanderbilt will default), compared to a \$13 million unrealized gain in fiscal 2014. During fiscal 2015, improvement to the estimated AA Higher Education credit spread and a decreased average remaining life of interest rate exchange agreements indicated a lower risk of Vanderbilt default as compared to fiscal 2014. Vanderbilt's calculated credit risk and the corresponding adjustment decreased accordingly, resulting in the aforementioned \$8 million unrealized loss and an increase to the interest rate exchange agreement liability.

Net assets related to noncontrolling interests decreased \$39 million due to distributions of \$49 million offset slightly by \$8 million of appreciation and \$2 million of cash contributions during fiscal 2015. Net, other nonoperating activity totaled \$38 million in fiscal 2015 compared to \$47 million in fiscal 2014. The decrease in other nonoperating activity resulted primarily from net endowment losses and losses on derivative financial instruments, partially offset by a \$30 million gain on sale of business.

Unrestricted Operating Activity

The change in unrestricted net assets from operating activity is the measure of the university's *operating results*. This unrestricted operating activity totaled \$134 million in fiscal 2015 and \$79 million in fiscal 2014.

Unrestricted Operating Revenues

Unrestricted operating revenues increased \$234 million, or 6.1%, to \$4,067 million in fiscal 2015 as compared to \$3,833 million in fiscal 2014.

Operating Revenues by Source

Unrestricted net assets, in millions

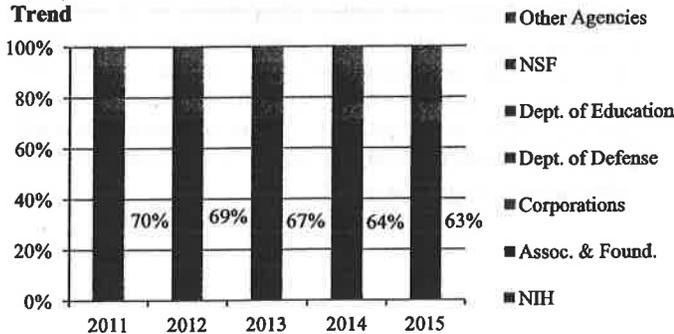
	2015	2014
Tuition and educational fees, net of financial aid	\$ 272	\$ 265
Government grants and contracts	348	359
Private grants and contracts	74	69
F&A costs recovery	138	140
Contributions, including net assets released from restrictions	120	122
Endowment distributions	86	77
Investment income	18	18
Health care services	2,816	2,613
Room, board, and other auxiliary services, net of financial aid	127	112
Other sources	68	58
Total operating revenues	\$ 4,067	\$ 3,833

Due largely to governmental budgetary constraints, government and private grants and contracts revenue, predominantly for research activities, declined 1.4% from fiscal 2014 to 2015 (to \$422 million from \$428 million). Within the pool of direct grant revenues, while government grants and contracts direct revenue declined by 3.1% from fiscal 2014 to 2015 (to \$348 million from \$359 million), private grants and contracts direct revenues increased 7.2% over the same time period (to \$74 million from \$69 million).

As shown in the next graph, the largest source of direct grant and contract revenue was the Department of Health and Human Services (National Institutes of Health, or NIH, funding source). Other external sources included state and local governments, industry, foundations, and private sources.

Five-year Grants and Contracts by Revenue Source

Trend



Grants and Contracts Revenues by Funding Source

in millions

	2015	%
Dept. of Health and Human Services	\$ 265	63%
Associations and foundations	29	7%
Corporations	36	8%
Dept. of Defense	24	6%
Dept. of Education	18	4%
National Science Foundation	20	5%
Other government and private agencies	30	7%
Total grants and contracts revenues by funding source	\$ 422	100%

Sponsored research and project awards (awards represent research funding commitments that have not yet been expended by Vanderbilt), which include multiple-year grants and contracts from government sources, foundations, associations, and corporations, totaled \$682 million in fiscal 2015 and \$657 million in fiscal 2014.

Sponsored Research and Project Awards

in millions

	2015	2014
Government awards	\$ 510	\$ 493
Private awards	172	164
Total sponsored research and project awards	\$ 682	\$ 657

Government awards accounted for 75% of the total sponsored funding during fiscal 2015 and increased \$17 million, or 3.4%, to \$510 million in fiscal 2015 from \$493 million in fiscal 2014. Private awards increased \$8 million, or 4.9%, to \$172 million in fiscal 2015 from \$164 million in fiscal 2014. The growth in government awards is particularly impressive given the pressures on federal funding, while the growth in private awards signals Vanderbilt's continued success in diversifying its research award pipeline.

Unrestricted Operating Expenses

Operating expenses increased \$179 million, or 4.8%, to \$3,933 million in fiscal 2015 as compared to \$3,754 million in fiscal 2014.

Operating Expenses by Natural Classification

in millions

	2015	2014
Salaries, wages, and benefits	\$ 2,332	\$ 2,272
Supplies, services, and other	1,364	1,241
Interest expense	60	65
Depreciation and amortization	177	176
Total operating expenses	\$ 3,933	\$ 3,754

The increase in total operating expenses was due largely to a 9.9% increase in supplies, services, and other expenses and a 2.6% increase in salaries, wages, and benefits consistent with increases in health care revenues.

Health Care

During fiscal 2015, the health care landscape continued to evolve. Enrollment in public insurance exchanges increased to approximately 10 million effectuated enrollees nationwide. As of June 30, 2015, thirty states and the District of Columbia had expanded their Medicaid programs resulting in decreased uncompensated care percentages and many health care providers in those states experiencing improved profitability. Despite a special session of the Tennessee legislature in February 2015 to consider the Medicaid expansion program known as "Insure Tennessee," Tennessee remains one of the states that has not yet expanded its Medicaid program (TennCare). Vanderbilt University Medical Center's (VUMC) uncompensated care (defined as charity, bad debt, and unreimbursed cost of TennCare/Medicaid) decreased \$8 million to a total of \$225 million in cost-based write-offs in fiscal 2015 from \$233 million in fiscal 2014.

To compete in a dynamic health care market, VUMC continues to develop strategies to increase revenue realization and reduce operating costs. During fiscal 2015, VUMC continued to focus on revenue cycle improvements, increasing overall revenue realization through improved back-office processes, charge capture, and data analytics. These activities introduced new technology and workflow that resulted in an improvement to net revenue of \$25 million in fiscal 2015.

Health care services revenue increased \$203 million, or 7.8%, to \$2,816 million in fiscal 2015 from \$2,613 million in fiscal 2014. This increase was due largely to outpatient volume increases, expansion of the retail pharmacy program and increased acuity of patients. Inpatient days increased 1.3%, due to increased length of stay resulting from increased acuity of patients, and outpatient visit volumes increased 2.7% in fiscal 2015 from fiscal 2014. Gross revenue from the retail pharmacy program increased \$78.2 million, or 51.7%, to \$229.7 million in fiscal 2015 from \$151.5 million in fiscal 2014.

Health care services expenses increased \$111 million, or 4.6%, to \$2,500 million in fiscal 2015 from \$2,389 million in fiscal 2014. This increase was due largely to an overall increase in patient days, continued expansion of the retail pharmacy program, and overall growth in ambulatory visits.

In fiscal 2015, VUMC continued to prudently manage salaries, wages, and benefits. As a result, salaries, wages, and benefits as a percent of net revenue for fiscal 2015 decreased to 38.3% compared to 39.9% for fiscal 2014. Paid Full-Time Equivalent (FTE) clinical employees were 9,697 for fiscal 2015 as compared to 9,473 for fiscal 2014. Clinical FTEs per adjusted occupied bed (AOB) for Vanderbilt University Hospital (VUH) were 5.2 in fiscal 2015 as compared to 4.7 in fiscal 2014. The increase of .5 Clinical FTEs per AOB relates to an increase in acuity of patients. As a result, the Case Mix Index (CMI) for VUH increased to 2.09 from 2.04 in the prior year. CMI-adjusted FTEs per AOB was 3.37 in fiscal 2015 and fiscal 2014. Monroe Carell Jr. Children's Hospital at Vanderbilt (MCJCHV) FTEs per adjusted occupied bed for fiscal 2015 were 5.0 as compared to 5.3 in fiscal 2014.

The following graph illustrates the overall hospital occupancy rate for inpatients based on licensed beds as compared to average daily census.

Percentage Occupancy and Average Daily Census



VUMC's overall hospital occupancy rate for inpatients based on licensed beds was 84.0% in fiscal 2015, a slight increase from 82.9% in fiscal 2014, due to the increased acuity of patients. The increased acuity of patients resulted in an increase in the average length of stay to 5.3 in fiscal 2015 from 5.2 days in fiscal 2014.

VUMC's internal measure of occupancy based on beds available and adjusted for outpatient utilization of bed capacity yielded an occupancy rate of 95% in fiscal 2015, an increase of 2% from an occupancy rate of 93% in fiscal 2014. Thus, VUMC continues to operate above optimal occupancy of 85% when total utilization of capacity is measured.

In October 2014, the Tennessee Health Services and Development Agency approved VUMC's master Certificate of Need for the relocation of the obstetrical program, the newborn nursery, and the neonatal unit from VUH to new space at MCJCHV and renovation of the vacated area in VUH. This planned project will add 23 new obstetrical beds, 24 neonatal/pediatric critical care beds, 61 adult acute care beds, and 63 observation beds. The bed expansions are necessary to avoid overcrowding and long wait times for patients in the emergency room, recovery rooms, and other procedural staging areas.

VUMC continues to maintain strong inpatient and outpatient volumes. While experiencing an increase in inpatient days, discharges in fiscal 2015 decreased slightly to 59,026 in fiscal 2015 from 59,112 in fiscal 2014. Total VUH and MCJCHV surgical operations increased 3.1% in fiscal year 2015. Volumes continued to shift from inpatient to outpatient surgeries as inpatient surgeries decreased by 4.5% and outpatient surgeries grew by 8.8%.

Overall hospital ambulatory visits (outpatient visits) increased 2.7% to 1.9 million in fiscal 2015 as VUMC continued its expansion of health care services offered outside the medical center's main campus. Approximately 45% of outpatient visits occurred at off-campus locations. Physician practice expansions in obstetrics, gynecology, and pediatrics in nearby communities contributed to the growth in ambulatory visits.

VUMC's overall CMI increased to 1.96 in fiscal 2015 from 1.90 in fiscal 2014. The CMI increase resulted from the increased acuity of patients and aligns with VUMC's continued focus on serving as Middle Tennessee's only tertiary/quaternary medical center while supporting patients receiving less intensive medical services in outpatient settings or community hospitals. VUH and MCJCHV continued to see an increase in medical patients, which comprised 54.2% of total discharges in fiscal 2015 compared to 52.8% in fiscal 2014, with the medical CMI increasing to 1.35 in fiscal 2015 from 1.30 in fiscal 2014. The largest increase in acuity was in the surgical specialties with the surgical case mix index increasing to 3.57 in fiscal 2015 as compared to 3.42 in fiscal 2014.

The following table presents payer mix percentages based on gross charges for Vanderbilt's hospitals and clinics in fiscal 2015 and fiscal 2014.

Payer Mix

Vanderbilt hospitals and clinics (% of gross charges)

	2015	2014
Commercial/Managed Care	47.8%	47.2%
Medicare/Managed Medicare	29.5%	29.5%
TennCare/Medicaid	18.0%	17.2%
Uninsured (self-pay)	4.7%	6.1%
Total payer mix	100.0%	100.0%

Overall uninsured patients decreased while governmental payers TennCare/Medicaid and commercial/managed care increased 80 and 60 basis points, respectively. The commercial/managed care increase primarily resulted from the growth in the retail pharmacy service line, which has a higher commercial/managed care payer mix than other service lines.

VUMC remains committed to providing high-quality health care services that meet key community needs, including providing substantial charity care for members of the community who otherwise would not be able to secure needed services.

VUMC maintains a charity care policy that sets forth the criteria for health care services provided without expectation of payment, or at a reduced payment rate, to patients who meet income criteria based on federal poverty limit guidelines. Vanderbilt does not report charity care services as revenue. These services represented 4.5% and 5.7% of total gross patient services revenue in fiscal 2015 and 2014, respectively.

Uncompensated Care

in millions

	2015	2014
Unreimbursed charity care cost	\$ 103	\$ 127
Unreimbursed cost of TennCare/Medicaid	103	76
Unreimbursed bad debt cost	19	30
Total uncompensated care	\$ 225	\$ 233
<i>Charity care as % of total uncompensated care</i>	<i>45.8%</i>	<i>54.5%</i>

In addition to the uncompensated care described above, the medical center provides a number of other services to benefit the economically disadvantaged for which the medical center receives little or no payment. This includes public health education and training for new health professionals and provides, without charge, services to the community at large, together with support groups for many patients with special needs.

The following table provides a summary of costs for the community benefit activities, reported in Vanderbilt's Form 990 filing (Return of Organization Exempt from Income Taxes).

Charity Care Assistance, Community Benefits, and Other Unrecovered Costs

in millions

	2015	2014
Charity care and community benefits		
Unreimbursed charity care cost	\$ 103	\$ 127
Resident and Allied Health education	84	91
Unreimbursed cost of TennCare/Medicaid	103	76
Other community health programs	4	1
Clinical and laboratory research support	128	107
Total costs of charity care and community benefits	422	402
Other unrecovered costs using IRS Form 990 Schedule H guidelines but not includable as community benefits		
Unreimbursed cost of Medicare	65	86
Unreimbursed bad debt costs	19	30
Unreimbursed cost of TRICARE	7	7
Total other unrecovered costs	91	123
Total cost of charity care, community benefits, and other unrecovered costs	\$ 513	\$ 525

In the preceding table, clinical and laboratory expense of \$128 million included sponsored research, primarily from the NIH as well as other federal and nonfederal agencies, for the support of basic and clinical research. In addition, institutional funds provided support for unfunded research such as bridge funds for faculty members between grant periods, and for new ideas or new science that may receive funding in future years.

Endowment

For fiscal 2015, Vanderbilt's endowment portfolio returned 3.7%. The endowment ended fiscal 2015 with a total market value of \$4,093 million, compared to \$4,046 million at the end of fiscal 2014. The difference between the investment return and change in absolute value of the endowment was attributable to the net impact of new endowment gifts, additions to institutional endowments (quasi-endowments), investment returns, costs for managing the endowment, and the distribution of endowment funds to support university operations. During fiscal 2015, the university added \$76 million to the endowment portfolio through new gifts and additions to institutional endowments. Endowment distributions totaled \$165 million in fiscal 2015, compared to \$158 million in fiscal 2014. These distributions support the university's education, research, and public service missions.

The past year witnessed a choppy capital market environment relative to the appreciation in risk-based assets over each of the prior five fiscal years. Global equity markets were up only 1%, with wide dispersion across the U.S. (up 7%), non-U.S. developed markets (up 4%), and emerging markets (down 5%). U.S. bond markets were sanguine (up 2%), a relatively small return attributable to historically low yields and credit spreads. Commodity prices crashed (down 37%), and in a related move the U.S. dollar appreciated (by 19%).

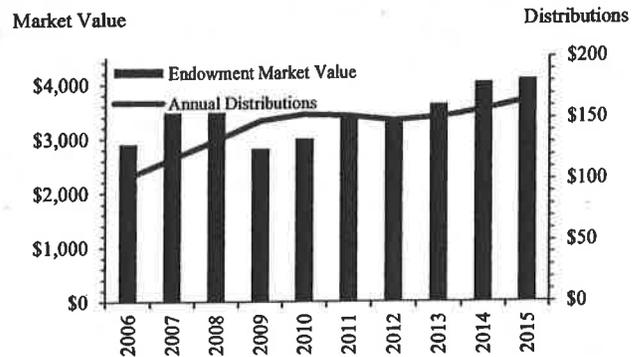
Given this environment, Vanderbilt's endowment held up well. Looking into the future, significant headwinds could still lie ahead. U.S. equity valuations are reasonably full, European equity markets are challenged by the volatility of the European Union and "Grexit" dynamics, and Asian markets are struggling in the midst of excessive leverage. And globally, markets are wrestling with government intervention, changing regulatory pressures, and slow-growth economies. In addition, conversations about when the U.S. Federal Reserve will normalize monetary policy and increase the Fed Funds rate continue to contribute to market volatility. That said, these challenges

Looking forward

As FY15 comes to a close, Vanderbilt's financial foundation remains strong despite a year of continued economic challenges including pressured health care reimbursements and declining federal support for research. Despite this environment, the health care enterprise continues to generate strong operating results while the academic and research areas demonstrate sustained stability.

will from time to time present chances to be opportunistic in deploying new investments. Meanwhile, Vanderbilt is laying a strong foundation for the endowment by collaborating with some of the world's best investment managers across all asset classes.

Endowment Market Value and Annual Distributions in millions



Endowment Asset Allocation As of June 30, 2015 (% of portfolio)

	Allocation
Global equities	22.3%
Hedged strategies	20.4%
Commodities	2.2%
Fixed income	5.0%
Cash and cash equivalents	9.2%
Total public investments	59.1%
Private capital	29.8%
Real estate	4.5%
Natural resources	6.6%
Total nonmarketable	40.9%
Total endowment	100.0%

The legal reorganization of Vanderbilt University Medical Center currently being explored will position both entities to better achieve their strategic priorities while remaining focused on a shared mission of scholarship, teaching, and creative experimentation. Vanderbilt made significant progress towards the legal separation over the past year and will maintain this momentum in FY16. Included in the pages that follow are Vanderbilt's audited financial statements, financial ratios, and other key financial metrics for fiscal 2015.

Financial Ratios

Expendable Net Assets to Debt

Expendable Net Assets / Project Debt and Lease Commitments

2011	2012	2013	2014	2015
2.3x	2.4x	2.7x	3.1x	3.1x

Expendable net assets to debt measures the university's leverage. Debt used for calculating this ratio consists of all project-related debt, the net present value of lease commitments, and debt guarantees.

Vanderbilt's expendable net assets to debt ratio for fiscal 2015 remained fairly stable. Vanderbilt's expendable net assets to debt improved in fiscal 2014 as the result of a net increase in endowment market value and a decline in outstanding debt. Vanderbilt aims to maintain expendable net assets to debt of at least 2.0.

Debt Service Coverage Ratio

Unrestricted Operating Results before Interest and Depreciation / Normalized Annual Debt Service

2011	2012	2013	2014	2015
4.0x	4.1x	2.1x	3.5x	4.3x

The *debt service coverage ratio* measures the university's ability to pay annual debt service obligations from current year operating activities. In this context, annual debt service is normalized to calculate long-term (25 years) level principal and interest payments that would be required based on the portfolio's then-prevailing weighted average interest rates inclusive of the effects of interest rate exchange agreements. The scope for this ratio is all outstanding debt, except for taxable commercial paper used for short-term liquidity support prior to fiscal 2012.

In fiscal 2015, better net operating results and slightly less normalized annual debt service resulted in an increase in the debt service coverage ratio. In fiscal 2014, net operating results increased from fiscal 2013, while normalized annual debt service decreased slightly resulting in an increased debt service coverage ratio. Vanderbilt aims to maintain a debt service coverage ratio of at least 2.0.

Debt Service Burden

Normalized Annual Debt Service / Unrestricted Operating Expenses

2011	2012	2013	2014	2015
2.9%	2.8%	2.6%	2.4%	2.2%

The *debt service burden* measures the percent of the annual operating budget devoted to servicing outstanding debt.

Consistent with the trend noted since fiscal 2011, Vanderbilt's debt service burden decreased in fiscal 2015 and 2014 due to increases in operating expenses, strengthened by decreases in normalized annual debt service. Vanderbilt aims to maintain a debt service burden below 5.0%.

Operating Cash Flow Margin

Unrestricted Operating Results before Interest and Depreciation / Unrestricted Operating Revenues

2011	2012	2013	2014	2015
11.1%	10.9%	5.5%	8.4%	9.1%

The *operating cash flow margin* measures the cash flow generated from each dollar of operating revenue. The resulting net cash flows may occur in the current or future years depending on changes in receivables and payables.

In fiscal 2015, Vanderbilt's unrestricted operating results before interest and depreciation increased 15.9% to \$371 million from \$320 million in fiscal 2014. Fiscal 2015 unrestricted operating revenues at \$4,067 million represented a 6.1% increase from \$3,833 million in fiscal 2014. The fiscal 2014 operating cash flow margin increased in comparison to fiscal 2013 due in part to the \$121 million change in estimate of net realizable value of patient receivable in fiscal 2013.

Capital Intensiveness Ratio

Acquisitions of Property, Plant, and Equipment / Unrestricted Operating Revenues

2011	2012	2013	2014	2015
3.6%	3.9%	6.2%	4.0%	4.2%

The *capital intensiveness ratio* measures the university's annual investments in property, plant, and equipment as a percentage of the university's annual operating revenues.

In fiscal 2015, the capital intensiveness ratio remained fairly stable with similar increases to both PP&E additions and operating revenues as compared to fiscal 2014. Vanderbilt's capital spending activity in fiscal 2014 decreased to \$153 million from fiscal 2013 capital spending of \$224 million as several large projects approached completion in fiscal 2014 (e.g., Warren College and Moore College, Vanderbilt Recreation and Wellness Center, and Alumni Hall).

Average Age of Plant

Accumulated Depreciation / Depreciation Expense

2011	2012	2013	2014	2015
10.2 yrs	11.2 yrs	11.8 yrs	12.6 yrs	12.5 yrs

The *average age of plant* metric provides a sense of the age of the university's facilities. A low average age of plant indicates that an institution has made significant recent investments in its plant.

The retirement of \$150 million of fully depreciated equipment in fiscal 2015 resulted in a slightly improved ratio. Decreased capital spending combined with normal growth of accumulated depreciation (primarily in buildings and movable equipment categories) increased average age of plant to 12.6 years in fiscal 2014 from 11.8 years in fiscal 2013.

VANDERBILT  UNIVERSITY

Consolidated Financial Statements



Independent Auditor's Report

Board of Trust
Vanderbilt University

We have audited the accompanying consolidated financial statements of Vanderbilt University (the "University"), which comprise the consolidated statements of financial position as of June 30, 2015 and 2014, and the related consolidated statements of activities and cash flows for the years then ended.

Management's Responsibility for the Consolidated Financial Statements

Management is responsible for the preparation and fair presentation of the consolidated financial statements in accordance with accounting principles generally accepted in the United States of America; this includes the design, implementation, and maintenance of internal control relevant to the preparation and fair presentation of consolidated financial statements that are free from material misstatement, whether due to fraud or error.

Auditor's Responsibility

Our responsibility is to express an opinion on the consolidated financial statements based on our audits. We conducted our audits in accordance with auditing standards generally accepted in the United States of America. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free from material misstatement.

An audit involves performing procedures to obtain audit evidence about the amounts and disclosures in the consolidated financial statements. The procedures selected depend on our judgment, including the assessment of the risks of material misstatement of the consolidated financial statements, whether due to fraud or error. In making those risk assessments, we consider internal control relevant to the University's preparation and fair presentation of the consolidated financial statements in order to design audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the University's internal control. Accordingly, we express no such opinion. An audit also includes evaluating the appropriateness of accounting policies used and the reasonableness of significant accounting estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our audit opinion.

Opinion

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of Vanderbilt University at June 30, 2015 and 2014, and the changes in its net assets and its cash flows for the years then ended in accordance with accounting principles generally accepted in the United States of America.

PricewaterhouseCoopers LLP

October 22, 2015

Vanderbilt University Consolidated Statements of Financial Position

As of June 30, 2015 and 2014 (in thousands)

	2015	2014
ASSETS		
Cash and cash equivalents	\$ 1,291,631	\$ 1,244,720
Accounts receivable, net	404,145	414,565
Prepaid expenses and other assets	92,296	89,192
Contributions receivable, net	82,418	74,820
Student loans and other notes receivable, net	35,438	40,251
Investments	4,465,738	4,179,606
Investments allocable to noncontrolling interests	110,954	150,067
Property, plant, and equipment, net	1,748,410	1,765,244
Interests in trusts held by others	40,154	39,790
Total assets	\$ 8,271,184	\$ 7,998,255
LIABILITIES		
Accounts payable and accrued liabilities	\$ 251,670	\$ 212,167
Accrued compensation and withholdings	174,115	216,117
Deferred revenue	100,511	92,985
Actuarial liability for self-insurance	116,753	113,626
Actuarial liability for split-interest agreements	33,757	35,667
Government advances for student loans	22,356	22,366
Commercial paper	263,454	209,845
Long-term debt and capital leases	971,415	1,083,285
Fair value of securities sold short	187,431	-
Fair value of interest rate exchange agreements	174,713	168,451
Total liabilities	2,296,175	2,154,509
NET ASSETS		
Unrestricted net assets controlled by Vanderbilt	3,167,702	3,029,763
Unrestricted net assets related to noncontrolling interests	110,954	150,067
Total unrestricted net assets	3,278,656	3,179,830
Temporarily restricted net assets	1,461,162	1,467,482
Permanently restricted net assets	1,235,191	1,196,434
Total net assets	5,975,009	5,843,746
Total liabilities and net assets	\$ 8,271,184	\$ 7,998,255

The accompanying notes are an integral part of the consolidated financial statements.

Vanderbilt University

Consolidated Statement of Activities

Year Ended June 30, 2015 (in thousands)

	2015			Total
	Unrestricted	Temporarily Restricted	Permanently Restricted	
REVENUES				
Tuition and educational fees	\$ 489,018	\$ -	\$ -	\$ 489,018
Less student financial aid	(216,815)	-	-	(216,815)
Tuition and educational fees, net	272,203	-	-	272,203
Grants and contracts:				
Government sponsors	348,356	-	-	348,356
Private sponsors	74,142	-	-	74,142
Facilities and administrative costs recovery	137,626	-	-	137,626
Total grants and contracts	560,124	-	-	560,124
Contributions	30,602	29,047	37,880	97,529
Endowment distributions	86,369	77,426	1,036	164,831
Investment income	17,517	119	(1,215)	16,421
Health care services, net	2,816,116	-	-	2,816,116
Room, board, and other auxiliary services, net	126,215	-	-	126,215
Other sources	68,381	-	-	68,381
Net assets released from restrictions	89,463	(89,463)	-	-
Total revenues and other support	4,066,990	17,129	37,701	4,121,820
EXPENSES				
Salaries, wages, and benefits	2,331,715	-	-	2,331,715
Supplies, services, and other	1,364,217	-	-	1,364,217
Interest expense	60,034	-	-	60,034
Depreciation	177,176	-	-	177,176
Total expenses	3,933,142	-	-	3,933,142
Change in unrestricted net assets from operating activity	133,848			
OTHER CHANGES IN NET ASSETS				
Change in appreciation of endowment, net of distributions	(10,454)	(18,242)	-	(28,696)
Change in appreciation of self-insurance assets	1,975	-	-	1,975
Change in appreciation of other investments	(1,985)	-	-	(1,985)
Change in appreciation of interest rate exchange agreements	(27,728)	-	-	(27,728)
Contributions for plant	3,145	4,866	-	8,011
Net assets released from restrictions for plant	16,752	(16,752)	-	-
Nonoperating net asset reclassifications	(7,735)	6,679	1,056	-
Other	30,121	-	-	30,121
Total other changes in net assets	4,091	(23,449)	1,056	(18,302)
Increase (decrease) in net assets controlled by Vanderbilt	137,939	(6,320)	38,757	170,376
Decrease in net assets related to noncontrolling interests	(39,113)	-	-	(39,113)
Total increase (decrease) in net assets	\$ 98,826	\$ (6,320)	\$ 38,757	\$ 131,263
Net assets, June 30, 2014	\$ 3,179,830	\$ 1,467,482	\$ 1,196,434	\$ 5,843,746
Net assets, June 30, 2015	\$ 3,278,656	\$ 1,461,162	\$ 1,235,191	\$ 5,975,009

The accompanying notes are an integral part of the consolidated financial statements.

Vanderbilt University

Consolidated Statement of Activities

Year Ended June 30, 2014 (in thousands)

	2014			Total
	Unrestricted	Temporarily Restricted	Permanently Restricted	
REVENUES				
Tuition and educational fees	\$ 478,320	\$ -	\$ -	\$ 478,320
Less student financial aid	(213,543)			(213,543)
Tuition and educational fees, net	264,777	-	-	264,777
Grants and contracts:				
Government sponsors	358,632	-	-	358,632
Private sponsors	69,466	-	-	69,466
Facilities and administrative costs recovery	140,051	-	-	140,051
Total grants and contracts	568,149	-	-	568,149
Contributions	38,182	23,980	55,551	117,713
Endowment distributions	76,525	79,900	1,135	157,560
Investment income	18,264	3,268	6,655	28,187
Health care services, net	2,613,441	-	-	2,613,441
Room, board, and other auxiliary services, net	111,925	-	-	111,925
Other sources	58,517	-	-	58,517
Net assets released from restrictions	83,582	(83,582)	-	-
Total revenues and other support	3,833,362	23,566	63,341	3,920,269
EXPENSES				
Salaries, wages, and benefits	2,271,831	-	-	2,271,831
Supplies, services, and other	1,241,393	-	-	1,241,393
Interest expense	65,478	-	-	65,478
Depreciation	175,779	-	-	175,779
Total expenses	3,754,481	-	-	3,754,481
Change in unrestricted net assets from operating activity	78,881			
OTHER CHANGES IN NET ASSETS				
Change in appreciation of endowment, net of distributions	128,449	193,706	-	322,155
Change in appreciation of self-insurance assets	10,049	-	-	10,049
Change in appreciation of other investments	27,237	-	-	27,237
Change in appreciation of interest rate exchange agreements	6,352	-	-	6,352
Contributions for plant	3,235	6,445	-	9,680
Net assets released from restrictions for plant	6,405	(6,405)	-	-
Nonoperating net asset reclassifications	(15,778)	15,104	674	-
Total other changes in net assets	165,949	208,850	674	375,473
Increase in net assets controlled by Vanderbilt	244,830	232,416	64,015	541,261
Decrease in net assets related to noncontrolling interests	(36,834)	-	-	(36,834)
Total increase in net assets	\$ 207,996	\$ 232,416	\$ 64,015	\$ 504,427
Net assets, June 30, 2013	\$ 2,971,834	\$ 1,235,066	\$ 1,132,419	\$ 5,339,319
Net assets, June 30, 2014	\$ 3,179,830	\$ 1,467,482	\$ 1,196,434	\$ 5,843,746

The accompanying notes are an integral part of the consolidated financial statements.

Vanderbilt University Consolidated Statements of Cash Flows

Years Ended June 30, 2015 and 2014 (in thousands)

	2015	2014
CASH FLOWS FROM OPERATING ACTIVITIES		
Change in total net assets	\$ 131,263	\$ 504,427
Adjustments to reconcile change in total net assets to net cash provided by operating activities:		
Change in net assets related to noncontrolling interests	39,113	36,834
Realized and unrealized gain on investments, net	(164,715)	(426,297)
Contributions for plant and endowment	(47,540)	(75,606)
Contributions of securities other than for plant	(13,082)	(20,717)
Proceeds from sale of donated securities	2,590	2,773
Depreciation	177,176	175,779
Amortization of bond discounts and premiums	(4,600)	(5,210)
Payments to terminate interest rate exchange agreements	21,467	31,930
Gain on sale of business	(28,932)	-
Loss from disposals of property, plant, and equipment	6,635	1,670
Net change in fair value of interest rate exchange agreements	6,262	(38,282)
Change in:		
Accounts receivable, net of accrued investment income	10,921	(1,271)
Prepaid expenses and other assets	(3,104)	(3,517)
Contributions receivable	(7,598)	(4,518)
Interests in trusts held by others	-	(908)
Change in:		
Accounts payable and accrued liabilities, net of nonoperating items	37,660	(23,014)
Accrued compensation and withholdings	(42,002)	(19,052)
Deferred revenue	7,526	(44)
Actuarial liability for self-insurance	3,127	6,112
Actuarial liability for split-interest agreements	(1,910)	1,699
Net cash provided by operating activities	130,257	142,788
CASH FLOWS FROM INVESTING ACTIVITIES		
Purchases of investments	(4,240,401)	(2,734,836)
Proceeds from sales of investments	4,306,051	3,122,144
Purchases of investments allocable to noncontrolling interests	(1,478)	(4,004)
Proceeds from sales of investments allocable to noncontrolling interests	48,685	70,668
Change in accrued investment income	(501)	(122)
Payments to terminate interest rate exchange agreements	(21,467)	(31,930)
Acquisitions of property, plant, and equipment	(172,218)	(152,862)
Proceeds from sale of business	36,016	-
Student loans and other notes receivable disbursed	(1,337)	(2,439)
Principal collected on student loans and other notes receivable	6,150	5,770
Net cash (used in) provided by investing activities	(40,500)	272,389
CASH FLOWS FROM FINANCING ACTIVITIES		
Contributions for plant and endowment	47,540	75,606
Change in government advances for student loans	(10)	314
Payments to retire or defease debt	(112,269)	(43,129)
Proceeds from debt refinancing	58,608	-
Proceeds from sale of donated securities restricted for endowment	10,492	17,944
Proceeds from noncontrolling interests in investment partnerships	1,478	4,004
Payments to noncontrolling interests in investment partnerships	(48,685)	(70,668)
Net cash used in financing activities	(42,846)	(15,929)
Net change in cash and cash equivalents	\$ 46,911	\$ 399,248
Cash and cash equivalents at beginning of year	\$ 1,244,720	\$ 845,472
Cash and cash equivalents at end of year	\$ 1,291,631	\$ 1,244,720
Supplemental disclosure of cash flow information:		
Cash paid for interest	\$ 65,377	\$ 71,657
Donated securities	13,082	20,717

The accompanying notes are an integral part of the consolidated financial statements.

Vanderbilt University

Notes to the Consolidated Financial Statements

1. Organization

The Vanderbilt University (Vanderbilt) is a private, coeducational, not-for-profit, nonsectarian institution located in Nashville, Tennessee. Founded in 1873, Vanderbilt owns and operates educational, research, and health care facilities as part of its mission to be a leading center for informed and creative teaching, scholarly research, and public service. Vanderbilt provides educational services to approximately 6,900 undergraduate and 5,800 graduate and professional students enrolled across its 10 schools and colleges.

The consolidated financial statements include the accounts of all entities in which Vanderbilt has a significant financial interest and over which Vanderbilt has control. The patient care enterprise includes

Vanderbilt University Hospitals and Clinics (the Hospital); Vanderbilt Medical Group, a physician practice plan; and Vanderbilt Health Services, Inc. (VHS), which includes wholly owned and joint ventured businesses primarily consisting of community physician practices, imaging services, outpatient surgery centers, radiation oncology centers, a home health care agency, a home infusion and respiratory service, an affiliated health network, and a rehabilitation hospital.

Vanderbilt eliminates all material intercompany accounts and transactions in consolidation.

2. Summary of Significant Accounting Policies

Basis of Presentation

The consolidated financial statements of Vanderbilt have been prepared on the accrual basis in accordance with U.S. generally accepted accounting principles (GAAP). Based on the existence or absence of donor-imposed restrictions, Vanderbilt classifies resources into three categories: unrestricted, temporarily restricted, and permanently restricted net assets.

Unrestricted net assets are free of donor-imposed restrictions. This classification includes all revenues, gains, and losses not temporarily or permanently restricted by donors. Vanderbilt reports all expenditures in the unrestricted class of net assets, since the use of restricted contributions in accordance with donors' stipulations results in the release of the restriction.

Temporarily restricted net assets contain donor-imposed stipulations that expire with the passage of time or that can be satisfied by action of Vanderbilt. These net assets may include unconditional pledges, split-interest agreements, interests in trusts held by others, and accumulated appreciation on donor-restricted endowments not yet appropriated by the Board of Trust for distribution.

Permanently restricted net assets are amounts held in perpetuity as requested by donors. These net assets may include unconditional pledges, donor-restricted endowments (at historical value), split-interest agreements, and interests in trusts held by others. Generally, the donors of these assets permit Vanderbilt to use a portion of the income earned on related investments for specific purposes.

Vanderbilt reports expirations of temporary restrictions on net assets, i.e., the passage of time and/or fulfilling donor-imposed stipulations, as net assets released from restrictions between the applicable classes of net assets in the consolidated statements of activities.

Cash and Cash Equivalents

Cash and cash equivalents are liquid assets with minimal interest rate risk and maturities of three months or less when purchased. Such assets, reported at fair value, primarily consist of depository account balances, money market funds, and short-term U.S. Treasury securities.

Prepaid Expenses and Other Assets

Prepaid expenses and other assets primarily represent inventories, prepaid expenses, and other segregated investment-related assets managed by third parties related to a legacy deferred compensation program that are earmarked to ultimately settle certain liabilities. Vanderbilt excludes this latter group of assets, reported at fair value, from the investments category since it will not directly benefit from the investment return.

Fair Value Measurements

Fair value measurements represent the price received to sell an asset or price paid to transfer a liability in an orderly transaction between market participants at the measurement date. GAAP establishes a three-level hierarchy for fair value measurements based on the observable inputs to the valuation of an asset or liability at the measurement date. Inputs to the valuation techniques used are prioritized to measure fair value by giving the highest priority to unadjusted quoted prices in active markets for identical assets or liabilities (Level 1 measurements) and the lowest priority to measurements involving significant unobservable inputs (Level 3 measurements).

Vanderbilt gives consideration to certain investment funds that do not have readily determinable fair values including private investments, hedge funds, real estate, and other funds. Vanderbilt uses net asset value per share or its equivalent in estimating the fair value of interests in investment companies for which a readily determinable fair value is not available.

Investments

Vanderbilt reports investments at fair value using the three-level hierarchy established under GAAP. After review and evaluation, Vanderbilt utilizes estimates provided by fund managers for certain alternative investments, mainly investments in limited partnerships where a ready market for the investments does not exist.

Vanderbilt has exposure to a number of risks including liquidity, interest rate, counterparty, basis, tax, regulatory, market, and credit risks for both marketable and nonmarketable securities. Due to the level of risk exposure, it is possible that near-term valuation changes for investment securities may occur to an extent that could materially affect the amounts reported in Vanderbilt's financial statements.

Vanderbilt University

Vanderbilt sometimes uses derivatives to manage investment market risks and exposure. The consolidated financial statements contain derivatives, which consist of both internally managed transactions and those entered into through external investment managers, at fair value. The most common instruments utilized are futures contracts and hedges against currency risk for investments denominated in other than U.S. dollars. For internally managed transactions, Vanderbilt utilizes futures contracts with durations of less than three months.

Vanderbilt records purchases and sales of securities on the trade dates, and realized gains and losses are determined based on the average historical cost of the securities sold. Vanderbilt reports net receivables and payables arising from unsettled trades as a component of investments.

Unless donor-restricted endowment gift agreements require separate investment, Vanderbilt manages all endowment investments as an investment pool.

Investments Allocable to Noncontrolling Interests and Net Assets Related to Noncontrolling Interests

Vanderbilt reports the respective assets for entities in which other organizations are minority equity participants at fair value as investments allocable to noncontrolling interests on the consolidated statements of financial position.

The balance representing such organizations' minority or noncontrolling interests is recorded based on contractual provisions, which represent an estimate of a settlement value assuming the entity was liquidated in an orderly fashion as of the report date.

Split-Interest Agreements and Interests in Trusts Held by Others

Vanderbilt's split-interest agreements with donors consist primarily of irrevocable charitable remainder trusts, charitable gift annuities, and life income funds for which Vanderbilt serves as trustee. Vanderbilt reports assets held in these trusts in investments at fair value. Vanderbilt recognizes contribution revenue at the dates the trusts are established, net of the liabilities for the present value of the estimated future payments to the donors and/or other beneficiaries. Annually, Vanderbilt records the change in fair value of split-interest agreements based on the assets that are associated with each trust and recalculates the liability for the present value of the estimated future payments to the donors and/or other beneficiaries.

Vanderbilt is also the beneficiary of certain trusts held and administered by others. Vanderbilt records its share of these trust assets at fair value as interests in trusts held by others with any resulting gains or losses reported as investment income.

Property, Plant, and Equipment

Purchased property, plant, and equipment, recorded at cost, includes, where appropriate, capitalized interest on construction financing net of income earned on unspent proceeds. Vanderbilt capitalizes donated assets at fair value on the date of donation, expenses repairs and maintenance costs as incurred, and expenses additions to the library collection at the time of purchase.

Vanderbilt calculates depreciation using the straight-line method to allocate the cost of various classes of assets over their estimated useful lives. Vanderbilt removes property, plant, and equipment from the accounting records upon disposal.

Conditional asset retirement obligations related to legal requirements to perform certain future activities associated with the retirement, disposal, or abandonment of assets are accrued utilizing site-specific

surveys to estimate the net present value for applicable future costs, e.g., asbestos abatement or removal.

Vanderbilt reviews long-lived assets for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Vanderbilt recognizes an impairment charge when the fair value of the asset or group of assets is less than the carrying value. Refer to the property, plant, and equipment footnote for further discussion.

Debt Portfolio Financial Instruments

Vanderbilt reports long-term debt and capital leases at carrying value. The carrying value of Vanderbilt's debt is the par amount adjusted for the net unamortized amount of bond premiums and discounts. Vanderbilt employs derivatives, primarily interest rate exchange agreements, to help manage interest rate risks associated with variable-rate debt. The consolidated statements of activities include any gain or loss resulting from recording the fair value of derivative financial instruments as a nonoperating item. In addition to the credit risk of the counterparty owing a balance, Vanderbilt calculates the fair value of interest rate exchange agreements based on the present value sum of future net cash settlements that reflect market yields as of the measurement date and reports periodic net cash settlement amounts with counterparties as adjustments to interest expense on the related debt.

Parties to interest rate exchange agreements are subject to risk for changes in interest rates as well as risk of credit loss in the event of nonperformance by the counterparty. Vanderbilt deals only with high-quality counterparties that meet rating criteria for financial stability and credit worthiness. Additionally, the agreements require the posting of collateral when amounts subject to credit risk under the contracts exceed specified levels.

Revenue Recognition

Vanderbilt's revenue recognition policies are:

Tuition and educational fees, net—Vanderbilt recognizes student tuition and educational fees as revenues in the year the related academic services occur and defers amounts received in advance of services rendered. Vanderbilt reflects financial aid provided for tuition and educational fees as a reduction of tuition and educational fees. Financial aid does not include payments made to students for services provided to Vanderbilt.

Grants and contracts—Vanderbilt recognizes revenues from grants and contracts when allowable expenditures under such agreements occur.

Facilities and administrative (F&A) costs recovery—Vanderbilt recognizes F&A costs recovery as revenue. This activity represents reimbursement, primarily from the federal government, of F&A costs on sponsored activities. Vanderbilt's federal F&A costs recovery rate for on-campus research was 57.0% in fiscal 2015 and 56.0% in fiscal 2014. Vanderbilt's federal F&A costs recovery rate for off-campus research was 28.5% in both fiscal 2015 and 2014.

Health care services—Vanderbilt reports health care services revenue at established rates, net of contractual adjustments, charity care, and provision for bad debt. Vanderbilt accrues third party contractual revenue adjustments under governmental reimbursement programs on an estimated basis in the period the related services occur. Vanderbilt adjusts the estimated amounts for Medicare based on final settlements determined by Vanderbilt's Medicare Administrative Contractor (MAC).

Contributions

Vanderbilt recognizes unconditional promises to give (pledges) as contribution revenue upon receipt of a commitment from the donor. Vanderbilt records pledges with payments due in future periods as increases in temporarily restricted or permanently restricted net assets at the estimated present value of future cash flows, net of an allowance for estimated uncollectible promises. Vanderbilt calculates an allowance for uncollectible contributions receivable based upon an analysis of past collection experience and other judgmental factors.

Vanderbilt records contributions with donor-imposed restrictions as unrestricted revenue if the university meets the restrictions and receives the contribution in the same reporting period. Otherwise, Vanderbilt records contributions with donor-imposed restrictions as increases in temporarily restricted or permanently restricted net assets, depending on the nature of the restriction.

After meeting donor stipulations, Vanderbilt releases contributions recorded as temporarily restricted from restrictions and recognizes these contributions as unrestricted net assets. Vanderbilt releases from restrictions contributions for plant facilities and recognizes these contributions as a nonoperating item only after incurring expenses for the applicable plant facilities or when the related asset is placed in service based on donor intent.

In contrast to unconditional promises as described above, Vanderbilt does not record conditional promises (primarily bequest intentions) until the university substantially meets donor contingencies.

Unrestricted Operating Results

Unrestricted operating results (change in unrestricted net assets from operating activity) in the consolidated statements of activities reflect all transactions that change unrestricted net assets, except for nonoperating activity related to endowment and other investments, changes in the fair value of derivative financial instruments, contributions for plant facilities, and certain other nonrecurring items.

Endowment distributions reported as operating revenue consist of endowment return (regardless of when such income arose) distributed to support current operational needs in the current period. Vanderbilt's Board of Trust approves the distribution amount from the endowment pool on an annual basis, determined by applying a spending rate to an average of the previous three calendar year-end market values. The primary objective of the endowment distribution methodology is to reduce the impact of capital market fluctuations on operational programs.

Operating investment income consists of dividends, interest, and gains and losses on unrestricted, non-endowed investments directly related to core operating activities, as well as investment returns on Vanderbilt's working capital assets. For working capital assets invested in long-term pooled investments managed in conjunction with endowment funds, the amount resulting from pre-established distributions from pooled investments is deemed operating investment income; the difference between total returns for these pooled investments and the aforementioned pre-established distributions is reported as nonoperating activity. Operating investment income excludes investment returns on segregated gift funds and funds set aside for nonoperating purposes such as segregated assets for self-insurance relative to malpractice and professional liability and assets on deposit with trustees.

Vanderbilt allocates management and administrative support costs attributable to divisions that primarily provide health care or auxiliary services based upon institutional budgets. Thus, institutional support expense reported in the functional expense footnote relates

to Vanderbilt's other primary programs such as instruction, research, and public service.

Vanderbilt allocates costs related to the operation and maintenance of physical plant, including depreciation of plant assets, to operating programs and supporting activities based upon facility usage. Additionally, the university allocates interest expense to the activities that have benefited most directly from the debt proceeds.

Income Taxes

Vanderbilt is a tax-exempt organization as described in Section 501(c)(3) of the Internal Revenue Code (the Code), and generally is exempt from federal income taxes on related income pursuant to Section 501(a) of the Code. Vanderbilt is, however, subject to federal and state income tax on unrelated business income, and provision for such taxes is included in the accompanying consolidated financial statements.

Use of Estimates

The preparation of financial statements requires the use of estimates and assumptions that affect the reported amounts of assets, liabilities, revenues, and expenses during the reporting period as well as the disclosure of contingent assets and liabilities. Actual results ultimately could differ from management's estimates.

Reclassifications

Vanderbilt made certain reclassifications within endowment distributions, net assets released from restriction, health care services revenue, other sources revenue, and certain functional expense categories to prior year amounts to conform to the current year presentation. These reclassifications were not material to the financial statements.

Gain on Sale of Business

During fiscal year 2015, Vanderbilt sold its air ambulance service, LifeFlight, for \$36 million, resulting in a gain of \$29 million. Vanderbilt reported the gain on sale as a component of other changes in net assets in the accompanying consolidated statement of activities.

Subsequent Events

Vanderbilt evaluated events subsequent to June 30, 2015, through October 22, 2015, the date of issuance of the consolidated financial statements. During this period, Vanderbilt terminated fixed-payer interest rate exchange agreements with notional values totaling \$65 million. Vanderbilt did not identify any other material subsequent events for recognition or disclosure.

Recent Accounting Pronouncements

In April 2014, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update (ASU) 2014-08, Presentation of Financial Statements and Property, Plant, and Equipment—Reporting Discontinued Operations and Disclosures of Disposals of Components of an Entity (ASU 2014-08). Pursuant to ASU 2014-08, only those components of an entity that represent a strategic shift that has, or will have, a major effect on an entity's operations and financial results qualify for treatment as discontinued operations upon disposal. The provisions of ASU 2014-08 are effective prospectively for all disposals or classifications of components of an entity as held for sale that occur within annual periods beginning on or after December 15, 2014. Vanderbilt will adopt ASU 2014-08 for fiscal 2016.

Vanderbilt is in the process of exploring alternative arrangements with Vanderbilt University Medical Center (VUMC) as a not-for-profit academic medical center that is financially distinct from Vanderbilt. As of the time of issuance of the fiscal 2015 financial statements, the arrangement has not been finalized or formally approved by the Board, and therefore does not meet the criteria required for classification as held for sale as of the balance sheet date.

In May 2014, the FASB issued ASU 2014-09, Revenue from Contracts with Customers. ASU 2014-09 outlines a single comprehensive standard for revenue recognition across all industries and supersedes most existing revenue recognition guidance. In addition, ASU 2014-09 will require new and enhanced disclosures. ASU 2014-09 will become effective for annual and interim reporting periods beginning after December 15, 2018, with early adoption permitted in periods beginning after December 15, 2017. Vanderbilt is currently evaluating the effect of the new revenue recognition guidance.

3. Accounts Receivable

Accounts receivable as of June 30 were as follows (in thousands):

2015			
	Gross Receivable	Bad Debt Allowance	Net Receivable
Patient care	\$ 378,462	\$ (76,720)	\$ 301,742
Tuition/fees, grants, other	101,586	(1,885)	99,701
Accrued investment income	2,702	-	2,702
Accounts receivable and related allowance	\$ 482,750	\$ (78,605)	\$ 404,145
<i>Days receivable</i>			36.2

2014			
	Gross Receivable	Bad Debt Allowance	Net Receivable
Patient care	\$ 386,271	\$ (70,522)	\$ 315,749
Tuition/fees, grants, other	98,679	(2,064)	96,615
Accrued investment income	2,201	-	2,201
Accounts receivable and related allowance	\$ 487,151	\$ (72,586)	\$ 414,565
<i>Days receivable</i>			39.5

Patient care receivables represented 78.4% and 79.3% of total gross accounts receivables as of June 30, 2015 and 2014, respectively. The largest portion of patient care receivables relates to the Hospital and in turn, the largest component of the Hospital's receivables was from third party payers.

4. Contributions Receivable

Contributions receivable as of June 30 were as follows (in thousands):

	2015	2014
Unconditional promises expected to be collected:		
in one year or less	\$ 41,072	\$ 33,929
between one year and five years	53,058	51,461
in more than five years	502	841
Contributions receivable	94,632	86,231
Less: Discount	1,612	1,404
Less: Allowance for uncollectible promises	10,602	10,007
Contributions receivable, net	\$ 82,418	\$ 74,820

Vanderbilt discounts contributions receivable at a rate commensurate with the scheduled timing of receipt. Vanderbilt applied discount rates ranging from 0.5% to 1.5% to amounts outstanding as of June 30, 2015, and June 30, 2014. Vanderbilt's methodology for calculating an allowance for uncollectible promises consists of analyzing

In May 2015, the FASB issued ASU 2015-07, Disclosures for Investments in Certain Entities that Calculate Net Asset Value per Share (or its Equivalent). ASU 2015-07 removes the requirement to categorize within the fair value hierarchy all investments measured at fair value using the net asset value per share practical expedient. The provisions of ASU 2015-07 are effective for fiscal years beginning after December 15, 2016 (with early adoption permitted) and will require retrospective application to all periods presented. Vanderbilt expects to early adopt ASU 2015-07 for fiscal 2016.

The Hospital provides services to patients in advance of receiving payment and generally does not require collateral or other security for those services. However, the Hospital routinely obtains assignment of (or is otherwise entitled to receive) patients' benefits payable under their health insurance programs, plans, or policies (e.g., Medicare, Medicaid, TennCare, Blue Cross, health maintenance organizations, or other commercial insurance policies).

As of June 30, the Hospital had receivables, net of related contractual allowances, including estimated amounts for cost reports and other settlements with government payers, from the following payers (in thousands):

	2015	2014
Medicare	\$ 42,959	\$ 37,794
TennCare/Medicaid	36,734	34,453
Blue Cross	50,847	68,031
Other commercial carriers	108,726	95,570
Patient responsibility	21,735	34,811
Total Hospital receivables, net	\$ 261,001	\$ 270,659

Patient care bad debt charges, reported as a reduction to health care services revenue on the consolidated statements of activities, totaled \$59.1 million and \$96.6 million as of June 30, 2015 and 2014, respectively (both recorded at gross charge level).

write-offs as a percentage of gross pledges receivable along with assessing the age and activity of outstanding pledges.

In addition to pledges reported as contributions receivable, Vanderbilt had cumulative bequest intentions and conditional promises to give of approximately \$282.3 million and \$242.2 million as of June 30, 2015 and 2014, respectively. Due to their conditional nature, Vanderbilt does not recognize intentions to give as assets.

Contributions receivable, net as of June 30, were as follows (in thousands):

	2015	2014
Contributions receivable, net:		
Temporarily restricted	\$ 38,933	\$ 32,859
Permanently restricted	43,485	41,961
Total	\$ 82,418	\$ 74,820

5. Student Loans and Other Notes Receivable

Student loans and other notes receivable as of June 30 were as follows (*in thousands*):

2015			
	Gross Receivable	Bad Debt Allowance	Net Receivable
Federal loans	\$ 22,489	\$ (2,146)	\$ 20,343
Institutional loans	17,095	(6,637)	10,458
Faculty mortgages	4,637	-	4,637
Student loans, other notes receivable and related allowance	\$ 44,221	\$ (8,783)	\$ 35,438
2014			
	Gross Receivable	Bad Debt Allowance	Net Receivable
Federal loans	\$ 20,077	\$ (1,995)	\$ 18,082
Institutional loans	19,238	(2,820)	16,418
Faculty mortgages	5,751	-	5,751
Student loans, other notes receivable and related allowance	\$ 45,066	\$ (4,815)	\$ 40,251

Vanderbilt remains committed to “no loans” for its undergraduate students, meaning that the university is meeting full demonstrated financial need with scholarship and grant assistance. For other groups (e.g., professional school students), participation in several federal revolving loan programs, including the Perkins, Nursing, and Health Professionals Student Loan programs, has continued. Vanderbilt carries loans to students at cost, which, based on secondary market information, approximates the fair value of education loans with similar interest rates and payment terms. The availability of funds for new loans under these programs is dependent on reimbursements to the

pool from repayments on outstanding loans. Vanderbilt assigns loans receivable from students under governmental loan programs, also carried at cost, to the federal government or its designees. Vanderbilt classifies refundable advances from the federal government as liabilities in the statements of financial position. Outstanding loans cancelled under a governmental program result in a reduction of the funds available for loan and a decrease in the university’s liability to the government.

Vanderbilt establishes bad debt allowances based on prior collection experience and current economic factors which, in management’s judgment, could influence the ability of loan recipients to repay amounts due. When deemed to be uncollectible, Vanderbilt writes off institutional loan balances.

Included in institutional loans as of June 30, 2015, is an outstanding note receivable of \$3.6 million from McKendree Village, LLC, an affiliate of Vanderbilt that sold all of its operations in fiscal 2012 and is in the process of dissolving. Because it is unlikely McKendree Village, LLC will repay this debt, it has been fully reserved in the consolidated financial statements.

As part of Vanderbilt’s efforts to attract and retain a world-class faculty, Vanderbilt provides various incentives and historically provided home mortgage financing assistance in select situations. Notes receivable amounting to \$4.6 million were outstanding at June 30, 2015. Deeds of trust on properties concentrated in the surrounding region collateralize these notes. Vanderbilt has not recorded an allowance for doubtful accounts against these loans based on their collateralization and prior collection history.

6. Investments

Investments consist of the following as of June 30 (*in thousands*):

	2015	2014
Derivative contract collateral and short-term securities ¹	\$ 82,139	\$ 77,839
Global equities ¹	1,094,368	1,205,839
Fixed income ⁵	248,978	177,867
Hedged strategies ⁶	904,782	781,368
Private capital ³	1,406,331	1,439,513
Real estate ³	228,975	279,042
Natural resources ³	294,298	335,955
Equity method securities	16,010	15,782
Commodities ²	98,311	-
Trusts ⁴	4,258	4,652
Other investments ⁴	10,811	11,816
Total value	\$ 4,389,261	\$ 4,329,673
Total cost	\$ 3,595,067	\$ 3,382,507

¹ Quoted prices in active markets determine fair value or fund managers provide the net asset value per share of the specific investment to establish fair value.

² Quoted prices in active markets determine fair value.

³ Fund managers provide the net asset value of Vanderbilt’s ownership interests at the fund level to establish fair value.

⁴ Carrying value provides a reasonable estimate of fair value for certain components.

⁵ Quoted prices in active markets determine fair value or fund managers provide the net asset value per share of the specific investment to establish fair value. Includes \$32 million of equity short positions.

⁶ Quoted prices in active markets determine fair value or fund managers provide the net asset value per share of the specific investment to establish fair value. Includes \$155 million of equity short positions.

Included in the amounts reported in the table above are investments allocable to noncontrolling interests (i.e., minority limited partners)

reported at fair value. During fiscal 2015, the minority limited partners funded capital commitments totaling \$1.5 million. Additionally, Vanderbilt made payments to the minority limited partners of \$48.7 million reflecting a distribution of earnings and returned capital from the underlying private fund assets. For the year ended June 30, 2015, the minority limited partners’ interests in the results of the underlying returns from the private fund assets were \$248.3 million. The balance of unrestricted net assets related to noncontrolling interests, calculated in accordance with the partnership agreements, was \$111.0 million as of June 30, 2015.

Investments, along with cash and cash equivalents, provide liquidity support for Vanderbilt’s operations. Of these combined amounts, based on prevailing market conditions as of June 30, 2015, \$1,374.5 million of liquid assets were available on a same-day basis and an additional \$872.1 million was available within 30 days.

Derivative contract collateral and short-term securities are composed primarily of amounts posted as collateral in accordance with interest rate exchange agreements and unspent bond proceeds with trustees.

Global equities consist of investment funds globally diversified across public markets including U.S. markets, other developed markets, and emerging and frontier markets. Fund managers of these investments have the ability to shift investments from value to growth strategies, from small to large capitalization stocks, and from a net long position to a net short position.

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Fixed income includes investments directed towards capital preservation and predictable yield as well as more opportunistic strategies focused on generating return on price appreciation. These investments are primarily public investments such as U.S. Treasuries and other government obligations, investment-grade corporate bonds, high-yield corporate bonds, bank debt, commercial mortgage-backed securities, residential non-agency mortgage-backed securities, asset-backed securities, direct lending, and below investment-grade developed and emerging market sovereign debt. Vanderbilt may make investments through commingled vehicles, separately managed accounts, synthetic transactions, and limited partnership interests.

Hedged strategies investments reflect multiple strategies such as event driven, relative value, and equity funds to diversify risks and reduce volatility in the portfolio generally in hedge fund structures. These strategies also include investments in both long and short primarily credit-oriented securities. Investments may include mortgage-backed securities, trade finance, debt and asset-backed securities, repurchase agreements, senior loans, and bank loans. The fair value of open short positions is recorded as a liability and the university records an unrealized gain or loss to the extent of the difference between the proceeds received and the value of the open short position. By entering into short sales, the university bears the market risk of increases in the value of the security sold short in excess of the proceeds received. Possible losses from short sales differ from losses that could be incurred from purchases of securities because losses from short sales may be unlimited whereas losses from purchases cannot exceed the total amount invested.

Private capital consists of illiquid investments in buyouts, distressed debt, mezzanine debt, growth equity, and venture capital. Vanderbilt may make investments through commingled vehicles, separately managed accounts, synthetic transactions, limited partnership interests, and direct investments.

Real estate comprises illiquid investments in residential and commercial real estate assets, projects, publicly traded REITs or land held directly through separately managed accounts, limited partnership interests, and direct investments in properties. The nature of the investments in this category is such that distributions generally reflect liquidation of the underlying assets of the funds.

Natural resources include illiquid investments in timber, oil and gas production, mining, energy, and related services businesses held directly or in commingled limited partnership funds.

Commodities include public investments such as commodity futures, commodity-related equities, and private investments in energy, power, infrastructure, and timber. Investments may be made through commingled vehicles, separately managed accounts, synthetic transactions, limited partnership interests, and direct investments.

Equity method securities and trusts are investments in joint ventures accounted for under the equity method of accounting and Vanderbilt's split-interest agreements with donors.

7. Investment Return

A summary of investment return, including endowment distributions, by net asset category for the fiscal years ended June 30 follows (in thousands):

	2015	2014
OPERATING		
<i>Unrestricted:</i>		
Endowment distributions	\$ 86,369	\$ 76,525
Investment income	17,517	18,264
Total operating return	103,886	94,789
NONOPERATING		
<i>Unrestricted:</i>		
Change in appreciation of institutional endowments, net of distributions	(10,454)	128,449
Change in appreciation of self-insurance assets	1,975	10,049
Investment (loss) income	(1,985)	27,237
<i>Temporarily restricted:</i>		
Endowment distributions	77,426	79,900
Investment income	119	3,268
Change in appreciation of donor-restricted endowments, net of distributions	(18,242)	193,706
<i>Permanently restricted:</i>		
Endowment distributions	1,036	1,135
Investment income	(1,215)	6,655
Total nonoperating return	\$ 48,660	\$ 450,399
Total investment return	\$ 152,546	\$ 545,188

The components of total investment return for the fiscal years ended June 30 were as follows (in thousands):

	2015	2014
Interest, dividend, and partnership income, net of fees	\$ (12,169)	\$ 118,891
Net realized gains (losses)	306,477	(63,811)
Change in unrealized appreciation	(141,762)	490,108
Total investment return	\$ 152,546	\$ 545,188

In addition to a core group of investment professionals dedicated to the management of Vanderbilt's endowment, Vanderbilt employs external investment managers. Particularly for alternative investments such as hedge funds, investment manager fee structures frequently have a base component along with a performance component relative to the entire life of the investments. Under these arrangements, management fees are frequently subject to substantial adjustments based on cumulative future returns for a number of years hence.

Vanderbilt reports investment returns net of returns attributed to limited partners on investments allocable to noncontrolling interests.

Vanderbilt incurred internal investment management costs of \$9.9 million in fiscal 2015 and \$11.9 million in fiscal 2014. Fees paid directly to external investment managers (i.e., segregated investment account fees) totaled \$13.8 million and \$4.5 million in fiscal 2015 and 2014, respectively. Vanderbilt reports investment returns net of these external manager fees.

8. Endowment

Endowment-related assets include donor-restricted endowments and institutional endowments (quasi-endowments). Vanderbilt's endowment does not include gift annuities, interests in trusts held by others, contributions pending donor designation, and contributions receivable.

The Board of Trust's interpretation of its fiduciary responsibilities for donor-restricted endowments under the Uniform Prudent Management of Institutional Funds Act (UPMIFA) requirements, barring the existence of any donor-specific provisions, is to preserve intergenerational equity. Under this broad guideline, future endowment beneficiaries should receive at least the same level of real economic support as the current generation. The overarching objective is to preserve and enhance the real (inflation-adjusted) purchasing power of the endowment in perpetuity. Vanderbilt invests assets to provide a relatively predictable and stable stream of earnings to meet spending needs and attain long-term return objectives without the assumption of undue risks.

UPMIFA specifies that unless stated otherwise in a gift instrument, donor-restricted assets in an endowment fund are restricted assets until appropriated for expenditure. Barring the existence of specific instructions in gift agreements for donor-restricted endowments, Vanderbilt reports the historical value for such endowments as permanently restricted net assets and the net accumulated appreciation as

temporarily restricted net assets. In this context, historical value represents the original value of initial contributions restricted as permanent endowments plus the original value of subsequent contributions and, if applicable, the value of accumulations made in accordance with the direction of specific donor gift agreements.

Specific appropriation for expenditure of Vanderbilt's endowment funds occurs each spring when the Board of Trust approves the university's operating budget for the ensuing fiscal year. For fiscal years 2015 and 2014, Vanderbilt's Board of Trust approved endowment distributions based on 4.5% of the average of the previous three calendar year-end market values. Vanderbilt reinvests actual realized endowment return earned in excess of distributions. For years when the endowment return is less than the distribution, the endowment pool's cumulative returns from prior years cover the shortfall.

Vanderbilt may not fully expend Board-appropriated endowment distributions in a particular fiscal year. In some cases, Vanderbilt will approve endowment distributions for reinvestment into the endowment.

A summary of Vanderbilt's endowment for the fiscal years ended June 30 follows (*in thousands*):

2015

	Unrestricted	Temporarily Restricted	Permanently Restricted	Total
Donor-restricted endowments at historical value	\$ -	\$ 22,021	\$ 1,123,852	\$ 1,145,873
Accumulated net appreciation of donor-restricted endowments	-	1,311,212	-	1,311,212
Reinvested distributions of donor-restricted endowments				
At historical value	95,019	11,696	-	106,715
Accumulated net appreciation	106,541	2,285	-	108,826
Institutional endowments				
At historical value	362,356	-	-	362,356
Accumulated net appreciation	1,058,406	-	-	1,058,406
Endowment net assets as of June 30, 2015	\$ 1,622,322	\$ 1,347,214	\$ 1,123,852	\$ 4,093,388

2014

	Unrestricted	Temporarily Restricted	Permanently Restricted	Total
Donor-restricted endowments at historical value	\$ -	\$ 24,785	\$ 1,080,443	\$ 1,105,228
Accumulated net appreciation of donor-restricted endowments	-	1,329,499	-	1,329,499
Reinvested distributions of donor-restricted endowments				
At historical value	94,224	3,783	-	98,007
Accumulated net appreciation	108,417	2,239	-	110,656
Institutional endowments				
At historical value	335,875	-	-	335,875
Accumulated net appreciation	1,066,985	-	-	1,066,985
Endowment net assets as of June 30, 2014	\$ 1,605,501	\$ 1,360,306	\$ 1,080,443	\$ 4,046,250

The components of the life-to-date accumulated net appreciation of pooled endowments as of June 30 were as follows (*in thousands*):

	2015	2014
Net realized appreciation less endowment distributions	\$ 1,814,157	\$ 1,708,468
Net unrealized appreciation	664,287	798,672
Total	\$ 2,478,444	\$ 2,507,140

In striving to meet the overarching objectives for the endowment, over the past 20 years the university has experienced an 11% annualized standard deviation in its returns. This level of risk is consistent with that accepted by peer institutions. Currently, the endowment

portfolio consists of three primary components designed to serve a specific role in establishing the right balance between risk and return. These three components are global, public, and private equity investments. Vanderbilt expects these three investments, including private capital and many hedge funds, to produce favorable returns in environments of accelerated growth and economic expansion. Vanderbilt expects hedged strategies and fixed income investments to generate stable returns and preserve capital during periods of poor equity performance. Vanderbilt uses real estate and natural resources allocations to provide an inflation hedge.

From time to time, the fair value of assets associated with an endowed fund may fall below the level that a donor or UPMIFA requires in

terms of maintenance of perpetual duration endowments. As of June 30, 2015 and 2014, Vanderbilt had deficiencies of this nature of approximately \$1.5 million consisting of 66 endowments and \$1 million consisting of 50 endowments, respectively. These deficiencies resulted from unfavorable market declines that occurred after the investment of recent permanently restricted contributions. Vanderbilt

believes these declines are modest in relation to the total market value for donor-restricted endowments and that these deficiencies will be relatively short-term in nature.

Changes in endowment net assets for the fiscal years ended June 30 were as follows (*in thousands*):

2015

	Unrestricted	Temporarily Restricted	Permanently Restricted	Total
Endowment net assets as of June 30, 2014	\$ 1,605,501	\$ 1,360,306	\$ 1,080,443	\$ 4,046,250
Endowment investment return:				
Investment income, net of fees	(2,097)	(3,651)	-	(5,748)
Net appreciation (realized and unrealized)	56,383	98,152	-	154,535
Total endowment investment return	54,286	94,501	-	148,787
Gifts and additions to endowment, net	27,291	5,134	43,409	75,834
Endowment distributions	(60,139)	(104,692)	-	(164,831)
Transfers for internal management costs	(3,604)	(6,273)	-	(9,877)
Other	(1,013)	(1,762)	-	(2,775)
Endowment net assets as of June 30, 2015	\$ 1,622,322	\$ 1,347,214	\$ 1,123,852	\$ 4,093,388

2014

	Unrestricted	Temporarily Restricted	Permanently Restricted	Total
Endowment net assets as of June 30, 2013	\$ 1,450,322	\$ 1,163,129	\$ 1,021,892	\$ 3,635,343
Endowment investment return:				
Investment income, net of fees	49,319	74,375	-	123,694
Net appreciation (realized and unrealized)	146,586	221,057	-	367,643
Total endowment investment return	195,905	295,432	-	491,337
Gifts and additions to endowment, net	26,730	3,471	58,551	88,752
Endowment distributions	(62,822)	(94,738)	-	(157,560)
Transfers for internal management costs	(4,754)	(7,170)	-	(11,924)
Other	120	182	-	302
Endowment net assets as of June 30, 2014	\$ 1,605,501	\$ 1,360,306	\$ 1,080,443	\$ 4,046,250

9. Property, Plant, and Equipment

Vanderbilt reports property, plant, and equipment at cost or, if a gift, at fair value as of the date of the gift, net of accumulated depreciation. Vanderbilt computes depreciation using the straight-line method over the estimated useful lives of the assets.

Property, plant, and equipment as of June 30 were as follows (*in thousands*):

	2015	2014
Land	\$ 78,825	\$ 73,897
Buildings and improvements	2,933,333	2,902,231
Moveable equipment	840,582	937,059
Construction in progress	113,750	67,483
Property, plant, and equipment	3,966,490	3,980,670
Less: Accumulated depreciation	2,218,080	2,215,426
Property, plant, and equipment, net	\$ 1,748,410	\$ 1,765,244

Purchases for the library collection are not included in the amounts above since Vanderbilt expenses them at the time of purchase. As of June 30, 2015, the estimated replacement cost for library collections, including processing costs to properly identify, catalog, and shelve materials, totaled \$375 million. The replacement cost remained flat because some Vanderbilt University libraries are transitioning to e-books.

Vanderbilt did not capitalize interest in either fiscal 2015 or fiscal 2014 due to immateriality.

Vanderbilt capitalized internal-use software development costs of \$1.0 million and \$6.5 million in fiscal 2015 and 2014, respectively.

Vanderbilt reviews property, plant, and equipment for recoverability whenever events or changes in circumstances indicate that the carrying amount may not be recoverable. The university recognizes an impairment loss only if the carrying amount of a long-lived asset is not recoverable and exceeds its fair value. The carrying amount of a long-lived asset is not recoverable if it exceeds the sum of the undiscounted cash flows expected to result from the use and eventual disposition of the asset. Vanderbilt booked impairment losses of \$6.3 million and \$1.3 million in fiscal 2015 and 2014, respectively, related to property, plant, and equipment.

Vanderbilt identified conditional asset retirement obligations, primarily for the costs of asbestos removal and disposal, resulting in liabilities of \$17.2 million and \$16.5 million as of June 30, 2015 and 2014, respectively. These liability estimates, included in accounts payable and accrued liabilities in the consolidated statements of financial position, use an inflation rate of 4.0% and a discount rate of 5.0% based on relevant factors at origination.

10. Long-Term Debt, Capital Leases, and Commercial Paper

Long-term debt consists of bonds and notes payable with scheduled final maturity dates at least one year after the original issuance date. Outstanding long-term debt, capital leases, and commercial paper

(CP) obligations reflected in the financial statements at carrying value as of June 30 were as follows (*in thousands*):

	Years to Nominal Maturity	Outstanding Fixed Coupon Interest Rates as of June 30, 2015	Fiscal 2015 Effective Interest Rate ²	Outstanding Principal 2015	Outstanding Principal 2014
FIXED-RATE DEBT					
Series 2008A	4	5.00%	4.0%	\$ 94,600	\$ 109,600
Series 2008B ¹	4	4.00%-5.00%	4.0%	59,550	78,185
Series 2009A	25	4.00%-5.50%	4.9%	97,100	97,100
Series 2009B ¹	25	5.00%-5.50%	5.0%	232,900	232,900
Series 2009A Taxable	4	5.25%	5.3%	250,000	250,000
Series 2012C	3	3.00%-5.00%	1.4%	17,955	18,620
Series 2012D	23	3.00%-5.00%	3.2%	106,230	106,230
Series 2012E	5	2.00%-5.00%	0.9%	33,550	39,490
Fixed-rate debt			4.4%	891,885	932,125
VARIABLE-RATE DEBT					
Series 2012A	24		0.5%	-	67,000
Series 2012B			0.7%	67,000	67,000
Variable-rate debt			0.6%	67,000	134,000
Par amount of long-term debt			4.0%	958,885	1,066,125
Net unamortized premium			-	12,530	17,131
Total long-term debt			4.0%	971,415	1,083,256
Capital leases			2.3%	-	29
Total long-term debt and capital leases			4.0%	971,415	1,083,285
Tax-exempt commercial paper	<1		0.2%	90,000	95,000
Taxable commercial paper	<1		0.3%	173,454	114,845
Total commercial paper			0.2%	263,454	209,845
Total long-term debt, capital leases, and commercial paper			3.3%	\$ 1,234,869	\$ 1,293,130

¹ Issued under Master Trust Indenture structure.

² Exclusive of interest rate exchange agreements. Inclusive of these agreements, the overall portfolio effective interest rate was 4.8%.

The preceding table reflects fixed/variable allocations before the effects of interest rate exchange agreements. A successive note discusses these agreements in more detail.

The Health and Educational Facilities Board of The Metropolitan Government of Nashville and Davidson County, Tennessee (HEFB) issued Vanderbilt's tax-exempt CP and all of the aforementioned bonds, with the exception of the Series 2009A Taxable notes. As a conduit issuer, the HEFB loans the debt proceeds to Vanderbilt. Pursuant to loan agreements, Vanderbilt's debt service requirements under these loan agreements coincide with required debt service of the actual HEFB bonds.

All debt instruments are general obligations of Vanderbilt. Vanderbilt did not pledge any of its assets as collateral for this debt.

Included in the foregoing table are Hospital bonds, with a \$292.5 million principal balance outstanding as of June 30, 2015, that were issued under a Master Trust Indenture (MTI) structure. The MTI provides the flexibility for multiple parties to participate in debt issuances as part of an obligated group. Presently, Vanderbilt's hospitals and clinics have no other members participating in the obligated group. Bonds issued under the MTI are payable from hospital revenues. A Vanderbilt debt service guarantee supplements all outstanding MTI bonds.

Trust indentures for certain bond issues contain covenants and restrictions involving the issuance of additional debt, maintenance of a specified debt service coverage ratio, and the maintenance of credit facilities for liquidity purposes. Vanderbilt was in compliance with such covenants and restrictions as of June 30, 2015.

The components of interest for total long-term debt, capital leases, CP, and interest rate exchange agreements follows (*in thousands*):

	2015	2014
Payments for interest costs	\$ 65,377	\$ 71,657
Accrued interest expense	\$ 60,034	\$ 65,478

Payments for interest costs, including amounts capitalized, occur on varying scheduled payment dates for debt, maturity dates for CP, and settlement dates for interest rate exchange agreements. Vanderbilt calculates accrued interest expense for its debt, CP, and interest rate exchange agreements based on applicable interest rates for the respective fiscal year.

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Principal retirements and scheduled sinking fund requirements based on nominal maturity schedules for long-term debt due in subsequent fiscal years ending June 30 are as follows (in thousands):

2016	\$	54,245
2017		44,875
2018		47,070
2019		342,300
2020		17,165
Thereafter		453,230
Total long-term debt principal retirements	\$	958,885

Requirements in earlier years in the preceding table could be greater if Vanderbilt must purchase either a portion or all of its floating-rate notes or CP in the event of failed remarketings, on mandatory tender dates, or scheduled maturities as described in the following paragraphs.

During fiscal 2015, Vanderbilt redeemed the \$67.0 million 2012A floating rate notes. This redemption was funded by the issuance of two \$30.0 million tranches of taxable CP and \$7.0 million of operating cash. Vanderbilt had \$67.0 million of variable-rate bonds outstanding as of June 30, 2015, consisting entirely of floating-rate notes with a mandatory tender date of October 1, 2017.

As of June 30, 2015, Vanderbilt had \$90.0 million of tax-exempt CP outstanding and \$173.5 million of taxable CP outstanding. The weighted average duration of Vanderbilt's CP portfolio totaled 92 days as of June 30, 2015, and 97 days as of June 30, 2014.

Vanderbilt's current tax-exempt CP program began on March 29, 2010, with all draws completed by September 30, 2011. The final maturity under the current tax-exempt CP program is May 31, 2036. Vanderbilt can issue an additional \$411.5 million under its current taxable CP program.

Debt liquidity support with short-term remarketing periods (CP totaling \$263.5 million) is provided by Vanderbilt's self-liquidity. As of June 30, 2015, Vanderbilt estimates that \$1,374.5 million of liquid assets were available on a same-day basis and an additional \$872.1 million was available within 30 days.

A second tier of debt liquidity support consists of two revolving credit facilities with maximum available commitments totaling \$400 million as of June 30, 2015, dedicated to Vanderbilt's debt portfolio liquidity support. One of these lines totaling \$200 million

includes a general use provision. These commitments expire in March 2016 and April 2017. The maximum repayment period, which may extend beyond the expiration date, ranges from 90 days to three years. Vanderbilt has never borrowed against revolving credit agreements to support redemptions of debt.

Vanderbilt has entered into an agreement with one bank to provide a general use line of credit with a maximum available commitment totaling \$100.0 million as of June 30, 2015. This line of credit expires in October 2015. Vanderbilt had no outstanding draws against these credit facilities as of June 30, 2015, or June 30, 2014.

Vanderbilt reports long-term debt at carrying value, which is the par amount adjusted for the net unamortized amount of bond premiums and discounts. The carrying value and estimated fair value of Vanderbilt's long-term debt as of June 30 were as follows (in thousands):

	2015	2014
Carrying value of long-term debt	\$ 971,415	\$ 1,083,256
Fair value of long-term debt	\$ 1,053,467	\$ 1,175,327

Vanderbilt bases estimated fair value of long-term debt on market conditions prevailing at fiscal year-end reporting dates. Besides potentially volatile market conditions, fair value estimates typically also reflect limited secondary market trading. Vanderbilt reports capital leases and commercial paper at carrying value, which closely approximates fair value for those liabilities.

None of Vanderbilt's fixed-rate debt has a mandatory tender date preceding the respective final maturity date. The Series 2008A and 2008B bonds include amortizing principal amounts each year but these bonds are noncallable before their October 2018 final maturity date. The Series 2009A and 2009B bonds include amortizing principal amounts each year beginning fiscal 2016 and a call feature at par beginning October 2019. The Series 2009A Taxable notes do not amortize and include a call feature before the April 2019 maturity date only if Vanderbilt pays a make-whole call provision to the bondholders. The Series 2012C bonds include annual amortizing principal amounts each year, excluding October 2015, until their final maturity in October 2017. The Series 2012D bonds include amortizing principal amounts each year beginning in fiscal 2021 and a call feature at par beginning October 2023. The Series 2012E bonds include annual amortizing principal amounts beginning October 2013, until their final maturity in October 2019.

11. Interest Rate Exchange Agreements

Vanderbilt utilizes interest rate exchange agreements as part of its debt portfolio management strategy. These agreements result in periodic net cash settlements paid to, or received from, counterparties. Adjustments to interest expense for net settlements due to counterparties totaled \$18.9 million and \$23.0 million in fiscal 2015 and 2014, respectively.

Vanderbilt estimates the fair value of interest rate exchange agreements by calculating the present value sum of future net cash settlements that reflect market yields as of the measurement date and estimated amounts that Vanderbilt would pay, or receive, to terminate the contracts as of the report date. Vanderbilt considers current interest rates and creditworthiness of the interest rate exchange counterparties when estimating termination settlements. The estimated fair value of Vanderbilt's outstanding interest rate exchange agreements represented liabilities of \$174.7 million and \$168.4 million as of June 30, 2015 and 2014, respectively.

Vanderbilt did not enter into any new interest rate exchange agreements during fiscal 2015 or 2014. During fiscal 2015, Vanderbilt terminated \$60.0 million notional of fixed-rate payer interest rate exchange agreements at a cost of \$21.5 million to reduce collateral exposure and eliminate ongoing settlement costs. Following the terminations and scheduled amortizations, Vanderbilt had \$482.9 million of aggregate fixed-payer interest rate exchange agreements outstanding for which the university receives 68.2% of one-month LIBOR and pays a weighted average fixed rate of 3.86%. Vanderbilt also had \$500.0 million of basis interest rate exchange agreements outstanding in fiscal 2015 and 2014 for which the university receives 81.5% of one-month LIBOR and pays SIFMA. Vanderbilt did not terminate any basis interest rate exchange agreements in either fiscal year.

Changes in the fair value of interest rate exchange agreements, reported in the nonoperating section of the consolidated statements of activities, resulted in net losses of \$27.7 million in fiscal 2015 and

net gains of \$6.4 million in fiscal 2014. The \$27.7 million change in appreciation of interest rate exchange agreements in fiscal 2015 includes an \$8.6 million unrealized loss to adjust the discount rate to reflect counterparty credit risk partially offset by a \$2.4 million net unrealized gain from the combination of the positive effect of the termination of fixed-rate payer interest rate exchange agreements and the decrease in the long-term LIBOR rate. The \$6.4 million change in appreciation of interest rate exchange agreements in fiscal 2014 includes a \$13.4 million unrealized gain resulting from an adjustment to the discount rate to reflect counterparty credit risk and a \$24.9 million net unrealized gain from the combination of the positive effect of the termination of fixed-rate payer interest rate exchange agreements and the decrease in the long-term LIBOR rate. LIBOR decreased to 2.9% as of June 30, 2015, from 3.3% as of June 30, 2014. In fiscal 2015 Vanderbilt incurred costs of \$21.5 million to terminate interest rate exchange agreements compared to \$31.9 million in fiscal 2014. These costs are reflected in the change in appreciation of interest rate exchange agreements in the respective periods.

The interest rate exchange agreements include collateral pledging requirements based on the fair value of the contracts. Collateral held by counterparties as of June 30, 2015 and 2014, totaled \$84.4 million and \$75.8 million, respectively. Vanderbilt estimates that a decline in long-term LIBOR rates to approximately 1% would result in the fair value of the portfolio being a liability of approximately \$390 million and correspondingly increase Vanderbilt's collateral pledging requirements to approximately \$260 million. As of June 30, 2015, 30-year LIBOR was 2.9%.

As of June 30, 2015, Vanderbilt's adjusted debt portfolio, after taking into account outstanding fixed-payer interest rate exchange agreements, was fully hedged.

The notional amounts of Vanderbilt's outstanding interest rate exchange agreements as of June 30 were as follows (*in thousands*):

Description	Rate Paid	Rate Received	Maturity	2015	2014
Fixed-payer interest rate exchange agreements	Avg fixed rate of 3.86%	Avg of 68.2% of one-month LIBOR ¹	16 to 25 years	\$ 482,900	\$ 544,800
Basis interest rate exchange agreements	SIFMA ²	Avg of 81.5% of one-month LIBOR ¹	20 to 21 years	\$ 500,000	\$ 500,000

¹ LIBOR (London Interbank Offered Rate) is a reference rate based on interest rates at which global banks borrow funds from other banks in the London interbank lending market.

² SIFMA (Securities Industry and Financial Markets Association) is a seven-day high-grade market index rate based upon tax-exempt variable rate debt obligations.

12. Net Assets

Unrestricted net assets consist of the following internally designated groups:

Designated for operations represents cumulative operating activity. These net assets also reflect the realized losses of derivative financing activities.

Designated gifts and grants include gift and grant funds.

Designated for student loans represents Vanderbilt funds set aside to serve as revolving loan funds for students.

Designated for plant facilities represents (a) Vanderbilt's investment in property, plant, and equipment, net of accumulated depreciation, as well as (b) funds designated for active construction projects and retirement of capital-related debt, offset by (c) Vanderbilt's conditional asset retirement obligation.

Reinvested distributions of donor-restricted endowments at historical value are amounts related to donor-restricted endowments re-invested in the endowment in accordance with donor requests.

Vanderbilt University

Accumulated net appreciation of reinvested distributions represents cumulative appreciation on reinvestments of donor-restricted endowments.

Institutional endowments (quasi-endowments) at historical value are amounts set aside by Vanderbilt to generate income in perpetuity to support operating needs.

Accumulated net appreciation of institutional endowments represents cumulative appreciation on institutional endowments.

Fair value of interest rate exchange agreements, net represents the mark-to-market valuation for interest rate exchange contracts.

Net assets related to noncontrolling interests represents minority partners' share of the equity in two partnerships (endowment private equity and real estate partnerships) formed to acquire, hold, and manage private fund assets.

Based on the foregoing designations, **unrestricted net assets** as of June 30 were composed of the following (*in thousands*):

	2015	2014
Designated for operations	\$ 929,122	\$ 791,540
Designated gifts and grants	69,450	78,893
Designated for student loans	18,681	22,227
Designated for plant facilities	702,840	700,053
Reinvested distributions of donor-restricted endowments at historical value	95,019	94,224
Accumulated net appreciation of reinvested distributions	106,541	108,417
Institutional endowments at historical value	362,356	335,875
Accumulated net appreciation of institutional endowments	1,058,406	1,066,985
Fair value of interest rate exchange agreements, net	(174,713)	(168,451)
Net assets related to noncontrolling interests	110,954	150,067
Total unrestricted net assets	\$ 3,278,656	\$ 3,179,830

Temporarily restricted net assets as of June 30 were composed of the following (*in thousands*):

	2015	2014
Donor-restricted endowments at historical value	\$ 22,021	\$ 24,785
Accumulated net appreciation of donor-restricted endowments	1,311,212	1,329,499
Reinvested distributions of donor-restricted endowments at historical value	11,696	3,783
Accumulated net appreciation of reinvested distributions	2,285	2,239
Contributions	92,130	86,153
Interests in trusts held by others	6,916	5,769
Life income and gift annuities	14,902	15,254
Total temporarily restricted net assets	\$ 1,461,162	\$ 1,467,482

Temporarily restricted net assets were designated by donors and Vanderbilt for the following purposes as of June 30 (*in thousands*):

	2015	2014
Student scholarships	\$ 466,907	\$ 469,118
Endowed chairs	377,934	384,130
Operations	298,565	294,966
Program support	109,039	107,802
Capital improvements	28,709	15,954
Subsequent period operations and other	180,008	195,512
Total temporarily restricted net assets	\$ 1,461,162	\$ 1,467,482

Permanently restricted net assets as of June 30 were composed of the following (*in thousands*):

	2015	2014
Donor-restricted endowments at historical value	\$ 1,123,852	\$ 1,080,443
Contributions	43,484	41,961
Interests in trusts held by others	33,238	34,021
Life income and gift annuities	34,617	40,009
Total permanently restricted net assets	\$ 1,235,191	\$ 1,196,434

Based on relative fair values as of June 30, donor-restricted endowments supported the following:

	2015	2014
Financial aid	35%	35%
Endowed chairs	29%	29%
Operations	21%	21%
Program support	8%	8%
Research, lectureships, fellowships, and other	7%	7%
Total support	100%	100%

13. Fair Value Measurement

Vanderbilt utilizes a fair value hierarchy that prioritizes the inputs to valuation techniques used to measure fair value into three levels:

Level 1 consist of quoted prices (unadjusted) in active markets for identical assets or liabilities accessible at the measurement date.

Level 2 include inputs other than quoted prices in Level 1 directly or indirectly observable for the assets or liabilities.

Level 3 are unobservable inputs for the assets or liabilities.

The level in the fair value hierarchy within which a fair value measurement in its entirety is classified depends on the lowest level input that is significant to the fair value measurement.

The significance of the unobservable inputs to the overall fair value measurement determines the classification of a financial instrument within level 3.

The consolidated statements of activities reflect: all net realized and unrealized gains and losses on level 3 investments as changes in endowment appreciation or changes in appreciation of other investments; gains and losses on investments allocable to noncontrolling interests as a component of net endowment appreciation; and net realized and unrealized gains and losses on interests in trusts held by others as changes in appreciation of other investments.

Rollforwards of amounts for level 3 financial instruments for the fiscal years ended June 30 follow (*in thousands*):

	Beginning balance as of June 30, 2014	Net realized gains (losses)	Net change in unrealized gains (losses)*	Purchases	Sales	Transfers into/(out of) level 3	Ending balance as of June 30, 2015
LEVEL 3 ASSETS							
Fixed income	\$ 19,987	\$ 30	\$ 657	\$ 1,613	\$ (5,107)	\$ -	\$ 17,180
Global equities	112,179	37,801	(37,310)	2,838	(83,170)	-	32,338
Hedge strategies	370,881	(33,170)	(34,486)	5,083	(199,783)	-	108,525
Private capital	1,437,157	235,571	36,543	169,427	(485,962)	-	1,392,736
Real estate	279,042	3,290	19,876	27,333	(100,566)	-	228,975
Natural resources	335,955	4,991	(48,950)	44,032	(41,870)	-	294,158
Trusts	4,652	310	(548)	-	(156)	-	4,258
Other investments	11,224	60	-	207	(3,433)	-	8,058
Interests in trusts held by others	39,790	-	364	-	-	-	40,154
Total Level 3	\$ 2,610,867	\$ 248,883	\$ (63,854)	\$ 250,533	\$ (920,047)	\$ -	\$ 2,126,382

*Total change in unrealized gains/(losses) relating to Level 3 investment assets held by the University at June 30, 2015 is \$24,761 and is reflected in "Net change in unrealized appreciation on investments" in the Consolidated Statements of Cash Flows.

	Beginning balance as of June 30, 2013	Net realized gains (losses)	Net change in unrealized gains (losses)*	Purchases	Sales	Transfers into/(out of) level 3	Ending balance as of June 30, 2014
LEVEL 3 ASSETS							
Fixed income	\$ 19,040	\$ 5	\$ (608)	\$ 2,397	\$ (847)	\$ -	\$ 19,987
Global equities	164,301	(1,611)	23,011	5,583	(79,105)	-	112,179
Hedge strategies	650,561	(210,225)	21,853	53,488	(245,784)	100,988	370,881
Private capital	1,260,275	143,299	239,591	171,833	(377,841)	-	1,437,157
Real estate	292,746	8,137	13,763	35,044	(70,648)	-	279,042
Natural resources	286,397	18,411	39,072	48,903	(56,828)	-	335,955
Trusts	4,137	1,613	690	1,710	(3,498)	-	4,652
Other investments	11,176	(38)	-	216	(130)	-	11,224
Interests in trusts held by others	38,091	908	791	-	-	-	39,790
Total Level 3	\$ 2,726,724	\$ (39,501)	\$ 338,163	\$ 319,174	\$ (834,681)	\$ 100,988	\$ 2,610,867

*Total change in unrealized gains/(losses) relating to Level 3 investment assets held by the University at June 30, 2014 is \$337,819 and is reflected in "Net change in unrealized appreciation on investments" in the Consolidated Statements of Cash Flows.

The tables on the following pages present the amounts within each valuation hierarchy level for those assets and liabilities carried at fair value: cash and cash equivalents; investments; investments allocable to noncontrolling interests (in Vanderbilt-controlled real estate and other partnerships); interests in trusts held by others; and the fair value of interest rate exchange agreements.

Noted in the tables on the following page, as a measure of liquidity, are the redemption terms and restrictions of investments, along with the numbers of days notice required to liquidate these investments. Most investments classified as levels 2 and 3 consist of shares or units in investment funds as opposed to direct interests in the funds' underlying holdings. Vanderbilt uses the net asset value reported by the fund as a practical expedient to estimate the fair value of interest therein for the majority of these assets; Vanderbilt's ability to redeem its interest at or near the financial statement date determines the net

Vanderbilt University

assets classification as level 2 or level 3. Vanderbilt defines near-term as within 90 days of the financial statement date.

Derivative contract collateral and short-term securities are primarily composed of amounts posted as collateral in accordance with interest rate exchange agreements and unspent bond proceeds with trustees. Vanderbilt deems a redemption or liquidation frequency for these amounts as nonapplicable. Global equities and fixed income provide varying levels of liquidity as defined in the following tables. Hedged strategies include daily, quarterly, and annual redemption frequencies. These strategies allow Vanderbilt to provide notice to the fund managers to exit from the respective funds in the time periods noted. Lockup provisions range from none to five years.

The total asset values for private capital, real estate, natural resources, and other investments are illiquid as of June 30, 2015. These amounts predominantly consist of limited partnerships. Under the

terms of these limited partnership agreements, Vanderbilt is obligated to remit additional funding periodically as capital calls are exercised by the general partner. These partnerships have a limited existence and the agreements may provide for annual extensions relative to the timing for disposing portfolio positions and returning capital to investors. Depending on market conditions, the ability or inability of a fund to execute its strategy, and other factors, the general partner may extend the terms or request an extension of terms of a fund beyond its originally anticipated existence or may liquidate the fund prematurely. Unforeseen events prevent Vanderbilt from anticipating such changes. As a result, the timing and amount of future capital calls or distributions in any particular year are uncertain and the related asset values are illiquid.

The following tables summarize the fair value measurements and terms for redemptions or liquidations for those assets and liabilities carried at fair value as of June 30 (*in thousands*):

Assets Reported at Fair Value as of June 30, 2015

	Fair Value Measurements			Total	Redemption Terms	Redemption Restriction
	Level 1	Level 2	Level 3			
Cash and cash equivalents	\$ 1,291,631	\$ -	\$ -	\$ 1,291,631	Daily, with same-day to 90 day notice	No restrictions
Derivative contract collateral and short-term securities	82,139	-	-	82,139	N/A	Not redeemable
Global equities	1,016,529	45,501	32,338	1,094,368	Daily to annually, with 1 to 90 day notice	Lock-up provision ranging from none to 4 years
Fixed income	231,798	-	17,180	248,978	Daily with 1 to 5 day notice	No restrictions
Private capital	13,595	-	1,392,736	1,406,331	N/A	Not redeemable
Hedged strategies	752,434	43,823	108,525	904,782	Daily to annually, with 1 to 90 day notice	Lock-up provision ranging from none to 3 years
Commodities	98,311	-	-	98,311	Daily to monthly, with 1 to 30 day notice	No restrictions
Natural resources	140	-	294,158	294,298	N/A	Not redeemable
Real estate	-	-	228,975	228,975	N/A	Not redeemable
Trusts	-	-	4,258	4,258	N/A	Not redeemable
Other investments	2,753	-	8,058	10,811	N/A	Not redeemable
Interests in trusts held by others	-	-	40,154	40,154	N/A	Not redeemable
Total assets reported at fair value	\$ 3,489,330	\$ 89,324	\$ 2,126,382	\$ 5,705,036		

Liabilities Reported at Fair Value as of June 30, 2015

Interest rate exchange agreements	\$ -	\$ 174,713	\$ -	\$ 174,713
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Vanderbilt University

Assets Reported at Fair Value as of June 30, 2014

	Fair Value Measurements			Total	Redemption Terms	Redemption Restriction
	Level 1	Level 2	Level 3			
Cash and cash equivalents	\$ 1,244,720	\$ -	\$ -	\$ 1,244,720	Daily, with same-day to 90 day notice	No restrictions
Derivative contract collateral and short-term securities	77,839	-	-	77,839	N/A	Not redeemable
Global equities	1,091,046	2,614	112,179	1,205,839	Daily to annually, with 1 to 90 day notice	Lock-up provision ranging from none to 4 years
Fixed income	157,880	-	19,987	177,867	Daily, with 2 to 30 day notice	No restrictions
Private capital	2,356	-	1,437,157	1,439,513	N/A	Not redeemable
Hedged strategies	316,367	94,120	370,881	781,368	Daily to annually, with 1 to 180 day notice	Lock-up provision ranging from none to 2 years*
Natural resources	-	-	335,955	335,955	N/A	Not redeemable
Real estate	-	-	279,042	279,042	N/A	Not redeemable
Trusts	-	-	4,652	4,652	N/A	Not redeemable
Other investments	592	-	11,224	11,816	N/A	Not redeemable
Interests in trusts held by others	-	-	39,790	39,790	N/A	Not redeemable
Total assets reported at fair value	\$ 2,890,800	\$96,734	\$2,610,867	\$ 5,598,401		

*Certain partnerships not redeemable

Liabilities Reported at Fair Value as of June 30, 2014

Interest rate exchange agreements	\$ -	\$ 168,451	\$ -	\$ 168,451
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14. Retirement Plans

Vanderbilt's full-time faculty and staff members participate in defined contribution retirement plans administered by third-party investment and insurance firms. For eligible employees with one year of continuous service, these plans require employee and matching employer contributions. The employee immediately vests in these contributions.

Vanderbilt funds the obligations under these plans through monthly transfers to the respective retirement plan administrators with the corresponding expenses recognized in the year incurred. Vanderbilt's retirement plan contributions for fiscal 2015 and 2014 were \$63.8 million and \$63.1 million, respectively.

15. Student Financial Aid

Vanderbilt provides financial aid to students based upon need and merit. Institutional resources, contributions, endowment distributions, and externally sponsored programs fund this financial assistance.

For the fiscal years ended June 30, financial aid for tuition and education fees was as follows (in thousands):

	2015	2014
Tuition and educational fees, gross	\$ 489,018	\$ 478,320
Less: Financial aid for tuition and educational fees	(216,815)	(213,543)
Tuition and educational fees, net	\$ 272,203	\$ 264,777

For the fiscal years ended June 30, financial aid for room and board was as follows (in thousands):

	2015	2014
Room and board, gross	\$ 77,476	\$ 70,809
Less: Financial aid for room and board	(32,663)	(30,303)
Room and board, net	\$ 44,813	\$ 40,506

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16. Functional Classification of Expenses and Allocations

For the fiscal years ended June 30, operating expenses incurred were as follows (*in thousands*):

	2015	2014
Instruction	\$ 489,383	\$ 495,824
Research	419,003	434,009
Health care services	2,500,022	2,389,431
Public service	42,229	41,298
Academic support	158,312	139,026
Student services	107,172	99,969
Institutional support	117,303	61,778
Room, board, and other auxiliary services	99,718	93,146
Total operating expenses	\$ 3,933,142	\$ 3,754,481

Natural expense classifications include certain allocations of institutional and other support costs to Vanderbilt's primary programs. Based on the functional uses of space on its campus, Vanderbilt allocated depreciation and interest on indebtedness to the functional operating expense categories as follows (*in thousands*):

2015

	Depreciation	Interest
Instruction	\$ 19,509	\$ 2,762
Research	23,340	5,385
Health care services	76,430	38,198
Academic support	11,667	1,325
Student services	8,766	693
Institutional support	12,024	994
Room, board, and other auxiliary services	25,440	10,677
Total	\$ 177,176	\$ 60,034

2014

	Depreciation	Interest
Instruction	\$ 20,997	\$ 3,448
Research	23,792	6,189
Health care services	79,652	40,672
Academic support	8,314	1,122
Student services	6,739	790
Institutional support	11,724	1,107
Room, board, and other auxiliary services	24,561	12,150
Total	\$ 175,779	\$ 65,478

17. Charity Care Assistance and Community Benefits

VUMC (including hospitals, clinics, and physician practice units) maintains a policy which sets forth the criteria to provide without expectation of payment or at a reduced payment rate health care services to patients who have minimal financial resources to pay for medical care. VUMC does not report these charity care services as revenue.

The medical center maintains records to identify and monitor the level of charity care it provides, and these records include the amount of gross charges and patient deductibles, co-insurance and co-payments forgone for services furnished under its charity care policy, and the estimated cost of those services. Charity care utilizes a tiered grid to determine the level of assistance based on federal poverty guidelines. State of Tennessee law mandates uninsured patient eligibility for a discount from billed charges for medically necessary services, in addition to charity care assistance. VUMC provides additional discounts based on the income level of the patient household using a sliding scale for those patients with a major catastrophic medical event that do not qualify for full charity assistance.

The total cost of uncompensated care (charity care and bad debt) was \$225.0 million and \$233.2 million for fiscal 2015 and 2014, respectively. Of the total uncompensated care, charity care represented 45.8% and 54.5% in fiscal 2015 and 2014, respectively.

In addition to the charity care services described above, the medical center provides a number of other services to benefit the economically disadvantaged for which the medical center receives little or no payment. TennCare/Medicaid and state indigent programs do not cover the full cost of providing care to beneficiaries of those programs. As a result, in addition to direct charity care costs, the medical center provided services related to TennCare/Medicaid and state indigent programs and was reimbursed substantially below the cost of rendering such services.

The medical center also provides public health education and training for new health professionals and provides, without charge, services to the community at large, together with support groups for many patients with special needs.

18. Related Parties

Intermittently, members of Vanderbilt's Board of Trust or Vanderbilt employees may be directly or indirectly associated with companies engaged in business activities with the university. Accordingly, Vanderbilt has a written conflict of interest policy that requires, among other things, that members of the university community (including trustees) may not review, approve, or administratively control contracts or business relationships when (a) the contract or business relationship is between Vanderbilt and a business in which the individual or a family member has a material financial interest or (b) the individual or a family member is an employee of the business and is directly involved with activities pertaining to Vanderbilt.

Furthermore, Vanderbilt's conflict of interest policy extends beyond

the foregoing business activities in that disclosure is required for any situation in which an applicable individual's financial, professional, or other personal activities may directly or indirectly affect, or have the appearance of affecting, an individual's professional judgment in exercising any university duty or responsibility, including the conduct or reporting of research.

The policy extends to all members of the university community (including trustees, university officials, and faculty and staff and their immediate family members). Each applicable person is required to certify compliance with the conflict of interest policy on an annual basis. This certification includes specifically disclosing whether Vanderbilt conducts business with an entity in which he or she (or an

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immediate family member) has a material financial interest as well as any other situation that could appear to present a conflict with Vanderbilt's best interests.

When situations exist relative to the conflict of interest policy, Vanderbilt takes active measures to manage appropriately the actual or perceived conflict in the best interests of the university, including periodic reporting of the measures taken to the Board of Trust Audit Committee.

19. Lease Obligations

Vanderbilt primarily classifies certain equipment and real property leases as operating leases with lease terms of up to 15 years. Total operating lease expense in fiscal 2015 and 2014 was \$83.2 million and \$70.8 million, respectively.

As of June 30, 2015, future committed minimum rentals by fiscal year on significant noncancelable operating leases with initial terms in excess of one year were as follows (*in thousands*):

2016	\$ 53,768
2017	47,783
2018	39,163
2019	29,307
2020	24,764
Thereafter	134,242
Total future minimum rentals	\$ 329,027

Detail of significant noncancelable operating leases by type:

	% of Minimum Rentals	Minimum Rentals
Property leases (132 leases)	84%	\$ 277,895
Equipment leases (142 leases)	16%	51,132
Total future minimum rentals	100%	\$ 329,027

Property leases for One Hundred Oaks (46%) and 2525 West End Avenue (7%) account for approximately 53% of the total future minimum rentals.

20. Commitments and Contingencies

(A) *Construction.* As of June 30, 2015, Vanderbilt had contractual commitments for approximately \$115.6 million of projects under construction and equipment purchases. The largest components of these commitments were for the Engineering and Science Building (\$71.4 million).

(B) *Litigation.* Vanderbilt is a defendant in several legal actions. One such legal action is a qui tam civil action related to billing and government reimbursement for certain professional health care services provided by the Vanderbilt University Medical Center. The lawsuit was unsealed in the fall of 2013, and the government has decided not to intervene in the litigation at this time. Accordingly, the litigation is currently in the discovery phase with private plaintiffs. Vanderbilt believes that the outcome of these actions will not have a significant effect on its consolidated financial position.

(C) *Regulations.* Vanderbilt's compliance with regulations and laws is subject to future government reviews and interpretations, as well as regulatory actions unknown at this time. Vanderbilt believes that the liability, if any, from such reviews will not have a significant effect on Vanderbilt's consolidated financial position.

(D) *Medical Malpractice Liability Insurance.* Vanderbilt is self-insured for the first level of medical malpractice claims. The current self-insured retention is \$5.5 million per occurrence, not to exceed an annual aggregate of \$43.0 million. Vanderbilt segregates investments for this self-insured retention. An independent actuarial firm performs studies to determine the funding for these segregated assets. Excess malpractice and professional liability coverage has been obtained from commercial insurance carriers on a claims-made basis for claims above the retained self-insurance risk levels.

(E) *Employee Health and Workers Compensation Insurance.* Vanderbilt is self-insured for employee health insurance and workers compensation coverage. Vanderbilt bases estimated liabilities upon studies conducted by independent actuarial firms.

(F) *Federal and State Contracts and Other Requirements.* Expenditures related to federal and state grants and contracts are subject to adjustment based upon review by the granting agencies. Amounts of expenditures that granting agencies might disallow cannot be determined at this time. These amounts affect government grants and contract revenue as well as facilities and administrative cost recovery. Vanderbilt would not expect these costs to influence the consolidated financial position significantly.

(G) *Health Care Services.* Revenue from health care services includes amounts paid under reimbursement agreements with certain third-party payers and is subject to examination and retroactive adjustments. Vanderbilt reports any differences between estimated year-end settlements and actual final settlements at the time of final settlement. The financial statements include substantially all final settlements through the year ended June 30, 2010. Vanderbilt expects to receive final settlements relative to periods through June 30, 2011, during fiscal 2016.

(H) *HIPAA Compliance.* Under the Health Insurance Portability and Accountability Act of 1996 (HIPAA), the federal government has authority to complete fraud and abuse investigations. HIPAA has established substantial fines and penalties for offenders. Vanderbilt maintains policies, procedures, and organizational structures to enforce and monitor compliance with HIPAA, as well as other applicable local, state, and federal statutes and regulations.

(I) *Partnership Investment Commitments.* There were \$472.1 million of commitments to venture capital, real estate, and private equity investments as of June 30, 2015. At the request of the general partners, Vanderbilt may draw down funds over the next several years. Vanderbilt expects to finance these commitments with available cash and expected proceeds from the sales of securities. In addition, Vanderbilt is a secondary guarantor for \$13.2 million of commitments for certain investment vehicles where minority limited partners in subsidiaries that Vanderbilt controls have the primary obligations.



**Attachment C. Contribution to the
Orderly Development of
Healthcare.7.c**

Licensure & Accreditation

Board for Licensing Health Care Facilities

State of Tennessee



DEPARTMENT OF HEALTH

No. of Beds 0000000027
1025

This is to certify, that a license is hereby granted by the State Department of Health to

VANDERBILT UNIVERSITY (THE)

to conduct and maintain a

Hospital

VANDERBILT UNIVERSITY HOSPITALS

Located at

1561 21ST AVE. SOUTH, MCN-AAA-1204, NASHVILLE

County of

DAVIDSON

Tennessee

This license shall expire

APRIL 29

2016, and is subject

to the provisions of Chapter 1, Tennessee Code Annotated. This license shall not be assignable or transferable, and shall be subject to revocation at any time by the State Department of Health, for failure to comply with the laws of the State of Tennessee or the rules and regulations of the State Department of Health issued thereunder.

In Witness Whereof, we have hereunto set our hand and seal of the State this 29TH day of APRIL, 2015.

GENERAL HOSPITAL
REDI/ATRI/O PRO/HOSPITAL
TRAUMA CENTER LEVEL 1

By JAMES J. DAVIS, MPH
DIRECTOR, DIVISION OF HEALTH CARE FACILITIES

By John D. ...
COMMISSIONER



Vanderbilt University

Nashville, TN

has been Accredited by



The Joint Commission

Which has surveyed this organization and found it to meet the requirements for the
Hospital Accreditation Program

July 25, 2015

Accreditation is customarily valid for up to 36 months.

Rebecca J. Patchin MD

Rebecca J. Patchin, MD
Chair, Board of Commissioners

ID #7892

Print/Reprint Date: 10/02/2015

Mark R. Chassin

Mark R. Chassin, MD, FACP, MPP, MPH
President

The Joint Commission is an independent, not-for-profit national body that oversees the safety and quality of health care and other services provided in accredited organizations. Information about accredited organizations may be provided directly to The Joint Commission at 1-800-994-6610. Information regarding accreditation and the accreditation performance of individual organizations can be obtained through The Joint Commission's web site at www.jointcommission.org.



**Attachment C. Contribution to the
Orderly Development of
Healthcare.7.d**

**Licensure Certification &
Plan of Correction**

Vanderbilt University

Organization ID: 7892

1161 22nd Avenue Nashville, TN 37232-2101

Accreditation Activity - 45-day Evidence of Standards Compliance Form

Due Date: 9/13/2015

HAP Standard EC.02.03.01 The hospital manages fire risks.

Findings: EP 1 §482.41(b) - (A-0709) - §482.41(b) Standard: Life Safety from Fire The hospital must ensure that the life safety from fire requirements are met. This Standard is NOT MET as evidenced by: Observed in Building Tour at Vanderbilt University (1161 22nd Avenue, Nashville, TN) site for the Hospital deemed service. In VUH above ceiling there was an open junction box adjacent to room 11001. Corrected on site. Observed in Building Tour at Vanderbilt University (1161 22nd Avenue, Nashville, TN) site for the Hospital deemed service. In VHU the cylinder storage / manifold room had non-flammable gases stored in a quantity greater than 3000 cubic feet. The electric light switch located inside the room was less than five feet above the finished floor level. Corrected on site.

Elements of Performance:

1. The hospital minimizes the potential for harm from fire, smoke, and other products of combustion.

Scoring Category: C

Corrective Action Taken:

WHO: Assistant Vice Chancellor, Facilities and Construction

WHAT:

OPEN JUNCTION BOX - The issue with the open junction box adjacent to room 11001 was corrected when the surveyor was on site. COMPRESSED GAS STORAGE – 1. The electrical switch in VUH cylinder

storage room B306 was corrected when the surveyor was on site. 2. The following language has been added to the organizational policy (SA 10-10.09) regarding storage, use, and management of compressed gas: "Indoor rooms used for storage of greater than 3,000 cubic feet of compressed gas: iii. are built such that electrical devices are physically protected, either by use of a protective barrier around the electrical devices, or by location of the electrical device that prevents physical damage to the cylinder or containers. For example, the device is located at or above 5 feet above finished floor or other location that does not allow the possibility of the cylinders or containers to come into contact with the electrical device." VUMC Safety policy, SA 10-10.09, was reviewed and approved by the VUMC Safety Committee and the Executive Policy Committee.

WHEN:

The open junction box adjacent to Room 11001 was corrected on 7/24/2015 when the surveyor was on site. All additional areas with recent above ceiling work were checked for open junction boxes and deficiencies were corrected by 8/21/2015. The electrical switch in VUH cylinder storage room, B306, was corrected on 7/23/2015. All electric light switches in additional compressed gas storage stored in a quantity greater than 3000 cubic feet deficiencies were corrected by 8/21/2015. VUMC Safety Policy SA 10-10.09 was approved on 9/4/2015.

HOW:

OPEN JUNCTION BOX – All additional areas with recent above ceiling work were checked for open junction boxes and deficiencies were corrected. Random checks are performed by Plant Services Carpentry Shop, at least monthly, throughout the facility to verify above ceiling work close out inspections are being performed properly. These checks include verification that all junction boxes are closed. When deficiencies are noted, a root cause investigation is performed to determine corrective actions to prevent further reoccurrences. **COMPRESSED GAS** - All additional electric light switches in compressed gas storage stored in a quantity greater than 3000 cubic feet were surveyed and all deficiencies were corrected. Representatives from Vanderbilt Environmental Health and Safety (VEHS) conduct monthly environment of care rounds throughout the organization to include these storage areas. Reviews of these storage areas include the required parameters of signage, security, electrical safety, and cleanliness. Results are reported to the Safety Committee. When deficiencies are noted, a root cause investigation is performed to determine corrective actions to prevent further reoccurrences.

HAP Standard EC.02.04.03 The hospital inspects, tests, and maintains medical equipment.

Findings: EP 2 §482.41(c)(2) - (A-0724) - (2) Facilities, supplies, and equipment must be maintained to ensure an acceptable level of safety and quality. This Standard is NOT MET as evidenced by: Observed in Building Tour at Vanderbilt University (1161 22nd Avenue, Nashville, TN) site for the Hospital deemed service. Observed on the CCT10 Unit, a transport Defibrillator with a time displayed at 0941 hours that was behind/incorrect by 1 hour. Defibrillator time was corrected during the survey. Observed in Tracer Activities at Vanderbilt University (1161 22nd Avenue, Nashville, TN) site for the Hospital deemed service. During a tour of the Cardiac Catheterization lab, the time on a transport defibrillator was off by one hour. Subsequent to the surveyor visit, all defibrillators were checked by staff to ensure times coincided with the official time utilized in the area.

Elements of Performance:

2. The hospital inspects, tests, and maintains all high-risk equipment. These activities are documented. (See also EC.02.04.01, EPs 3 and 4; PC.02.01.11, EP 2) Note: High-risk medical equipment includes life-support equipment.

Scoring Category: A

Corrective Action Taken:

WHO: Director, Clinical Engineering

WHAT:

The date and time on the transport defibrillators in the CCT10 unit and Cardiac Catheterization lab were corrected during the survey. Clinical Engineering has revised the Preventive Maintenance (PM) frequency in the Computer Maintenance Management System (CMMS) on all defibrillators to coincide with Daylight Saving Time start/end. This will occur in March and November each year. The Resuscitation Committee approved the addition of date/time checks on the clinical staff's daily defibrillator checklist for the crash carts. The desk phone is used as the official time. If the time or date is found to be incorrect a call will be placed to Clinical Engineering.

WHEN:

The date and time on the Transport defibrillators in the CCT10 unit and Cardiac Catheterization lab were corrected on 7/23/2015. All other defibrillators were checked and if incorrect were corrected on 7/31/2015. The update to the CMMS was completed by 8/31/2015. Defibrillator checklist for the crash carts was updated 8/18/2015.

HOW:

Defibrillators throughout the organization were checked for the correct date and time and deficiencies were corrected upon discovery. Per Vanderbilt Medical Equipment Management Plan, Clinical Engineering documents in the CMMS all service associated with high risk equipment (including life support). Preventive Maintenance is part of the documentation. All high risk equipment under the Medical Equipment Management Plan are required to have a Preventive Maintenance completion rate of 100% within the month of the work order issuance (March/November for Defibrillators). Preventive Maintenance completion rates are reported through the Environment of Care (EOC) committee. During EOC rounds the surveyor checks the daily checklist for correct date/time on defibrillators in the department being surveyed. A call is placed to Clinical Engineering for immediate correction on any defibrillator found to have an incorrect date/time.

HAP Standard EC.02.05.01 The hospital manages risks associated with its utility systems.

Findings: EP 15 §482.42 - (A-0747) - §482.42 Condition of Participation: Condition of Participation: Infection Control This Condition is NOT MET as evidenced by: Observed in Building Tour at Vanderbilt at One Hundred Oaks (719 Thompson Lane, Nashville, TN) site for the Hospital deemed service. During a tracer of the sterile processing department, the decontamination room had a positive pressure and the clean room had a negative pressure. This was corrected during survey and confirmed by the surveyor.

Elements of Performance:

15. In areas designed to control airborne contaminants (such as biological agents, gases, fumes, dust), the ventilation system provides appropriate pressure relationships, air-exchange rates, and filtration efficiencies. (See also EC.02.06.01, EP 13) Note: Areas designed for control of airborne contaminants include spaces such as operating rooms, special procedure rooms, delivery rooms for patients diagnosed with or suspected of having airborne communicable diseases (for example, pulmonary or laryngeal tuberculosis), patients in 'protective environment' rooms (for example, those receiving bone marrow transplants), laboratories, pharmacies, and sterile supply rooms. For further information, see Guidelines for Design and Construction of Health Care Facilities, 2010 edition, administered by the Facility Guidelines Institute and published by the American Society for Healthcare Engineering (ASHE).

Scoring Category: A

Corrective Action Taken:

WHO: Assistant Vice Chancellor, Facilities and Construction

WHAT:

During Vanderbilt's 2015 triennial survey, the sterilization/decontamination areas at One Hundred Oaks had deficient pressurization when evaluated by one of the surveyors. The root cause of the problem was a failure of the variable speed frequency drive unit for the exhaust fan serving this area. The issue was corrected during the survey by replacement of the computer driver card.

WHEN:

This issue was discovered during survey on 7/21/2015 and the computer driver card was replaced on 7/22/2015. Operational status alarm features were enabled on 8/19/2015.

HOW:

To ensure prompt response in addressing future ventilation events, throughout the One Hundred Oaks facility, operational status alarm features were enabled for this fan and for any other fans serving areas where pressure relationships are required to be maintained. These features were enabled on 8/19/2015. If the operational status alarm goes off in the Delta Center for the fan in the decontamination room and the clean room at One Hundred Oaks (OHO), a call will be made to the Manager of Quality Control for Sterile Processing. At that point, operations at the OHO location will cease until appropriate pressures are restored. Weekly pressure checks are performed and logged by a member of the Heat/Air/Refrigeration (HAR) Shop to verify required pressure is maintained. Responsible HAR staff use smoke generation equipment to check the applicable areas for correct pressurization. If problems are encountered, staff convey the information to the applicable site manager, initiate a 'trouble call' and complete a 'Non-Compliant Pressure Room Report'. The trouble call is submitted to Plant Services for evaluation and repair.

HAP	Standard IC.02.02.01	The hospital reduces the risk of infections associated with medical equipment, devices, and supplies.
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Findings: EP 2 §482.51 - (A-0940) - §482.51 Condition of Participation: Condition of Participation: Surgical Services This Standard is NOT MET as evidenced by: Observed in Building Tour at Vanderbilt University (1161 22nd Avenue, Nashville, TN) site for the Hospital deemed service. Reviewed, in the Ultrasound/Radiology Department, the cleaning process for transvaginal probes with Cidex OPA. During an interview with two staff members, discussed the quality control process to test newly opened Cidex OPA test strips. Both staff indicated that they tested a newly opened bottle by testing one strip in full-strength solution. The manufacturer's recommendation is to test 3 + and 3 - control strips with a full concentration and diluted concentration of Cidex OPA solution. Staff were re-trained, signage to guide staff was posted and auditing began during survey. Organization is currently in compliance. Observed in Individual Tracer at Vanderbilt University Medical Center (2200 Children's Way, Nashville, TN) site for the Hospital deemed service. During a tracer in the PCICU & PICU the staff stated that soiled instruments including surgical trays were sent to Central Sterile Processing in biohazard bags on a cart. Soiled items were not kept moist in transport containers with a moist towel or sprayed with an enzymatic foam as recommended by the AAMI Standards in regards to the transportation of soiled instruments. This was confirmed by the Unit Manager. EP 4 §482.51 - (A-0940) - §482.51 Condition of Participation: Condition of Participation: Surgical Services This Standard is NOT MET as evidenced by: Observed in Building Tour at Vanderbilt University (1161 22nd Avenue, Nashville, TN) site for the Hospital deemed service. During tracer activity in the GI Endoscopy Lab a specialty scope was noted to be stored in a cabinet of insufficient height to allow the scope to hang freely in a vertical position without touching the bottom of the cabinet. Staff had looped the scope in such a manner to prevent the scope from touching the bottom of the cabinet. Best practice in AAMI standards require that scopes not be looped while in storage. Observed in Individual Tracer at Vanderbilt University Medical Center (2200 Children's Way, Nashville, TN) site for the Hospital deemed service. During tracer activity in the VCH Endoscopy Suite an adult endoscopy scope was noted to be stored in a cabinet of insufficient height to allow the scope to hang freely in a vertical position without touching the bottom of the cabinet. Staff had looped the scope in such a manner to prevent the scope from touching the bottom of the cabinet. Best practice and AAMI standards require that scopes not be looped while in storage. This was corrected and verified during the survey. Observed in Individual Tracer at Vanderbilt University Medical Center (1301 Medical Center Drive, Nashville, TN) site for the Hospital deemed service. During tracer activity in the VUH endoscopy disinfection processing area of the OR, an endoscope was noted to be stored in such a manner to allow the tubing to touch the bottom of the cabinet. Best practice and AAMI standards require that scopes hang freely in a vertical position without touching the bottom of the cabinet. This was immediately corrected and verified during the survey. Observed in Individual Tracer at Vanderbilt University Medical Center (1215 21st Ave. South, Nashville, TN) site for the Hospital deemed service. During a tracer activity in the Cardiac Intervention unit, TEE probes were hanging in a storage cabinet. The probes, which had been cleaned to a high level of disinfection, were touching the sides of the cabinet in several places. Observed in Building

Tour at Vanderbilt University Medical Center (1215 21st Ave. South, Nashville, TN) site for the Hospital deemed service. During a tour of the ENT clinic, several scopes were high level disinfected. The scopes were hanging in a cabinet. Each scope was suspended in plastic tubes. Several of the scopes were touching the inside of the tubes which were not cleaned between use.

Elements of Performance:

2. The hospital implements infection prevention and control activities when doing the following: Performing intermediate and high-level disinfection and sterilization of medical equipment, devices, and supplies. * (See also EC.02.04.03, EP 4) Note: Sterilization is used for items such as implants and surgical instruments. High-level disinfection may also be used if sterilization is not possible, as is the case with flexible endoscopes. Footnote *: For further information regarding performing intermediate and high-level disinfection of medical equipment, devices, and supplies, refer to the website of the Centers for Disease Control and Prevention (CDC) at http://www.cdc.gov/hicpac/Disinfection_Sterilization/acknowledg.html (Sterilization and Disinfection in Healthcare Settings).

Scoring Category: A

Corrective Action Taken:

WHO: Director of Infection Prevention

WHAT:

Ultrasound/Radiology Department: The Testing and Use of Cidex OPA® 0.55% Orthophthalaldehyde High-Level Disinfectant IC 10-10.08 policy was developed by the Director of Infection Control and Prevention. The policy was endorsed by the Infection Control and Prevention Executive Committee, the Clinical Practice Committee and the Medical Center Medical Board. The Quality control procedure for Cidex OPA is addressed in the policy in the following manner: "3. Testing Procedure Following the directions for use on the bottle of test strips: a. Submerge three test strips in each of the above freshly prepared solutions for three seconds each. b. Remove. c. The three test strips dipped into the full-strength positive control should exhibit a complete color change on the indicator pad at 90 seconds for ortho-phthalaldehyde(Cidex OPA®). The three strips dipped into the diluted negative control either should remain unchanged or exhibit an incomplete color change when read at 90 seconds, depending on the product. Refer to the color chart on the test strip bottle. Record results on the log. d. Testing frequency: Do the QC test on each freshly opened bottle of test strips. e. Unsatisfactory QC Test Results: If the QC test indicates that the test strips are not functioning properly, stop using the test strips, and open another bottle of test strips (repeat QC test.)" Non-compliant staff was re-educated on the day of the survey. Re-educated staff in the Ultrasound/Radiology Department who are using Cidex

OPA regarding the Cidex OPA Test Strip testing in the Cidex OPA policy by electronic communication. PCICU & PICU: The Standard Operating Procedure for pre-cleaning soiled devices and instruments was developed and endorsed by Infection Control. Enzyme spray was added to carts and utility rooms in both areas. The pre-cleaning of soiled devices and instruments using enzymatic cleaner is addressed in the SOP in the following manner: "II. General Information: A. The pre-cleaning of soiled devices or instruments should begin in the point of use to prevent drying of blood, soil and debris on the surface, crevices, and within lumens. B. Enzymes enhance detergent cleaning for medical use by breaking down proteins and other substances found in blood and other gross soil that cannot be easily removed with solutions containing just detergents, surfactants, and water. D. Use enzymatic spray, gel, or solution according to manufacturing recommendations." Staff sending devices and instruments to Central Sterile Processing were educated to the pre-cleaning devices and instruments standard operating procedure by electronic communication.

WHEN:

Ultrasound/Radiology Department: The Testing and Use of Cidex OPA® 0.55% Orthophthalaldehyde High-Level Disinfectant IC 10-10.08 policy was approved and effective since August 2012. Re-education was sent via electronic communication on 8/31/2015. PCICU & PICU: Enzyme spray was added to the areas on the day of the survey. The Standard Operating Procedure for pre-cleaning soiled devices and instruments was developed and endorsed by Infection Control on 8/28/2015. Re-education for both areas was sent via electronic communication on 8/31/2015.

HOW:

Ultrasound/Radiology Department: Random observation by managers in Ultrasound/Radiology areas using Cidex OPA for compliance to policy. Non-compliance will be addressed by leadership. PCICU & PICU: Random observation by managers in PCICU & PICU areas that perform pre-cleaning of soiled instruments and devices for compliance of standard operating procedure. Non-compliance will be addressed by leadership. Central Sterile Processing will monitor the pre-cleaning of devices or instruments that are reprocessed in Central Sterile Processing. Non-compliance will be addressed by the non-compliant area's leadership.

4. The hospital implements infection prevention and control activities when doing the following: Storing medical equipment, devices, and supplies.

Scoring Category: C

Corrective Action Taken:

WHO: Director of Infection Prevention

WHAT:

The Device Reprocessing IC 10-10.27 online policy was developed by a multidisciplinary task force led by the hospital epidemiologist. The purpose of the task force was to ensure a standardized institution-wide program for reprocessing endoscopes (through either sterilization or high-level disinfection [HLD], as indicated) as well as HLD of other devices (e.g. vaginal ultrasound probes, transesophageal echocardiogram probes) in accordance with recommended guidelines and national standards. The procedure for storing scopes and reprocessed devices is addressed in the policy in the following manner: "B. Device Storage 1. Flexible channeled endoscopes are stored in a vertical position in clean cabinets that provide protection from contamination and damage. Labels indicating reprocessing date are placed on each flexible endoscope device. 2. Other reprocessed devices are stored in a clean environment to prevent re-contamination." Re-educated staff in all areas that store scopes to the Device Reprocessing Policy section B. 1&2 through electronic communication by Infection Control.

WHEN:

The Device Reprocessing IC 10-10.27 policy was approved and effective July 2014. Re-education to Device Reprocessing policy section B.1&2 was sent via electronic communication on 8/31/2015.

HOW:

Infection Preventionists and Quality Consultants will perform monthly observations of all scopes storage areas to assess ongoing compliance. Any non-compliance observed will be addressed at the time of discovery with the area personnel.

Evaluation Method: Measure compliance to Device Reprocessing policy in all scope storage areas each month for 4 consecutive months. Numerator = # of scopes areas with appropriately stored scopes. Denominator = Total number of scopes areas observed. Compliance will be reported monthly to the Infection Prevention Regulatory Committee.

Measure of Success Goal (%): 90

HAP Standard LS.02.01.20 The hospital maintains the integrity of the means of egress.

Findings: EP 8 §482.41(b)(1)(i) - (A-0710) - (i) The hospital must meet the applicable provisions of the 2000 edition of the Life Safety Code of the National Fire Protection Association. The Director of the Office of the Federal Register has approved the NFPA 101®2000 edition of the Life Safety Code, issued January 14, 2000, for incorporation by reference in accordance

with 5 U.S.C. 552(a) and 1 CFR part 51. A copy of the Code is available for inspection at the CMS Information Resource Center, 7500 Security Boulevard, Baltimore, MD or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to:

http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.

Copies may be obtained from the National Fire Protection Association, 1 Batterymarch Park, Quincy, MA 02269. If any changes in this edition of the Code are incorporated by reference, CMS will publish notice in the Federal Register to announce the changes. This Standard is NOT MET as evidenced by: Observed in Building Tour at Vanderbilt University (1161 22nd Avenue, Nashville, TN) site for the Hospital deemed service. In VHU the path to the public way was obstructed by sand bags located within ten feet of the MRI emergency exit.

Corrected on site. EP 13 §482.41(b)(1)(i) - (A-0710) - (i) The hospital must meet the applicable provisions of the 2000 edition of the Life Safety Code of the National Fire Protection Association. The Director of the Office of the Federal Register has approved the NFPA 101®2000 edition of the Life Safety Code, issued January 14, 2000, for incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. A copy of the Code is available for inspection at the CMS Information Resource Center, 7500 Security Boulevard, Baltimore, MD or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to:

http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.

Copies may be obtained from the National Fire Protection Association, 1 Batterymarch Park, Quincy, MA 02269. If any changes in this edition of the Code are incorporated by reference, CMS will publish notice in the Federal Register to announce the changes. This Standard is NOT MET as evidenced by: Observed in Building Tour at Vanderbilt University Medical Center (2200 Children's Way, Nashville, TN) site for the Hospital deemed service. The exit corridor in the basement of the Children's Hospital at stair five is cluttered with numerous items of stored medical equipment. The storage has reduced the width of the corridor to less than eight feet. Corrected on site. Observed in Building Tour at Vanderbilt University Medical Center (2200 Children's Way, Nashville, TN) site for the Hospital deemed service. The exit corridor in the basement of the Children's Hospital at stair five is cluttered with numerous items of stored equipment and other miscellaneous items. The storage has reduced the width of the corridor to less than eight feet. Corrected on site. Observed in Building Tour at Vanderbilt University (1161 22nd Avenue, Nashville, TN) site for the Hospital deemed service. In VUH at the ten north trauma unit there were two linen storage carts stored in the corridor that reduced the corridor width to less than eight feet. Corrected on site. Observed in Building Tour at Vanderbilt University (1161 22nd Avenue, Nashville, TN) site for the Hospital deemed service. In VUH at the cath lab the south corridor (5300G) width was reduced to less than eight feet due to the storage of four cabinets. Corrected on site. Observed in Building Tour at Vanderbilt University (1161 22nd Avenue, Nashville, TN) site for the Hospital deemed service. In VHU the corridors in the emergency department were reduced to less than eight feet width due to the storage of

stretchers that were not in use.

Elements of Performance:

8. Exits discharge to the outside at grade level or through an approved exit passageway that is continuous and terminates at a public way or at an exterior exit discharge. (For full text and any exceptions, refer to NFPA 101-2000: 7.2.6 and 7.7)

Scoring Category: A

Corrective Action Taken:

WHO: Assistant Director, Vanderbilt Environmental Health and Safety (VEHS)

WHAT:

1. The sand bags located within the public way were removed during the on-site survey. 2. Plant Services management reviewed flood mitigation procedures with their staff, particularly post event clean-up including use of sand bags.

WHEN:

The sandbags were removed to correct this deficiency during the on-site survey on 7/23/2015. Plant Services staff reviewed flood mitigation procedures on 8/3/2015.

HOW:

Members of the EOC Survey Team will perform monthly environment of care rounds throughout the organization including external exits to assess on-going compliance. When there is any emergency incident that does or could alter external exits, one of the post-event follow-up activities will include an assessment of the external exits by VEHS/Plant Services. The post-event assessment is performed by the VEHS team and is part of the EOC process. Any problems are immediately reported to Vanderbilt Environmental Health and Safety and / or Plant Services by submitting a work order is submitted to Plant Services for removal of sandbags or other items impeding egress.

13. Exits, exit accesses, and exit discharges are clear of obstructions or impediments to the public way, such as clutter (for example, equipment, carts, furniture), construction material, and snow and ice. (For full text and any exceptions, refer to NFPA 101-2000: 7.1.10.1)

Scoring Category: C

Corrective Action Taken:

WHO: Assistant Director, Vanderbilt Environmental Health and Safety (VEHS)

WHAT:

A. Individual findings were addressed during the Joint Commission Survey. 1. Medical equipment was removed from the exit corridor basement of Children's Hospital at stair five; 2. Medical equipment and miscellaneous stored items were removed from the exit corridor basement of Children's Hospital at stair five; 3. Linen carts were removed from the 10 N Trauma unit in VUH; 4. The cabinets were removed from the south corridor (5300G) of the VUH Cath Lab; 5. Excess stretchers were removed from VUH Emergency Department corridor. B. Review of policy/departmental responsibilities for Support Services: VUMC policy SA 50-10.02, Equipment and Materials in VUMC Corridors was reviewed via conference call by the Assistant Director of VEHS with leaders from Environmental Services, Linen Services, and Supply Chain/Materials Management to strategize on how the Support Services departments can assist with keeping corridors uncluttered. C. Re-education about corridor clutter (VUMC policy SA 50-10.02 Equipment and Materials in VUMC Corridors) was sent to all nursing and clinic managers via electronic communication by the VEHS Assistant Director.

WHEN:

A. Medical equipment was removed from exit corridor basement of Children's Hospital on 7/22/2015; medical equipment and miscellaneous items were removed from exit corridor basement of Children's Hospital on 7/22/2015; Linen carts were removed from VUH 10N Trauma unit on 7/22/2015; Cabinets were removed from the south corridor (5300G) of the VUH Cath Lab on 7/22/2015; and Excess stretchers were removed from the VUH Emergency Department corridors on 7/22/2015. B. Conference call review of policy/departmental responsibilities on 8/18/2015 with Support Services leaders. C. Nursing and clinical managers were re-educated on 9/1/2015 about VUMC policy SA 50-10.02 Equipment and Materials in VUMC Corridors via electronic communication distributed by the Assistant Director of VEHS.

HOW:

Monthly environment of care rounds are performed throughout the organization by members EOC Survey Team to assess on-going compliance with egress requirements. Areas will receive immediate feedback during the survey about compliance status. Quarterly summary reports regarding institutional compliance are provided to organizational leadership.

HAP Standard MM.05.01.07 The hospital safely prepares medications.

Findings: EP 1 §482.23(c) - (A-0405) - (c) Standard: Preparation and administration of drugs. This Standard is NOT MET as evidenced by: Observed in Individual Tracer at Vanderbilt University Medical Center (1500 21st Ave. South, Nashville, TN) site for the Hospital deemed service. The staff RN in the dialysis unit prepared all IV medications in a small medication room. Medications that were not emergency preparations were prepared by the dialysis RN. Vancomycin, for example, was mixed in the room by an RN without a laminar flow hood. The process was to reconstitute the Vancomycin and inject it in an IV mini bag for infusion. §482.25(b)(1) - (A-0501) - (1) All compounding, packaging, and dispensing of drugs and biologicals must be under the supervision of a pharmacist and performed consistent with State and Federal laws. This Standard is NOT MET as evidenced by: Observed in Building Tour at Hemodialysis Clinic East (20 Rachel Drive, Nashville, TN) site for the Hospital deemed service. During a review of IV medication practices in the outpatient dialysis center, several doses of antibiotic were available in the medication room. The IV medications, such as vancomycin, ceftriaxone, and other antibiotics were mixed by the RNs in the medication room without a laminar flow hood.

Elements of Performance:

1. A pharmacist, or pharmacy staff under the supervision of a pharmacist, compounds or admixes all compounded sterile preparations except in urgent situations in which a delay could harm the patient or when the product's stability is short.

Scoring Category: A

Corrective Action Taken:

WHO: Accreditation and Regulatory Administrator

WHAT:

Pharmacy, nursing, and medical staff leadership reviewed the medications prepared in non-urgent situations in the Village at Vanderbilt Dialysis Clinic and Vanderbilt Dialysis East Clinic and identified premixed or point-of-care activated options (e.g. ADD-Vantage®). This will eliminate mixing medications by RN's in the Dialysis Clinic without a laminar flow hood. Staff in-services were held to educate Dialysis clinic staff on the proper use of the point-of-care activated products selected.

WHEN:

Staff in-services were completed by 8/24/2015. The two clinics converted to the use of the identified premixed or point-of-care activated products by 8/25/2015.

HOW:

Ongoing assessment of compliance in the specified Dialysis Clinics will be accomplished via staff observations interviews during monthly MEDS Surveys and every 6 month Environment of Care Surveys. Any occurrence of non-compliance will be reported to clinic and pharmacy leadership.

HAP	Standard PC.02.01.03	The hospital provides care, treatment, and services as ordered or prescribed, and in accordance with law and regulation.
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Findings: EP 7 Observed in Individual Tracer at Vanderbilt University Medical Center (1601 23rd Ave. South, Nashville, TN) site. Observed in the Adult 1 Psychiatric Unit, two separate orders for anxiety/agitation (Haldol and Lorazepam po) that were given together, at the same time. The current orders did not indicate that the medications could be administered in combination. §482.57(b)(3) - (A-1163) - (3) Services must only be provided under the orders of a qualified and licensed practitioner who is responsible for the care of the patient, acting within his or her scope of practice under State law, and who is authorized by the hospital's medical staff to order the services in accordance with hospital policies and procedures and State laws. This Standard is NOT MET as evidenced by: Observed in Individual Tracer at Vanderbilt University (1161 22nd Avenue, Nashville, TN) site for the Hospital deemed service. Although appropriate, physician orders did not include care of the JP drain which was placed during surgery. The JP drain had not been mentioned in the physicians orders when this surveyor first looked at the orders, which was two days after placement. It was noted that the JP drain was addressed in physician orders after the tracer visit. Observed in Individual Tracer at Vanderbilt University (1161 22nd Avenue, Nashville, TN) site for the Hospital deemed service. The organization has a process (care transition order review) to reconcile physician orders when a patient is transferred between units or from surgery to a unit. The process reviews and/or updates orders to identify active orders. The process was not completed for the patient after surgery, and it could not be determined which orders were active.

Elements of Performance:

7. For hospitals that use Joint Commission accreditation for deemed status purposes: The hospital provides care, treatment, and services using the most recent patient order(s).

Scoring Category: A

Corrective Action Taken:

WHO: Chief of Staff, Vanderbilt University Hospital

WHAT:

Adult psychiatric pharmacy, nursing and medical staff leadership has approved a new order set for medication administration including (Haldol and Lorazepam) when being administered congruently for emergency situations. Medical Staff Rules and Regulations as approved by the Medical Center Medical Board (MCMB) & Medical Center Administrative Committee (MCAC) address patient orders in (section IV .a. ii. – iv.). “a. Patient Orders ... ii. Blanket reinstatement of orders: Blanket reinstatement of previous orders (or a summary order to resume all previous orders) for medication are not acceptable. iii. Orders automatically cancelled: All previous orders are automatically canceled when a patient goes to the operating room, is transferred to another clinical service, or changes level of care. New orders must be documented for such patients after transfer or other change in level of care. ... iv. Documentation required: All orders for treatment shall be documented in writing or electronically through the electronic order entry system.” The re-education of providers to the Medical Staff Rules and Regulations regarding patient orders and therapeutic duplication was completed via electronic communication from the Chief of Staff for Vanderbilt Health Services.

WHEN:

The Medical Staff Rules and Regulation was last approved on 5/21/2015 and published online on the policy website. The re-education of providers to the Medical Staff Rules and Regulations regarding patient orders and therapeutic duplication was completed via electronic communication from the Chief of Staff on 9/1/2015. The new medication order set was approved on 9/1/2015 and implemented 9/8/2015.

HOW:

Random audits will be conducted for provider order compliance to the Medical Staff Rules and Regulations. Non-compliance will be addressed by medical staff leadership.

HAP Standard PC.02.02.03 The hospital makes food and nutrition products available to its patients.

Findings: EP 11 Observed in Building Tour at Vanderbilt University (1161 22nd Avenue, Nashville, TN) site. Observed in the PTU, a nutrition refrigerator temperature log with out of range temperatures on 7, 9, 14, 15 and 16 July without evidence of a corrective action and appropriate temperature range. According to the temperature log instructions, temperatures that were out of range should be adjusted, retaken, then if it continued to be out of range, the operator should contact Plant Operations for assistance. Observed in Building Tour at Vanderbilt University (1161 22nd Avenue, Nashville, TN) site. Observed in the PTU, a nutrition freezer temperature log with out of range temperatures on 9,15 and 16 July without any evidence of corrective action and appropriate temperature range. According to the temperature log instructions, temperatures that were out of range should be adjusted, retaken, then if it continued to be out of range, the operator should contact Plant Operations for assistance. Observed in Tracer Activities at Vanderbilt University (1161 22nd Avenue, Nashville, TN) site. An open milk carton without an open or expiration date was observed in the refrigerator in the Burn ICU. Observed in Individual Tracer at Vanderbilt University Medical Center (2200 Children's Way, Nashville, TN) site. During the review of a PICU nutrition refrigerator temperature log, two dates were noted to be out of range (07/16/15 and 07/17/15). The staff wrote "Adjusted" on the temperature log. There was no documentation of a temperature recheck or return to correct temperature range during that 48 hour period.

Elements of Performance:

HAP Standard PC.03.01.03 The hospital provides the patient with care before initiating operative or other high-risk procedures, including those that require the administration of moderate or deep sedation or anesthesia.

Findings: EP 1 Observed in Individual Tracer at Vanderbilt University (1161 22nd Avenue, Nashville, TN) site. A presedation patient assessment was not in the medical record before moderate sedation was administered. It was also not in the medical record two hours after the debridement procedure was completed. The physician indicated that although the assessment had been completed and the documentation had been started, the

documentation had not been completed prior to the administration of the sedation. Observed in Individual Tracer at Vanderbilt University (1161 22nd Avenue, Nashville, TN) site. The preanesthesia patient assessment done prior to an organ transplant did not include documentation of an airway assessment. Other components of the preanesthesia assessment were present. EP 8 Observed in Individual Tracer at Vanderbilt Bone & Joint Surgery Center (225 Bedford Way, Franklin, TN) site. During tracer activity and review of the medical record of a surgical patient, there was no evidence that the patient was re-evaluated prior to induction of anesthesia/sedation. Observed in Individual Tracer at Vanderbilt Bone & Joint Surgery Center (225 Bedford Way, Franklin, TN) site. During tracer activity and review of the medical record of a surgical patient, there was no evidence that the patient was re-evaluated prior to induction of anesthesia/sedation. Observed in Individual Tracer at Vanderbilt University (1161 22nd Avenue, Nashville, TN) site. During tracer activity and review of the medical record of a surgical patient, there was no evidence that the patient was re-evaluated prior to induction of anesthesia/sedation. Observed in Individual Tracer at Vanderbilt University (1161 22nd Avenue, Nashville, TN) site. During tracer activity and review of the medical record of a surgical patient, there was no evidence that the patient was re-evaluated prior to induction of anesthesia/sedation. Observed in Individual Tracer at Vanderbilt University (1161 22nd Avenue, Nashville, TN) site. During tracer activity and review of the medical record of a surgical patient, there was no evidence that the patient was re-evaluated prior to induction of anesthesia/sedation. Observed in Individual Tracer at Vanderbilt University (1161 22nd Avenue, Nashville, TN) site. During tracer activity and review of the medical record of a surgical patient, there was no evidence that the patient was re-evaluated prior to induction of anesthesia/sedation. Observed in Individual Tracer at Vanderbilt University (1161 22nd Avenue, Nashville, TN) site. There was no evidence that the patient was reevaluated immediately before administering moderate sedation prior to a debridement procedure. Observed in Individual Tracer at Vanderbilt University (1161 22nd Avenue, Nashville, TN) site. There was no evidence that the patient was reevaluated immediately before administering anesthesia prior to an organ transplant. Observed in Individual Tracer at Vanderbilt University Medical Center (2200 Children's Way, Nashville, TN) site. During tracer activity in the PACU the record of a patient who had received anesthesia did not contain evidence of reevaluation immediately prior to induction of anesthesia as required by regulation. This was verified by Medical Directors of Anesthesia and Cardiac Anesthesia.

Elements of Performance:

1. Before operative or other high-risk procedures are initiated, or before moderate or deep sedation or anesthesia is administered: The hospital conducts a presedation or preanesthesia patient assessment. (See also RC.02.01.01, EP 2)

Scoring Category: A

Corrective Action Taken:

WHO: The Vice Chair for Clinical Affairs, Anesthesiology

WHAT:

One to one conversation with the non-compliant providers was performed. The departmental policy for pre-anesthesia patient assessment was discussed in the Anesthesia Department meeting.

WHEN:

One to one conversation with the non-compliant providers occurred during survey, 7/21/2015. Anesthesia Department meeting occurred 8/5/2015.

HOW:

Anesthesia will randomly audit records for compliance with pre-sedation/pre-anesthesia assessment. Any non-compliance will be addressed by Anesthesia Leadership.

8. The hospital reevaluates the patient immediately before administering moderate or deep sedation or anesthesia. (See also RC.02.01.01, EP 2)

Scoring Category: A

Corrective Action Taken:

WHO:

The Vice Chair for Clinical Affairs, Anesthesiology.

WHAT:

The Vice Chair for Clinical Affairs, Anesthesiology implemented the documentation of patient re-evaluation prior to induction of anesthesia/sedation in all perioperative anesthesia areas during the survey in response to guidance from the surveyors. This was communicated to all perioperative anesthesia areas through inter-office communications.

WHEN:

Inter-office communication sent 7/21/2015. This communication was reiterated 8/15/2015 at all-faculty meeting.

HOW:

Vanderbilt Coding and Billing Office will conduct random chart audits for compliance on patient re-evaluation prior to induction of anesthesia/sedation. Non-compliance will be addressed by Anesthesia Leadership.

Vanderbilt University**Organization ID: 7892****1161 22nd Avenue Nashville, TN 37232-2101****Accreditation Activity - 60-day Evidence of Standards Compliance Form****Due Date: 9/28/2015**

HAP Standard EC.02.01.01 The hospital manages safety and security risks.

Findings: EP 5 §482.41(a) - (A-0701) - §482.41(a) Standard: Buildings The condition of the physical plant and the overall hospital environment must be developed and maintained in such a manner that the safety and well-being of patients are assured. This Standard is NOT MET as evidenced by: Observed in Building Tour at Vanderbilt University Medical Center (2200 Children's Way, Nashville, TN) site for the Hospital deemed service. The trash compactor number one located at the receiving dock of the Children's Hospital was unattended with the operational key inserted allowing anyone to operate the compactor. Corrected on site. Observed in Building Tour at Vanderbilt University Medical Center (2200 Children's Way, Nashville, TN) site for the Hospital deemed service. The trash compactor number two located at the receiving dock of the Children's Hospital was unattended with the operational key inserted allowing anyone to operate the compactor. Corrected on site.

Elements of Performance:

5. The hospital maintains all grounds and equipment.

Scoring Category: C**Corrective Action Taken:****WHO:**

Assistant Vice Chancellor, Facilities and Construction

WHAT:

The keys for trash compactors number one and two, located at the receiving dock of Children's Hospital, were immediately removed from the trash compactors during the survey. Education was sent to appropriate responsible personnel via email communication that trash compactor keys are to be kept in a secure location and never left in the trash compactor.

WHEN:

The keys were removed during the survey on 7/21/2015. Education was sent to appropriate responsible personnel via email communication by 9/18/2015.

HOW:

Keys for the trash compactors are kept in a central location with access granted only to qualified personnel. Plant services will perform weekly observations for ongoing compliance of the security of the trash compactor keys.

Evaluation For the next 4 months, VUMC will observe the 4 trash compactors weekly to monitor **Method:** ongoing compliance with security of the compactor keys. The denominator is the total number of trash compactor inspections. The numerator is the total number of trash compactors found secured (no keys left unsecured). The results of these inspections will be reported to the VUMC Safety Committee.

**Measure of
Success Goal 90
(%):**

HAP	Standard EC.02.06.01	The hospital establishes and maintains a safe, functional environment. Note: The environment is constructed, arranged, and maintained to foster patient safety, provide facilities for diagnosis and treatment, and provide for special services appropriate to the needs of the community.
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Findings: EP 1 §482.41(a) - (A-0701) - §482.41(a) Standard: Buildings The condition of the physical plant and the overall hospital environment must be developed and maintained in such a manner that the safety and well-being of patients are assured. This Standard is NOT MET as evidenced by: Observed in Building Tour at Vanderbilt University (1161 22nd Avenue, Nashville, TN) site for the Hospital deemed service. Observed in the Interventional Radiology Procedure Room # 1077 Relocatable Power Taps in use in a patient care area that were not permanently attached to the equipment assembly and does not meet UL1363A or the organizational policy (Electrical Equipment, effective March 2015). The power strip was removed from the procedure room. Observed in Building Tour at Vanderbilt University (1161 22nd Avenue, Nashville, TN) site for the Hospital deemed service. Observed in the Interventional Radiology Procedure Room # 1074 Relocatable Power Taps in use in a patient care area that were not permanently attached to the equipment assembly and does not meet UL1363A or the organizational policy (Electrical Equipment, effective March 2015). The power strip was removed from the procedure room.

Elements of Performance:

1. Interior spaces meet the needs of the patient population and are safe and suitable to the care, treatment, and services provided.

Scoring Category: C

Corrective Action Taken:

WHO:

Assistant Vice Chancellor, Facilities and Construction

WHAT:

The issue with the unapproved Relocatable power taps(RPT) in Interventional Radiology (IR) rooms 1077 and 1074 (patient care areas) was corrected when the surveyor was on site. RPTs were removed from both rooms. VUMC policy, SA 50-10.01, Electrical Equipment policy provides information about Vanderbilt's election to use the Centers for Medicare and Medicaid Services (CMS) categorical

waiver (Reference S&C 14-46-LSC). This waiver and the policy (implemented in 3/2015) define the types of and requirements associated with the use of relocatable power taps within the organization. Plant Services and Informatics completed the assessment, appropriate attachment, and upgrade of RPT's in the following in-patient and clinic sites: Vanderbilt University Hospital, Monroe Carroll Jr. Children's Hospital at Vanderbilt, One Hundred Oaks, Vanderbilt Eye Institute, Doctor's Office Tower, The Vanderbilt Clinic, Med Center East North Tower, and Med Center East South Tower. Informatics staff facilitated the RPT assessment, appropriate attachment, removal and/or upgrade in off-site clinics. Informatics also performed the assessment, appropriate attachment, and upgrade of RPT's associated with on-site mobile computer workstations.

WHEN:

The unapproved RPT's in Interventional Radiology procedure rooms 1107 and 1104 were removed on 7/24/2015 when the surveyor was on site. SA 50-10.01, Electrical Equipment policy was revised in 3/2015. As of 9/21/2015, all additional VUMC patient care areas were assessed and the RPT's, if present, were either removed or replaced with approved RPT equipment that was appropriately attached.

HOW:

Plant Services and Informatics assessed all VUMC patient care areas. Any RPT's, if present, were either removed or replaced with approved RPT equipment that were appropriately attached. Plant Services electric shop will inspect 50 rooms monthly for compliance with RPTs.

Evaluation Based on the number of rooms where RPTs are located, Plant Services will randomly

Method: inspect 50 rooms per month for the next 4 months for ongoing compliance. The denominator equals the total number of RPTs in the rooms inspected. The numerator equals the total number of RPTs found to be compliant. The results of these inspections will be reported to the VUMC Safety Committee.

**Measure of
Success Goal 90
(%):**

HAP Standard IC.02.01.01 The hospital implements its infection prevention and control plan.

Findings:

EP 1 §482.42 - (A-0747) - §482.42 Condition of Participation: Condition of Participation: Infection Control This Condition is NOT MET as evidenced by: Observed in Tracer Activities at Vanderbilt Bone & Joint Clinic (206 Bedford Way, Franklin, TN) site for the Hospital deemed service. During tracer activity and tour of the occupational therapy cleaning of the hydrocollator had been performed every month versus every 14 days per manufacturers recommendation. The policy for this process had been corrected and implemented prior to the end of this survey. §482.13(c)(2) - (A-0144) - (2) The patient has the right to receive care in a safe setting. This Standard is NOT MET as evidenced by: Observed in Tracer Activities at Vanderbilt University (1161 22nd Avenue, Nashville, TN) site for the Hospital deemed service. The hospital does not always successfully implement activities to minimize, reduce, or eliminate the risk of infection. For example, dust was observed on the bronchoscopy tower cart and the bronchoscopy cart in the Burn ICU. Observed in Peds/ED, Tracer Activities at Vanderbilt University Medical Center (2200 Children's Way, Nashville, TN) site for the Hospital deemed service. During environment of care rounds, it was observed, three emergency carts with attached side shelves for

holding additional supplies. The carts were moderately to heavily soiled with dust. Observed in Peds/ED, Tracer Activities at Vanderbilt University Medical Center (2200 Children's Way, Nashville, TN) site for the Hospital deemed service. It was observed in a storage area, a cart with a pediatric weighing scale on top. The cart was moderately soiled with dust.

Elements of Performance:

1. The hospital implements its infection prevention and control activities, including surveillance, to minimize, reduce, or eliminate the risk of infection.

Scoring Category: C

Corrective Action Taken:

WHO:

Director of Infection Prevention

WHAT:

All medical equipment cited above was cleaned during the survey. Organization-wide re-education regarding the cleaning of medical equipment was sent by electronic communication.

WHEN:

All medical equipment cited above was cleaned by 7/24/2015 during the survey. Organization-wide re-education regarding the cleaning of medical equipment completed by 9/21/2015.

HOW:

Ongoing assessment of compliance to equipment cleaning will be accomplished via monthly Environment of Care Surveys. Any occurrence of non-compliance will be reported to unit leadership for correction.

HAP Standard LD.04.01.07 The hospital has policies and procedures that guide and support patient care, treatment, and services.

Findings: EP 2 Observed in Tracer Activities at Vanderbilt Medical Group at West End Ave. | 2611 West End Av (2611 West End Ave., Nashville, TN) site. During tracer activity and tour of the allergy/asthma clinic management of samples had not been in compliance with the organizational policy "Sample Medication Management" OP10-10.02 current as of June 2015. Although the clinic had a log of all samples, there was no documentation of who the medication was dispensed to, the date dispensed or the lot number or the medication dispensed. In addition, there was "message communication in the electronic medical record but no evidence of an order or education to the patient of the medication as directed by the policy. Observed in Individual Tracer at Vanderbilt University Medical Center | 2200 Children's Way, (2200 Children's Way, Nashville, TN) site. During a tracer in the PICU an observation was made of signage on the breast milk storage refrigerator which stated "Breast Milk Pumped (never frozen) May be Stored for Up to Seven Days." The nurse manager confirmed this is the procedure followed in the PICU. The HCO's Policy CL 30-19.17 (last revised date August 2007) "Breastfeeding; Expressing and Storage of Breast Milk-VCH" states "EBM should be frozen immediately if it is not to be used within 24 hours." The policy does not address storage of breast milk in the refrigerator for seven

days. The current CDC recommendation is to store expressed breast milk for a maximum of 5 days. Policies and Procedures were revised during survey and practice was changed to meet current CDC recommendations.

Elements of Performance:

2. The hospital manages the implementation of policies and procedures. (See also NR.02.03.01, EP 2)

Scoring Category: C

Corrective Action Taken:

WHO:

The Accreditation and Regulatory Administrator

WHAT:

Observation 1: The Sample Medication Management policy OP 10-10.02 was updated to include revised log sheets for documentation of sample medication to include: who the medication was dispensed to, the date dispensed, the lot number and medication dispensed. A Sample Medication Program Implementation Plan was developed by the Pharmacy detailing the required steps for compliance with the revised Sample Medication Management policy. In-services were held by the clinic manager to educate the Vanderbilt Asthma, Sinus, and Allergy Program (VASAP) providers and clinical staff regarding the new processes. Observation 2: Expressing and Storage of Breast Milk Policy CL 30-19.17 was reviewed and revised to include the following changes under section V.C, storage of breast milk (EBM): "EBM should be frozen immediately if it is not to be used within 48 hours. If EBM is fortified it should be used within 24 hours" and "Partially thawed EBM can be re-frozen in the hospital setting." Breast milk storage signs were developed and placed on all breast milk refrigerators in VCH. The sign reflects the updated storage timeframes according to the revised policy. Education to Vanderbilt Children's Hospital (VCH) staff was completed via newsletters summarizing updated breast milk storage guidelines.

WHEN:

Observation 1: The revised Sample Medication Management policy OP 10-10.02 was approved by the Pharmacy, Therapeutics and Diagnostics Committee and was approved and implemented by the Medical Center Medical Board on 9/3/2015. The Sample Medication Program Implementation Plan was provided to the VASAP Manager on 8/21/2015. VASAP Provider and staff education was completed via in-services and email notification by 9/9/2015. Revised processes were implemented on 9/10/2015. Observation 2: The revised Expressing and Storage of Breast Milk Policy was approved by the Medical Center Medical Board in 9/22/2015. Signs were placed on the breast milk refrigerators 9/18/2015. Staff education was completed by 9/21/2015.

HOW:

Observation 1: The Pharmacy Compliance and Process Improvement Manager performs monthly reviews of Sample Medication documentation to assess ongoing compliance. Observation 2: The Quality Improvement Analysts perform monthly observations of breast milk storage to assess ongoing compliance.

Evaluation

Method: Observation 1: Sample Medication documentation will be reviewed monthly for four consecutive months via log and chart reviews. The review will include documentation of who the medications was dispensed to, the date dispensed, the lot number of the medication dispensed, patient education, and the provider order. All patients who receive sample medication from the clinic will be audited. Denominator = the total number of patients who received sample medication; Numerator = number of patients

who received sample medication dispenses with specified documentation. Data will be reported to Pharmacy Therapeutics and Diagnostic Committee. Observation 2: All breast milk refrigerators will be reviewed monthly for four consecutive months via Quality Improvement Analysts. The review will include verification that the sign is affixed to the refrigerator. Denominator = the total number of refrigerators; Numerator = the number of refrigerators with compliant signage. All bottles of breast milk stored in all breast milk refrigerators will be reviewed. Denominator = the total number of bottles of breast milk; Numerator = the number of compliant bottles stored in the refrigerator. Data will be reported to the Children's Performance Management and Improvement Council.

**Measure of
Success Goal 90
(%):**

HAP Standard LS.02.01.10 Building and fire protection features are designed and maintained to minimize the effects of fire, smoke, and heat.

Findings: EP 9 §482.41(b)(1)(i) - (A-0710) - (i) The hospital must meet the applicable provisions of the 2000 edition of the Life Safety Code of the National Fire Protection Association. The Director of the Office of the Federal Register has approved the NFPA 101@2000 edition of the Life Safety Code, issued January 14, 2000, for incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. A copy of the Code is available for inspection at the CMS Information Resource Center, 7500 Security Boulevard, Baltimore, MD or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html. Copies may be obtained from the National Fire Protection Association, 1 Batterymarch Park, Quincy, MA 02269. If any changes in this edition of the Code are incorporated by reference, CMS will publish notice in the Federal Register to announce the changes. This Standard is NOT MET as evidenced by: Observed in Building Tour at Vanderbilt University Medical Center (2200 Children's Way, Nashville, TN) site for the Hospital deemed service. At the Children's Hospital there was a penetration above ceiling located on the seventh floor adjacent to room 7407 due to a four inch sleeve containing communication type wiring that was not properly filled with an approved fire resistance rated material in the two hour fire resistance rated separation . Corrected on site. Observed in Building Tour at Vanderbilt University Medical Center (2200 Children's Way, Nashville, TN) site for the Hospital deemed service. At the Children's Hospital there was a penetration above ceiling located on the sixth floor adjacent to room 6007 due to a two inch sleeve containing communication type wiring that was not properly filled with an approved fire resistance rated material in the two hour fire resistance rated separation . Corrected on site. Observed in Building Tour at Vanderbilt University Medical Center (1161 21st Ave. South, Nashville, TN) site for the Hospital deemed service. At Medical Center North there was a penetration in the two hour fire resistance rated separation adjacent to room 4404 due to a four inch sleeve containing communication wire where the interior space was not filled with an approved fire resistance rated material. Corrected on site. Observed in Building Tour at Vanderbilt University Medical Center (1161 21st Ave. South, Nashville, TN) site for the Hospital deemed service. At Medical Center North there was a penetration in the

two hour fire resistance rated separation adjacent to room 3402 due to a four inch sleeve containing communication wire where the interior space was not filled with an approved fire resistance rated material. Corrected on site. Observed in Building Tour at Vanderbilt University Medical Center (1215 21st Ave. South, Nashville, TN) site for the Hospital deemed service. At the East North Tower there was an above ceiling penetration located adjacent to stair 3 in the two hour fire resistance rated separation due to a one half inch sleeve not filled with an approved fire rated material. Corrected on site.

Elements of Performance:

9. The space around pipes, conduits, bus ducts, cables, wires, air ducts, or pneumatic tubes that penetrate fire-rated walls and floors are protected with an approved fire-rated material. Note: Polyurethane expanding foam is not an accepted fire-rated material for this purpose. (For full text and any exceptions, refer to NFPA 101-2000: 8.2.3.2.4.2)

Scoring Category: C

Corrective Action Taken:

WHO:

Assistant Vice Chancellor, Facilities and Construction

WHAT:

The above ceiling penetration in Children's Hospital located on the 7th floor adjacent to room 7407 and on the 6th floor adjacent to room 6007 were properly filled with an approved fire resistant rated material in the 2 hr fire resistance rated separation. The penetrations at MCN adjacent to room 4404 and at MCN adjacent to room 3402 were properly filled with an approved fire resistant rated material in the 2 hr fire resistance rated separation. The above ceiling penetration at East North Tower adjacent to stair 3 was filled with an approved fire material. VUMC has an above ceiling program, outlined by VUMC safety policy, SA 40-10.07, Above Ceiling Work(ACW). The policy requires an ACW Permit to be maintained at the work location and all personnel performing above ceiling work to carry a VUMC (ACW)certification card. Upon completion of ACW, the individual responsible for the work completes a completion checklist. The permit is considered closed out once the final inspection signature block and date fields are completed by VUMC authorizing representative.

WHEN:

The above ceiling penetrations in Children's Hospital located on the 7th floor adjacent to room 7407 and on the 6th floor adjacent to room 6007 were properly filled with an approved fire resistant rated material in the 2 hr fire resistance rated separation on 7/24/2015. The penetrations at MCN adjacent to room 4404 and at MCN adjacent to room 3402 were properly filled with an approved fire resistant rated material in the 2 hr fire resistance rated separation on 7/24/2015. The above ceiling penetration at East North Tower adjacent to stair 3 was filled with an approved fire material on 7/24/2015. Above Ceiling Work policy revised 4/2013.

HOW:

The Plant Services Department has a preventative maintenance (PM) program/building maintenance program (BMP). Fire/Smoke barrier assemblies are included as "assets" in the BMP and are checked continuously throughout the organization for penetrations in fire-rated walls. Any penetrations discovered during these inspections are properly filled with an approved fire resistant rated material. In addition to the Plant Services PM and BMP programs, VUMC also has an ACW Program, outlined by VUMC safety policy, SA 40-10.07, Above Ceiling Work policy. The policy requires an ACW permit to be maintained at the work location and that all personnel performing above ceiling work to carry a VUMC ACW Certification Card. Upon completion of ACW permit, the individual responsible

for the work completes a completion checklist. The permit is considered closed out once the final inspection signature block and date fields are completed by VUMC authorizing representative.

HAP Standard LS.02.01.30 The hospital provides and maintains building features to protect individuals from the hazards of fire and smoke.

Findings: EP 23 §482.41(b)(1)(i) - (A-0710) - (i) The hospital must meet the applicable provisions of the 2000 edition of the Life Safety Code of the National Fire Protection Association. The Director of the Office of the Federal Register has approved the NFPA 101@2000 edition of the Life Safety Code, issued January 14, 2000, for incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. A copy of the Code is available for inspection at the CMS Information Resource Center, 7500 Security Boulevard, Baltimore, MD or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html. Copies may be obtained from the National Fire Protection Association, 1 Batterymarch Park, Quincy, MA 02269. If any changes in this edition of the Code are incorporated by reference, CMS will publish notice in the Federal Register to announce the changes. This Standard is NOT MET as evidenced by: Observed in Building Tour at Vanderbilt University (1161 22nd Avenue, Nashville, TN) site for the Hospital deemed service. In VHU the smoke separation double door number 10636 had a gap greater than 1/8 inch at the location of where the two doors meet. Observed in Building Tour at Vanderbilt University (1161 22nd Avenue, Nashville, TN) site for the Hospital deemed service. In VHU the smoke separation double door number 9220 had a gap greater than 1/8 inch at the location of where the two doors meet. Observed in Building Tour at Vanderbilt University Medical Center (1601 23rd Ave. South, Nashville, TN) site for the Hospital deemed service. The double leaf smoke separation door adjacent to room 2178 did not close completely resulting in a gap greater than one eighth inches between the meeting edges.

Elements of Performance:

23. Doors in smoke barriers are self-closing or automatic-closing, constructed of 1 3/4-inch or thicker solid bonded wood core or constructed to resist fire for not less than 20 minutes, and fitted to resist the passage of smoke. The gap between meeting edges of door pairs is no wider than 1/8 inch, and undercuts are no larger than 3/4 inch. Doors do not have nonrated protective plates more than 48 inches above the bottom of the door. (For full text and any exceptions, refer to NFPA 101-2000: 18/19.3.7.5, 18/19.3.7.6, and 8.3.4.1)

Scoring Category: C

Corrective Action Taken:

WHO:

Assistant Vice Chancellor, Facilities and Construction

WHAT:

The gaps at the meeting edges of smoke separation double door number 10636, 9220, and the double leaf smoke separation door adjacent to room 2178 were corrected to a gap of less than 1/8 inch.

WHEN:

Gaps at the meeting edges of smoke separation double door numbers 10636, 9220, and the double leaf smoke separation door adjacent to room 2178 were corrected to a gap of less than 1/8 inch on 8/20/2015.

HOW:

The Plant Services Department has a preventative maintenance (PM) program/building maintenance program (BMP). Fire/Smoke barrier door assemblies are included as "assets" in the BMP and are checked continuously throughout the organization. The PM for 1 and 2 hr Fire/Smoke barrier door assemblies includes checking for gaps not greater than 1/8 inch. Any door discovered to have a gap greater than 1/8 inch between the meeting edges is reported to the Manager of Work Management & Compliance. A work order is generated for immediate attention to the doors. The Environment of Care team conducts weekly inspections throughout the organization and reviews doors for appropriate gaps as part of these inspections. Deficiencies are reported to the Manager of Work Management & Compliance for correction when observed.

HAP Standard MM.05.01.11 The hospital safely dispenses medications.

Findings: EP 4 Observed in Individual Tracer at Vanderbilt University Medical Center (1500 21st Ave. South, Nashville, TN) site. The dialysis unit routinely used a multidose vial of 30,000 units of heparin per ml for injection as a multidose vial. The multidose vial is used for different patients until empty. Observed in Building Tour at Hemodialysis Clinic East (20 Rachel Drive, Nashville, TN) site. During a tour of the outpatient dialysis unit, several bottles of heparin 30,000 units per cc vials were located in the medication room. The vials are used for several patients and are not used for one patient,

Elements of Performance:

4. Medications are dispensed in the most ready-to-administer forms commercially available and, if feasible, in unit doses that have been repackaged by the pharmacy or licensed repackager.

Scoring Category: C**Corrective Action Taken:****WHO:**

Accreditation and Regulatory Administrator

WHAT:

Pharmacy, nursing, and medical staff leadership reviewed heparin use in the Village at Vanderbilt Dialysis Clinic and Vanderbilt Dialysis East Clinic and identified the heparin 1,000 unit/mL, 10 mL vial size as the most ready-to-administer form commercially available. Staff in-services were held to educate staff on the new vial size and to limit use to one vial / one patient.

WHEN:

Dialysis clinic staff in-services were completed by 8/24/2015. The two Dialysis clinics converted to the use of heparin 1,000 unit/mL, 10 mL vial size and the use of one vial / one patient by 8/25/2015.

HOW:

1. Heparin Vial purchases: All heparin purchases will be reviewed to validate the purchase of heparin

1,000 unit/mL in the 10mL vial size rather than 30 mL at the Dialysis clinics. 2. Review of all heparin vials in stock during monthly survey. Dialysis clinic observations will be conducted monthly to validate the use of heparin vials for only one patient. Compliance will be reported monthly to Pharmacy, Therapeutics and Diagnostics Committee.

Evaluation All heparin purchases will be reviewed monthly by pharmacy to validate the purchase

Method: of heparin 1,000 unit/mL in the 10mL vial size rather than 30 mL at the Dialysis clinics. Denominator = the total number of heparin vials purchased each month; Numerator = the number of heparin vials purchased in the appropriate vial size. This will be monitored for 4 consecutive months. 2. Review of all heparin vials in stock during monthly survey. Dialysis clinic observations will be conducted monthly to validate the use of heparin vials for only one patient. Observations will be conducted of the area for no opened vials of heparin found in stock. Observation will be completed by pharmacy and regulatory specialist. Observations: Denominator= total number of heparin vials in stock; Numerator = the number of unopened heparin vials. Observations: Denominator= total number of staff observed; Numerator = the number of staff compliant. Both will be monitored for 4 consecutive months. Compliance for both indicators will be reported monthly to Pharmacy, Therapeutics and Diagnostics Committee.

**Measure of
Success Goal 90
(%):**

HAP Standard MS.06.01.03 **The hospital collects information regarding each practitioner's current license status, training, experience, competence, and ability to perform the requested privilege.**

Findings: EP 6 §482.11(c) - (A-0023) - (c) The hospital must assure that personnel are licensed or meet other applicable standards that are required by State or local laws. This Standard is NOT MET as evidenced by: Observed in Credentialing and Privileging at Vanderbilt University (1161 22nd Avenue, Nashville, TN) site for the Hospital deemed service. During review of a medical staff LIP credentials file, it was noted that the physician's license had expired on 6-30-14 and primary source verification of renewal was documented on 7-2-14. The physician's license was not documented as renewed on 6-30-14 as verified by both the Director and Manager of Medical Staff Provider Support Services. There was an attempt to verify the renewal of the license on 6-30-14, but the State was unable to verify the renewal due to the late submission of the application. The Medical Staff Provider Support Services coordinator stated that the physician submitted the reapplication on 6-30-2014. The physician practiced on 7-1-2014 as confirmed by the Accreditation and Regulatory Administrator. The license was validated as renewed on 7-2-14 by the credentialing specialist. Current documentation posted from the Tennessee Code states the physician's license was renewed from 7-1-2014 through 6-30-2016.

Elements of Performance:

6. The credentialing process requires that the hospital verifies in writing and from the primary source whenever feasible, or from a credentials verification organization (CVO), the following information: -

The applicant's current licensure at the time of initial granting, renewal, and revision of privileges, and at the time of license expiration - The applicant's relevant training - The applicant's current competence (See also PC.03.01.01, EP 1)

Scoring Category: A

Corrective Action Taken:

WHO:

Chief Medical Officer, VMG

WHAT:

The policy, Provider Support Services (PSS) License Renewal Verification Process was developed and approved by the Executive Committee of the Medical Center Medical Board. This policy outlines the process that ensures all credentialed providers maintain current State and Federal license requirements. The Medical Staff Bylaws and Rules & Regulations were approved by the Medical Center Medical Board, Medical Staff and the Medical Center Affairs Committee and address the responsibility of the licensed healthcare professionals to maintain current license without lapse in section 3.2.1: "Licensure: Hold a currently valid license issued by the State of Tennessee to practice medicine or dentistry or teach a new procedure or learn a new technique." The re-education of medical staff to the Medical Staff Bylaws and Rules & Regulations regarding expiring licenses was completed via electronic communication from the Chief of Staff. Clarifying information from the Board of Medical Examiners regarding the Board's interpretation of the 60 day "grace" period for license renewals was posted to the PSS SharePoint site for the PSS Staff and communicated to each member of the team.

WHEN:

The policy, Provider Support Services (PSS) License Renewal Verification Process was approved and implemented on 8/20/2015. The Medical Staff Bylaws and Rules & Regulations were last approved on 5/21/2015 and published online in Policy Tech. The re-education of the medical staff to the Medical Staff Bylaws and Rules & Regulations regarding expiring licenses was completed via electronic communication from the Chief of Staff by 9/7/2015. The SharePoint post and communication to PSS Staff occurred on 7/27/2015.

HOW:

Provider Support Leadership will monitor the activities of the process to ensure compliance with the Provider Support Services (PSS) License Renewal Verification Process on a monthly basis.

HAP Standard PC.01.03.01 The hospital plans the patient's care.

Findings: EP 44 Observed in Individual Tracer at Vanderbilt at One Hundred Oaks (719 Thompson Lane, Nashville, TN) site. A patient had the care need of anxiety identified by the provider. However, there were no specific goals identified as part of a patient treatment plan. Observed in Individual Tracer at Vanderbilt at One Hundred Oaks (719 Thompson Lane, Nashville, TN) site. Included in the provider visit note was a statement that the health goals of diet, exercise, substance abuse, and risk reduction were discussed. However, there was no description of these goals specific to this particular patient's care needs reflected in a treatment plan.

Elements of Performance:

44. For hospitals that elect The Joint Commission Primary Care Medical Home option: Patient self-management goals are identified, agreed upon with the patient, and incorporated into the patient's treatment plan. (Refer to RI.01.02.01, EP 1)

Scoring Category: A**Corrective Action Taken:****WHO:**

Medical Director of Vanderbilt Comprehensive Care Clinic (VCCC)

WHAT:

The provider progress note template was revised to include patient self management goals and incorporated into the patient's treatment plan with the patient's agreement. Comprehensive Care Clinic providers were educated to the new provider note template at the provider meeting.

WHEN:

Provider progress note template revised 9/3/2015. Provider education completed 9/9/2015.

HOW:

Random medical record audits will be conducted to verify the presence of self management goals that are agreed upon with the patient and incorporated into the patient's treatment plan.

HAP	Standard RI.01.04.03	For hospitals that elect The Joint Commission Primary Care Medical Home option: The primary care medical home provides patients with information about its functions and services.
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Findings: EP 1 Observed in Individual Tracer at Vanderbilt at One Hundred Oaks (719 Thompson Lane, Nashville, TN) site. A new patient information booklet had been developed that included this standard's information requirements. However, a patient's documented education was reviewed and there was no evidenced that the required information had been provided. The patient had been treated at the clinic for several years and was not considered a "new patient". Further, the patient's record indicated that she could not read. In discussion with clinic leadership staff, it was determined that there was not a mechanism in place to provide this required information to long-standing patients or those with literacy needs.

Elements of Performance:

1. For hospitals that elect The Joint Commission Primary Care Medical Home option: The primary care medical home provides information to the patient about: Its mission, vision, and goals. (Refer to LD.02.01.01, EP 3) Note: This may include how it provides for patient-centered and team-based comprehensive care, a systems-based approach to quality and safety, and enhanced patient access.

Scoring Category: A**Corrective Action Taken:****WHO:**

The Clinical Director of Vanderbilt Comprehensive Care clinic (VCCC)

WHAT:

Required Information: A process was developed to provide brochures describing the mission, vision, and goals for comprehensive care at VCCC. These brochures are available at the front desk and given to every patient at every visit. Front desk staff were trained to provide a brochure to each patient at intake. Health Literacy Needs: The provider progress note template was revised to address health literacy needs. Clinical staff were reeducated via on-screen demonstration and written communication in team meeting to discuss current process to verbally go over printed materials with patients who have a positive intake result for health literacy needs.

WHEN:

Required Information: The process for providing the brochures and the training of the front desk staff was completed 9/14/2015. Health Literacy Needs: The provider progress note template was revised and providers were educated at the provider meeting and the form was implemented by 9/9/2015. Clinical staff reeducation was completed 9/14/2015.

HOW:

Random observations that patients are receiving the required information, suitable to the patient, regarding the mission, vision and goals of the VCCC will be conducted. Random electronic medical record audits will be conducted to verify that health literacy is addressed in the provider note. Non compliance will be addressed by the clinical director of VCCC.

HAP Standard RI.01.05.01 The hospital addresses patient decisions about care, treatment, and services received at the end of life.

Findings:

EP 9 §482.13(b)(3) - (A-0132) - (3) The patient has the right to formulate advance directives and to have hospital staff and practitioners who provide care in the hospital comply with these directives, in accordance with §489.100 of this part (Definition), §489.102 of this part (Requirements for providers), and §489.104 of this part (Effective dates). This Standard is NOT MET as evidenced by: Observed in Individual Tracer at Vanderbilt Medical Group at Coolsprings Blvd. (324 Coolsprings Blvd., Franklin, TN) site for the Hospital deemed service. During review of the medical record of an oncology patient, there was no evidence that the patient had an advance directive or had been provided information regarding advance directives. This was not in compliance with the organizational policy "Health Care Decision Making/Advance Directives OP20-10.08 current as of June 2015. Education of advance directives and pilot program for implementation in outpatient Oncology is to take place in September. Observed in Individual Tracer at Vanderbilt Ingram Cancer Center - Franklin (2107 Edward Curd Lane, Franklin, TN) site for the Hospital deemed service. During review of the medical record of a radiation oncology patient, there was no evidence that the patient had an advance directive or had been provided information regarding advance directives. This was not in compliance with the organizational policy "Health Care Decision Making/Advance Directives OP20-10.08 current as of June 2015. Education of advance directives and pilot program for implementation in outpatient Oncology is to take place in September. Observed in Individual Tracer at Vanderbilt Medical Group at Green Hills - Bedford Ave. (3810 Bedford Ave., Suite 100, Nashville, TN) site for the Hospital deemed service. During review of the medical record of an infusion patient, there was no evidence that the patient had an advance directive or had been provided information regarding advance directives.

This was not in compliance with the organizational policy "Health Care Decision Making/Advance Directives OP20-10.08 current as of June 2015. Education of advance directives and pilot program for implementation in outpatient Oncology is to take place in September.

Elements of Performance:

9. The hospital documents whether or not the patient has an advance directive.

Scoring Category: C

Corrective Action Taken:

WHO:

Chief Nursing Officer of VUH and VMG.

WHAT:

Nursing Administrative Directors discussed process for documenting evidence that patient has an advanced directive or was given information. Process approved at the Advanced Directives Implementation Committee meeting. Electronic Clinic Intake Form revised to include Advanced Directive question. A memo was sent by VUH and VMG Chief Nursing Officer to VMG clinic managers regarding process to include question on electronic clinic intake form and audit to measure compliance. Training document developed to aid outpatient staff in what questions to ask patients, where to document the conversation and how to obtain Advanced Care Plan documents to give patients who request these. Education using the training document was completed for all necessary outpatient staff to include staff where observations occurred during onsite visit (Vanderbilt Medical Group at Coolsprings Blvd., Vanderbilt Ingram Cancer Center and Vanderbilt Medical Group at Green Hills). Staff trained on revised electronic clinic intake form. Implemented revised electronic clinic intake form in the outpatient settings.

WHEN:

8/24/2015: Nursing Administrative Directors meeting held to discuss process for documenting evidence that patient has an advanced directive or was given information. 9/2/2015: Process approved at the Advanced Directives Implementation Committee meeting. By 9/23/2015: Electronic clinic intake form was revised. 9/18/2015: A memo was sent by the VUH and VMG Chief Nursing Officer to VMG clinic managers regarding process to include question on electronic clinic intake form and audit to measure compliance. 9/11/2015: Training document developed to aid outpatient staff in what questions to ask patients, where to document the conversation and how to obtain Advanced Care Plan documents to give patients who request these. By 9/23/2015: Education was completed for all necessary outpatient staff to include staff where observations occurred during onsite visit (Vanderbilt Medical Group at Coolsprings Blvd., Vanderbilt Ingram Cancer Center and Vanderbilt Medical Group at Green Hills). By 9/23/2015: Staff were trained on revised clinic electronic intake form. By 9/23/2015: Revised clinic electronic intake form was implemented in the outpatient settings.

HOW:

Quality, Safety and Risk Prevention Department will perform random monthly medical record reviews of the clinic intake form for ongoing compliance of documentation for evidence the patient has an advance directive or provided information on advance directive.

Evaluation

Method: Quality, Safety and Risk Prevention Department will randomly audit 70 outpatient medical records for four consecutive months. The data will be reported to the Outpatient Nursing Leadership Board. Numerator: # of outpatient medical records compliant for documentation evidence that patient has an advance directive or was

given information. Denominator: # of electronic outpatient medical records reviewed
(70)

**Measure of
Success Goal 90
(%):**

HAP Standard UP.01.03.01 A time-out is performed before the procedure.

Findings: EP 2 Observed in Individual Tracer at Vanderbilt at One Hundred Oaks (719 Thompson Lane, Nashville, TN) site. During an observation of a pain procedure with moderate sedation, the time out was conducted and included the attending physician, RN, radiology technician and patient. An anesthesia fellow joined the procedure after the time out was performed and proceeded to complete a major portion of the procedure. There was no additional time out completed when this physician joined the team.

Elements of Performance:

2. The time-out has the following characteristics: - It is standardized, as defined by the hospital. - It is initiated by a designated member of the team. - It involves the immediate members of the procedure team, including the individual performing the procedure, the anesthesia providers, the circulating nurse, the operating room technician, and other active participants who will be participating in the procedure from the beginning.

Scoring Category: A

Corrective Action Taken:

WHO:

Associate Nursing Officer – Surgery Patient Care Center

WHAT:

The Universal Protocol - Identification of Correct Patient, Procedure, Site/Side CL 30-04.16 policy was developed and endorsed by the Clinical Practice Committee, and the Medical Center Medical Board. The time-out process is addressed in the policy in the following manner: "B. Time-out 1. Conduct a time-out immediately before starting the invasive procedure or making the incision with all relevant members of the team focused on the active verbal confirmation of the correct patient, procedure, and site/site" Attending physician as well as the Fellow were counseled one-on-one regarding time-out compliance requirement per policy by the Chief - Division of Pain Medicine. Time-out policy was reviewed with all staff and faculty in the Pain Clinic by the Manager of Vanderbilt Preoperative Evaluation Center (VPEC) & Interventional Pain Clinic. The reeducation of providers to the time-out requirement was completed via electronic communication from the Chief of Staff for Vanderbilt Health Services. This reeducation included situations in which an additional proceduralist joins the procedure after the time-out is performed, the time-out is repeated.

WHEN:

The Universal Protocol - Identification of Correct Patient, Procedure, Site/Side CL 30-04.16 policy was developed and endorsed by the Clinical Practice Committee, and the Medical Center Medical Board 7/2015. Attending physician as well as the Fellow were counseled one-on-one regarding time-out compliance requirement per policy on 7/23/2015. Time-out policy reviewed with all staff and

faculty in Pain Clinic on 7/23/2015. The reeducation of providers to the time-out requirement was completed via electronic communication from the Chief of Staff for Vanderbilt Health Services on 9/1/2015.

HOW:

Random observations by clinic manager in One Hundred Oaks Pain clinic procedural area will be conducted for compliance on time-out process. Non-compliance will be addressed by Patient Care Center Leadership.

Proof of Publication

COPY
Supplemental- #1

Vanderbilt University Hospitals

CN1602-010

February 25, 2016**2:57 pm****1. Section A, Applicant Profile, Item 9**

Please explain how there can be (10) CON approved but unimplemented Medical beds.

RESPONSE: The 10 unimplemented beds refer to licensed beds that are currently not in service. These beds were originally located in semi-private rooms; however, these rooms are now private rooms, and the license will be relocated to the vertical expansion approved in CN0710-075.

Please explain how there can be 96 licensed neonatal beds and 100 staffed beds.

RESPONSE: Please see the updated chart below. There are currently 96 licensed and staffed NICU beds at VUMC.

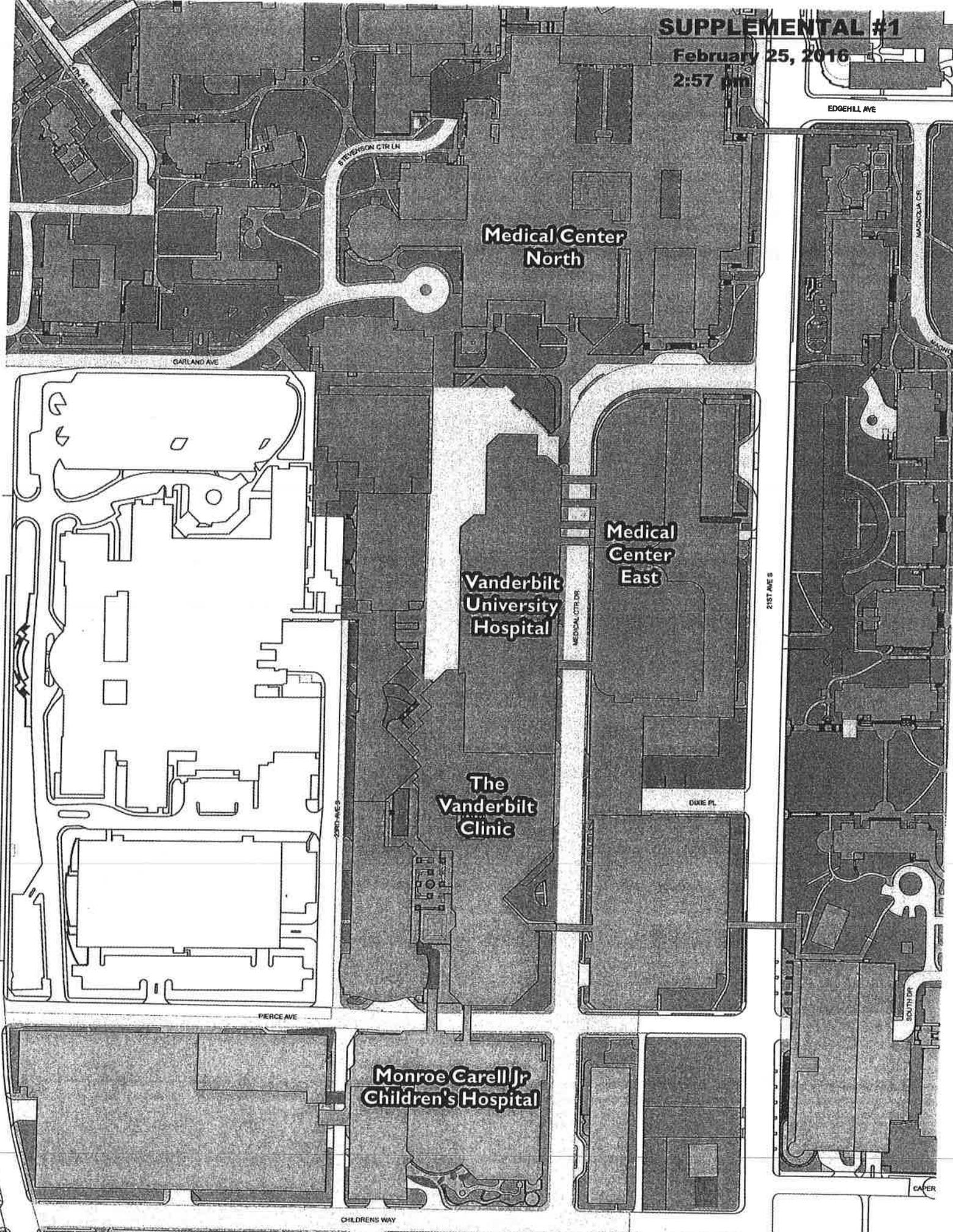
SUPPLEMENTAL #1**February 25, 2016****2:57 pm**

	Current Beds Licensed	CON Approved Bed Projects (Unimplemented)	Staffed Beds	Beds Proposed (in this CON)	Total Beds at Completion (of all Projects)
A. Medical	235	(10)	210	-	225
B. Surgical	222	61	222	-	283
C. Long-Term Care Hospital	-	-	-	-	-
D. Obstetrical	50	23	50	-	73
E. ICU/CCU (+PICU)	205	60	205	-	265
F. Neonatal	96	-	96	-	96
G. Pediatric	129	-	129	-	129
H. Adult Psychiatric	88	-	88	-	88
I. Geriatric Psychiatric	-	-	-	-	-
J. Child/Adolescent Psychiatric	-	-	-	-	-
K. Rehabilitation	-	-	-	-	-
L. Nursing Facility (non-Medicaid Certified)	-	-	-	-	-
M. Nursing Facility Level 1 (Medicaid only)	-	-	-	-	-
N. Nursing Facility Level 2 (Medicare only)	-	-	-	-	-
O. Nursing Facility Level 2 (dually certified Medicaid/Medicare)	-	-	-	-	-
P. ICF/MR	-	-	-	-	-
Q. Adult Chemical Dependency	-	-	-	-	-
R. Child and Adolescent Chemical Dependency	-	-	-	-	-
S. Swing Beds	-	-	-	-	-
T. Mental Health Residential Treatment	-	-	-	-	-
U. Residential Hospice	-	-	-	-	-
TOTAL	1,025	134	1,000	-	1,159

February 25, 2016**2:57 pm****2. Section B, Project Description, Item I**

Please provide a map of the Vanderbilt University Medical Center (VUMC) Campus which clearly identifies Medical Center North and identifies its proximity to the other hospital buildings that make up VUMC

RESPONSE: Please find the attached map.



**Medical Center
North**

**Medical
Center
East**

**Vanderbilt
University
Hospital**

**The
Vanderbilt
Clinic**

**Monroe Carell Jr
Children's Hospital**

41171 PMS ©

CAPER

Please provide more detail regarding the deficiencies of the 3rd Floor of Medical Center North (MCN) that make it no longer suitable for The Clinical Research Center (CRC).

RESPONSE: The 3rd Floor of Medical Center North was renovated for the CRC program in 1971. At that time, it was a state-of-the-art facility, designed specifically for the needs of the CRC. As the CRC program has evolved, the CRC has managed changes within the original space, with only minor renovations. Relocating to a different location will also allow a single move, as opposed to a phased renovation within the existing third floor space.

How will the space on the 3rd floor be utilized after the relocation of CRC?

RESPONSE: After the relocation of the CRC, the space will be temporarily utilized by other VUH nursing units while ongoing cosmetic upgrades are completed. A final use of that space has not been determined.

How is the space on the 2nd floor of the Round Wing currently being used? Will whatever program that is utilizing that space have to be relocated as well?

RESPONSE: The 2nd floor of the Round Wing was previously used as an Education and Learning Center. These functions were moved to alternate locations on the medical center campus through an improved scheduling system which maximized the use of existing shared spaces, leaving this space vacated. The Communicable Disease Response Unit (CDRU) is currently located in a small area of the second floor space and will be incorporated within the renovated CRC as a multi-use space.

Please provide more detail as to what enhancements the second floor of the Round Wing offer that will make it state of the art that is currently not available on the 3rd Floor.

RESPONSE: The second floor location provides a grade level drop-off and entry for ambulatory patients, a connection to the hospital via a patient-transport tunnel, and closer proximity to parking and shuttle services. The proposed CRC is also directly below 6 floors of inpatient beds and is located at the center of the clinical enterprise.

Is the Round Wing also in Medical Center North or a different building?

RESPONSE: The Round Wing is an extension of Medical Center North and is closer to the Vanderbilt University Hospital. See attached diagram below for proximity.

SUPPLEMENTAL #1

February 25, 2016

2:57 pm

146

LAB

PHYSICS

EXISTING CRC
MCN LEVEL 03

LANE

MEDICAL
CENTER
NORTH

PROPOSED CRC
ROUND WING,
MCN LEVEL 02

ZERFOSS
HEALTH CTR

PATIENT ELEVATORS
IN ROUND WING

UP=6 LEVELS OF INPATIENT CARE
DOWN=PATIENT TRANSPORT TUNNEL TO VUH

STEVENSON
173'-E 1/8

1225'

VUIIS

ESKIND
LIBRARY

635'

CURRENT CRC
PATIENT ELEVATORS

GARLAND AVE

MRB IV
LANGFORD

LIGHT HALL

VANDERBILT
UNIVERSITY
HOSPITAL

MEDICAL
CENTER
EAST
NORTH TOWER

MEDICAL
ARTS

XIE PLACE

MEDICAL CENTER NORTH

BLAIR + MUI DOWD ARCHITECTS, PC
DONALD BLAIR ARCHITECTS
100 LAFAYETTE ST. SUITE 604
NEW YORK NY 10013
TEL. 212 941.8825
FAX. 212 941.8415

CRC RELOCATION

VANDERBILT UNIVERSITY MEDICAL CENTER
NASHVILLE TENNESSEE

SCALE: N/A DATE: 02/23/2016

Please provide more detail regarding the programs that have utilized the CRC over the past five years.

RESPONSE: The CRC infrastructure and resources provide support to investigators, across all disciplines, for the efficient conduct of investigations of compelling quality, most of which would not be possible otherwise. The CRC focus is to allow the rapid translation of new medical research to clinical care in a patient care setting – ultimately improving health care in the nation. The investigators in the CRC are from the Vanderbilt School of Medicine, Vanderbilt School of Nursing, Vanderbilt Peabody School of Education and Human Development, Vanderbilt School of Engineering, the Lipscomb University School of Pharmacy, and the Meharry Medical and Dental Colleges. The CRC unit conducts a variety of clinical trials, including the study and treatment of rare diseases and the clinical and genetic evaluation of patients with undiagnosed diseases, elderly populations and health concerns for their demographic, including Alzheimer’s disease, oncology clinical trials, pediatric research trials, community health surveys, and other research in hard-to-reach populations. Finally, the CRC unit is an important resource available to junior investigators at all of these institutions who are training to conduct clinic research.

Vaccine Development

Vanderbilt University Medical Center is a Centers for Disease Control/NIH Division of Microbiology and Infectious Diseases - Vaccine and Treatment Evaluation Units (VTEU) site. The VTEUs perform Phase I, Phase 2, Phase 3, and Phase 4 clinical trials of bacterial, viral, and parasitic vaccines, as well as therapeutics and other interventions against infectious diseases. Eight funded VTEUs currently exist in the United States. Vanderbilt is frequently chosen as clinical test sites to assess safety, reactogenicity, and immunogenicity of vaccines, in the fields of pertussis, pneumococcus, and influenza.

The Vanderbilt CRC provides facility and nursing support to allow the rapid testing of these vaccines in large and diverse patient populations. The size and quick-start and end of these trials, particularly annual seasonal influenza vaccine testing, would not be possible without a dedicated clinical research facility. As a specific example, the Centers for Disease Control has selected the Vanderbilt CRC for the vaccine trial testing regarding H7N9, a new and potentially deadly virus. Originally H7N9 was transferred from animal to human with approximately 44 known deaths. Recently, the virus has mutated from animal- human transmission, to human to human transmission, with one known death. Currently, no treatment exists for this virus. Information gained from this study may provide doctors with valuable information to help prevent the spread of this virus.

Alzheimer’s Research

The Vanderbilt Memory & Aging Project (MAP) is a longitudinal study investigating vascular health and brain aging. Launched in 2012, the MAP cohort includes 335 community-dwelling participants age 60-92, including 168 individuals with mild cognitive impairment (MCI) and 167 cognitively normal adults. Participants were recruited through postal mailings, clinical referrals, radio advertisements, newsletters, research distribution emails, community events, websites, and word of mouth.

The Vanderbilt CRC provides facility and nursing support for memory testing of research subjects and their caregivers. It also provides facilities for the study team to perform lumbar punctures to collect CSF and other DNA, serum, and plasma specimen collection to facilitate biomarker analyses. This is a large cohort of patients and with

the large amount of testing involved and the fragile nature of the research subject, the CRC facility can be used as a home based to minimize the amount of testing locations the participant would need to visit.

Cancer Clinical Trials

The Vanderbilt Ingram Cancer Center is the only NCI-Designated Cancer Center in the state of Tennessee and conducts numerous Phase 1, 2, and 3 cancer clinical trials to develop new cancer treatments. Study drug testing in cancer patients requires pharmacokinetic testing to evaluate the condition of a patient's cardiovascular system in response to study drugs. This type of testing can be lengthy for the research subject and their caregivers.

The Vanderbilt CRC provides a safe environment to conduct study drug testing in patients. As an example, a study drug is currently being tested in advanced stage solid tumors. The clinical trial for this study requires electrocardiogram (EKG) testing as follows: 15 minutes, 30 minutes, 1 hour, 90 minutes, 2 hours, 3 hours, 4 hours, 6 hours, 8 hours, and 12 hours, with serial blood draws and specimen processing at similar time points. Additionally, many of these drugs are toxic and the study testing requires overnight stays for patient safety and the length of testing. The CRC is an ideal location for this important testing.

Kidney Disease & Diabetes Research

Vanderbilt participates in the national TrialNet study, which researches the natural history of the development and risk of development of type I diabetes. The major focus of this research is to perform prevention trials. Patients are randomly selected from a large number of people who agreed to be contacted, even if they did not have diabetes-related autoantibodies. This study will follow patients over a long period of time.

Another kidney study conducted at Vanderbilt is the Acute Kidney Injury (AKI) Consortium. This consortium includes Clinical Research Centers (CRCs) led by Kaiser Permanente of Northern California, Yale University, Vanderbilt University, and University of Washington as well as representatives from NIH National Institute of Diabetes and Digestive and Kidney Disease. This cohort will determine whether hospitalized persons who survive an episode of AKI have a greater risk of developing chronic kidney disease or faster progression of pre-existing chronic kidney disease than hospitalized persons without AKI after accounting for pre-existing level of kidney function and potential confounders. The study also seeks to determine whether hospitalized persons who suffer from an episode of AKI have a higher risk of death, cardiovascular events, and other adverse events after hospital discharge than matched persons who did not suffer AKI during hospitalization, after accounting for pre-existing level of kidney function and potential confounders. The proposed project will explore the contribution of acute kidney injury on the progression of chronic kidney disease. If this is the case, i.e. AKI events contribute to faster progression of CKD, then strategies to prevent AKI become even more important to prevent future development chronic kidney disease. The Vanderbilt site is expected to recruit 500 subjects.

The study will last for 96 months (8 years). The participants will have one visit in the hospital and 9 visits when they get out of the hospital. The visits after they get out of the hospital will be months 3, 12, 24, 36, 48, 60, 72, 84 and 96. Each visit will require collecting blood and urine, blood pressure, EKGs, height and weight. Each of these visits lasts up to 2 hours.

The Vanderbilt CRC facility is able to see the large volume of patients these cohorts require in a safe research setting. Additionally, the amount of data collection and case reporting required for these types of longitudinal studies could not be collected in a standard clinic setting.

Clinical Pharmacology Research

The presence at Vanderbilt of one of the nation's largest and most active Clinical Pharmacology divisions ensures a vibrant portfolio of advanced, mechanistic patient-oriented research and a full range of drug studies encompassing every stage of the process of drug development from new target identification to compound discovery through Phase 1 studies, and beyond. PK/PD studies which require very precise timing of drug administration, blood draws and processing, and constant monitoring for the highest standard of safety, are a particular strength. The CRC is critical to Vanderbilt's clinical pharmacology research.

Special Populations - Prader Willi Syndrome

Vanderbilt is supporting a pediatric research study to test the safety and effectiveness of a study drug Carbetocin for patients with Prader-Willi Syndrome. Carbetocin is an investigational drug that is a synthetic oxytocin and is not approved by the Food and Drug Administration (FDA) for general use in the United States; however, it is approved in other countries. Carbetocin may change behavior by affecting the brain and the central nervous system.

This is a special population of patient and administration of a research study drug in a pediatric patient population requires specialized facilities to monitor reactions. The Vanderbilt CRC facility and nurses are trained to meet safety requirements of a 1:1 patient to nurse ratio for the duration of this study. The research nurses are trained to help patients understand consent for a research study and to ensure the patient continues with consent, stopping the study as the participant indicates.

Undiagnosed Disease Network

The Undiagnosed Diseases Network (UDN) is a research study that is funded by the National Institutes of Health Common Fund. Its purpose is to bring together clinical and research experts from across the United States to solve the most challenging medical mysteries using advanced technologies. Through this study, we hope to both help individual patients and families and contribute to the understanding of how the human body works. As part of the Undiagnosed Diseases Network (UDN), the Vanderbilt Center for Undiagnosed Diseases (VCUD) strives to discover the etiology of undiagnosed diseases, as well as determine the pathophysiology of rare and new diseases, and identify better diagnostic and treatment options by examining detailed family history, phenotyping, lab, genotyping, environmental exposure, and other clues. The impact of our findings will be amplified by sharing these results across the network to identify commonalities amongst patients with such a rare disease. This

process will accelerate and ensure that our efforts will benefit the health of the American public, which is the compelling reason for this initiative.

The Vanderbilt CRC Unit provides facility and nursing support to assist with comprehensive workups for these patients. Each protocol within the network is unique and the research testing for each patient is individualized. These are research subjects who have a genetic disease so rare or unusual that doctors can't diagnose them. This type of research would not be conducive in a regular clinic setting. The patients are traveling from all over the United States and a central facility is necessary to provide the care.

3. Section B, Project Description, Item II.A.

According to the square footage chart the CRC on the 3rd floor currently has 20,325 square feet while the proposed relocated space in the Round Wing will have 13,672 SF. Please explain how reduction of 6,653 SF will improve the space for the CRC.

RESPONSE: Within the existing CRC, most patient rooms were designed as shared, oversized rooms; however, most are currently used as private rooms. The original CRC was built in 1971 and has been adapted by adding functions within existing spaces but without renovating to maximize efficiencies. The proposed project represents an efficient use of space and was developed over the past 8 months with guidance of the CRC leadership and staff.

Are there currently 5 inpatient medical/surgical beds and 6 exam and outpatient rooms in the current space? Is there ancillary and administration space in the existing space?

RESPONSE: The existing CRC has 14 licensed inpatient rooms, which are used for inpatients and outpatients. There is also additional administrative and ancillary space. The new CRC will have 5 inpatient rooms and 6 outpatient rooms to reflect current and projected patient growth. It will also have administrative space to support the unit.

If the Round Wing is on the second floor of the same building where the existing CRC is located on the third floor, please explain how this relocation down one floor will place CRC closer to the clinical core of the medical center. Additionally, what are the benefits of the CRC being closer to the clinical core of the medical center?

RESPONSE: Please see the diagram on page 6 to illustrate proximity to the clinical core. Relocation to the Round Wing would facilitate improved access for patients, families, and VU clinical providers.

4. Section C, Need, Item 1.a.

The applicant's response of "Not Applicable" is noted; however the criteria for "Construction, Renovation, Expansion, and Replacement of Health Care Institutions" are applicable.

Please provide a response to Standards 3.a. and 3.b.

February 25, 2016**2:57 pm**

RESPONSE: Please see the criteria and responses below for renovation or expansions of an existing licensed health care institution.

For renovation or expansions of an existing licensed health care institution:

The applicant should demonstrate that there is an acceptable existing demand for the proposed project.

RESPONSE: VUMC is a comprehensive healthcare facility dedicated to patient care, research, and biomedical education. The medical center's reputation for excellence in each of these areas has made VUMC a major patient referral center for the Mid-South. There are no comparable programs in Tennessee. The proposed project will continue to allow this type of research to be performed, thus allowing more treatment options to be discovered and better patient care delivered.

The applicant should demonstrate that the existing physical plant's condition warrants major renovation or expansion

RESPONSE: The 3rd floor of Medical Center North was renovated for the Clinical Research Center program in 1971. Since that time, the CRC program has evolved, and the existing space has been utilized with little change to the original design. In addition to various work-flow adaptations, changes in equipment, shifts to private patient rooms, and increases in outpatient services have made the existing space inefficient.

5. Section C, Need, Item 4.A

In Attachment C. Need. 4.A.-Primary Service Area Demographic Chart in the "TennCare Enrollees as a % of Total" Column, the percentages are very high and for some counties exceed well over 100%. This appears to be a calculation error.

Please make the necessary corrections and submit a revised Demographic Chart.

RESPONSE: Please see the revised Demographic Chart.

6. Section C, Need, Item 6

Please discuss in detail the programs that utilized the CRC in the last three years and complete the following table:

RESPONSE: Due to the complexity of these programs, it is very difficult to quantify the number of admissions, days and/ or visits by each individual program. The NIH NCATS Institute, which funds the CRC, does not require reporting on a per protocol basis. Therefore, we have not developed reporting metrics for this information. Many patients are participants in multiple grants and may be inpatients, outpatient or both. In order to complete the table as requested, thousands of pages of documents would have to be reviewed manually and it is not possible to extract this information without significant effort. The information below describes the programs underway at the Vanderbilt CRC.

Year	Program Name	Brief Program Description	Funding Source #1	Grant Title	Funding Amount Granted	Patient Admissions	Patient Days	Outpatient Visits
June 1, 2012	Fatty Acid Desaturase, Fish Oil and Colorectal Cancer	Colorectal cancer is the second leading cause of cancer-related mortality within the United States. Fish oils may be beneficial for cancer chemoprevention through their anti-inflammatory properties, however, variations in genes related to polyunsaturated fatty acid biosynthesis may attenuate these effects. This study will investigate the nutrigenomics of fish oil supplementation in colorectal cancer chemoprevention.	UL1 TR0000445	Vanderbilt Clinical and Translational Science Award	\$135,994	Not Available	Not Available	Not Available
February 25, 2012 2:57 pm	The Memory & Aging Project	The incidence of dementia is dramatically increasing, and in the absence of effective therapies, there is an urgent need to identify risk factors and prevention strategies. Our preliminary data suggest cardiac function may be an unrecognized risk factor for maladaptive brain aging. The proposed project will generate evidence to support the development of novel strategies for delaying dementia onset and progression.	UL1 TR0000445	Vanderbilt Clinical and Translational Science Award	\$100,000	Not Available	Not Available	Not Available
July 2, 2012	ANBL0032:Phase III Randomized Study of Chimeric Antibody 14.18 (CH.14.18) in High Risk Neuroblastoma Following Myeloablative Therapy and Autologous Stem Cell Rescue	Neuroblastoma is the third most common malignancy of childhood. More than one half of patients have high-risk tumors and have dismal outcome despite aggressive therapy (3 year event-free survival less than 15%). A somewhat improved outcome has been obtained with autologous bone marrow transplantation after intensive chemotherapy. However, more than one half of these patients will still relapse and succumb to the tumor. This is especially true for those patients who were diagnosed to have Stage IV neuroblastoma after 1 year of age.	UL1 TR0000445	Vanderbilt Clinical and Translational Science Award	\$60	Not Available	Not Available	Not Available
January 9, 2013	Predicting Cardiac Effects of Breast Cancer Therapy	Current work will influence how we monitor and treat early cardiotoxicity in patient undergoing chemotherapy.	UL1 TR0000445	Vanderbilt Clinical and Translational Science Award	\$174,047	Not Available	Not Available	Not Available
January 10, 2013	Long Term Follow-up on HIV-1 Infection in Participants Who Become Infected After Enrollment in EarlyPhase (phase I and 2a) HIV Vaccine Preparedness Cohorts		UL1 TR0000445	Vanderbilt Clinical and Translational Science Award		Not Available	Not Available	Not Available
February 22, 2013	Metabolic abnormalities and endothelial dysfunction in pulmonary arterial hypertension	Pulmonary arterial hypertension (PAH) is a devastating disease characterized by progressive obliteration of the pulmonary vasculature, right heart failure and death. Despite major advances in understanding development of PAH in recent decades, safe, effective and tolerable therapies remain elusive, and it is unclear why females are disproportionately affected by PAH, especially in heritable PAH (HPAH) in which females with a BMPR2 mutation are affected substantially more often than males with similar mutations. Recently, our group and others have explored the role of metabolic derangements in the pathogenesis of PAH; we now believe that oxidative stress associated with metabolic abnormalities such as those that relate to sex hormone metabolism promote PAH pathogenesis in susceptible subjects.	UL1 TR0000445	Vanderbilt Clinical and Translational Science Award	\$97,480	Not Available	Not Available	Not Available

SUPPLEMENTAL #1

Year	Program Name	Brief Program Description	Funding Source #1	Grant Title	Funding Amount Granted	Patient Admissions	Patent Days	Outpatient Visits
June 3, 2013	Host and Pathogen Risk Factors for Recurrent Clostridium difficile Infection (CDI) in Children	The primary objective is to investigate host and pathogen risk factors for recurrent CDI in children ages 12 months to 17 years 11 months. The host factors to be studied include IL-8 genetics, the humoral immune response, and the host inflammatory response to the initial episode of CDI. The pathogen factor to be studied involves the type of C. difficile strain causing the initial episode. The secondary objective is to study the epidemiology, clinical features, and outcomes of children with recurrent CDI. The knowledge gained from this study will hopefully provide greater understanding in how to treat Clostridium difficile (CD) in children.	Thrasher Grant	Host and Pathogen Factors Associated with Recurrent Clostridium difficile Infection in Children	\$26,541	Not Available	Not Available	Not Available
June 3, 2013	IRB# 130143 "A Phase IIb, Multinational, Double-Blind, Randomized, Placebo-Controlled	There is an unmet medical need for effective and safe treatments for patients with Amyotrophic Lateral Sclerosis(ALS). Currently, there is only 1 available medicine, Rilutek (riluzole), for the treatment of ALS with limited efficacy.	UL1 TR000445	Vanderbilt Clinical and Translational Science Award	\$7,893	Not Available	Not Available	Not Available
June 5, 2013	Protocol H6D-MC-LVHV (a) A Double-Blind Efficacy and Safety Study of the Phosphodiesterase Type 5 Inhibitor Tadalafil in Pediatric Patients with Pulmonary Arterial Hypertension	It has been suggested that the clinical course of PAH in children is less predictable than in adults. If untreated, the condition may progress more rapidly in children, leading to reduced survival in children than in adults over time. Importantly, the safety and efficacy of PAH therapies approved for adults have not been robustly established in pediatric patients due to limited data in children. Given the efficacy and safety results of tadalafil for the treatment of PAH in adults (Study LVGY), and recognizing the importance of providing prescribers and patients with recommendations reflecting tadalafil experience across developmental stages, Lilly is pursuing the development of tadalafil for the treatment of PAH in patients, aged 3% to 6 months to <18 years. Study LVIG is an open-label, multiple ascending-dose study to evaluate the safety and PK of tadalafil administered orally as a tablet or suspension to children with PAH. The primary objective of Period 1 of Study LVIG is to characterize the PK of tadalafil in a pediatric population with PAH. The objectives of Period 2 are to evaluate the long-term safety of tadalafil as well as clinical worsening (CW) of PAH in this patient population.	UL1 TR000445	Vanderbilt Clinical and Translational Science Award	\$47,400	Not Available	Not Available	Not Available

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 2:57 pm

Year	Program Name	Brief Program Description	Funding Source #1	Grant Title	Funding Amount Granted	Patient Admissions	Patient Days	Outpatient Visits
	<p>An Open-label extension study to determine safety, tolerability, and efficacy of long-term lacosamide as adjunctive therapy in children with partial-onset seizures</p>	<p>This study of Lacosamide (LCM) in pediatric subjects, is an open-label, dose- titration, safety, tolerability, and PK study to evaluate LCM as adjunctive therapy in children (aged 1 month to 17 years) with uncontrolled partial-onset seizures. The safety and PK data from this study are needed to select the target dose range (mg/kg/day) for controlled studies to evaluate the efficacy and safety of LCM for the treatment of partial-onset seizures in this patient population. A need remains for AEDs with improved effectiveness and tolerability (Sander, 1998). Among the newer AEDs, only 5 (gabapentin, lamotrigine, oxcarbazepine, topiramate, and levetiracetam) have successfully demonstrated efficacy as adjunctive therapy in children with difficult to treat partial-onset seizures (Appleton et al, 1999; Duchowny et al, 1999; Elerman et al, 1999; Glauser et al, 2000; Glauser et al, 2006). Despite the availability of new AEDs, more than 25% of pediatric patients have inadequate seizure control on currently-available AEDs, or experience significant adverse drug effects (Hadjiiozou and Bourgeois, 2007). Therefore, a need remains for AEDs with improved effectiveness and tolerability.</p> <p>Lacosamide (LCM, Vimpat, SPM 927, [R]-2-acetamido-N-benzyl-3-methoxypropionamide) belongs to a novel class of functionalized amino acids. It has minimal protein binding and effect on cytochrome P450 enzyme system function (reducing the risk of drug-drug interactions), high oral bioavailability, and a half-life of approximately 13 hours (in adults), which allows a bid dose regimen. It also displays dose-proportional PK following administration over a range of doses up to 800mg in adults. Lacosamide has been approved as adjunctive therapy in the treatment of partial-onset seizures with or without secondary generalization in patients 16 years of age and older in the European Union (oral tablets, oral solution (syrup), and solution for intravenous [iv] infusion) and in patients 17 years of age and older in the United States (oral tablets and solution for iv infusion). The oral solution (syrup) is a formulation suitable for administration to children. Bioequivalence has been shown between the tablet and oral solution (syrup) formulations, comparing 2 tablets of LCM 100mg and the oral solution (syrup) containing LCM 200mg, after single-dose administration in healthy subjects. The PK of LCM and SPM 12809 in plasma, urine, and saliva were identical or very similar after single oral doses of LCM 200mg administered as tablets or as oral solution (syrup).</p> <p>In the clinical development program for LCM, safety and tolerability of multiple doses of up to 400mg bid (800mg/day) were evaluated in approximately 700 unique volunteers who received LCM in Phase 1 studies. The safety and efficacy of LCM has also been evaluated in Phase 2/3 studies as adjunctive oral therapy in over 1300 adult subjects with partial-onset seizures and as oral monotherapy in over 2200 adult subjects in other indications (eg, neuropathic pain, osteoarthritis, fibromyalgia). In addition, LCM solution for infusion was evaluated as short-term replacement therapy in a subset of subjects with partial-onset seizures (199 patients) who were receiving adjunctive LCM tablets.</p>	UL1 TR000445	Vanderbilt Clinical and Translational Science Award	\$57,850	Not Available	Not Available	Not Available

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Year	Program Name	Brief Program Description	Funding Source #1	Grant Title	Funding Amount Granted	Patient Admissions	Patient Days	Outpatient Visits
<p>February 25, 2016 2:57 pm</p>		<p>When oral LCM was administered as adjunctive therapy at doses up to 600mg/day in the 3 double-blind, placebo-controlled, multicenter studies in subjects with partial-onset seizures, the most frequently reported treatment-emergent AEs (TEAEs) were central nervous system- and gastrointestinal-associated events. A dose relationship was seen for the most frequently reported common TEAEs, including dizziness, headache, nausea, and diplopia. The nature and frequency of AEs were comparable to adjunctive therapy with other marketed AEDs. Safety evaluations support the further development of LCM as an AED.</p> <p>SP847, the first study of LCM in pediatric subjects, is an open-label, dose-titration, safety, tolerability, and PK study to evaluate LCM as adjunctive therapy in children (aged 1 month to 17 years) with uncontrolled partial-onset seizures. The safety and PK data from this study are needed to select the target dose range (mg/kg/day) for controlled studies to evaluate the efficacy and safety of LCM for the treatment of partial-onset seizures in this patient population.</p>						
<p>July 1, 2013</p>	<p>A Phase 3, Open-Label, Randomized, Multi-Center Study to Assess the Safety and Tolerability of an Induction, Titration, and Maintenance Dose Regimen of BMN 165 Self-Administered by Adults Not Previously Treated with BMN 165</p>	<p>The PKU or Phe-restricted diet is difficult to maintain and is not without sequelae. Most adults with PKU are not able to adhere to the dietary Phe restriction to control blood Phe levels; 79% of adolescents and 78% of adults with PKU have blood Phe levels above the recommended target range. Uncontrolled blood Phe levels in adulthood are associated with executive dysfunction, depression, and a variety of behavioral and psychiatric problems. Biomarin Pharmaceutical Inc. is developing BMN 165 (recombinant Anabaena variabilis phenylalanine ammonia lyase-PEG [rAVPAL-PEG]) as an enzyme substitution therapy to reduce blood Phe concentrations in patients with PKU.</p>	<p>U11 TR000445</p>	<p>Vanderbilt Clinical and Translational Science Award</p>	<p>\$20,055</p>	<p>Not Available</p>	<p>Not Available</p>	<p>Not Available</p>
<p>July 1, 2013</p>	<p>A Phase 3, Multicenter, Randomized, Double-Blind, Placebo Controlled Study of Rilotumumab (AMG 102) with Epirubicin, Cisplatin, and Capecitabine (ECX) as First-line Therapy in Advanced MET-Positive Gastric or Gastroesophageal Junction Adenocarcinoma</p>	<p>The purpose of this study is to find out more about rilotumumab (also known as AMG 102) when given to people with gastric cancer. This study will see if there is benefit in adding rilotumumab to a standard chemotherapy compared with treatment with chemotherapy alone and whether the combination of treatment causes any side effects. To do this, rilotumumab will be compared to placebo. Participants may or may not receive a direct benefit from participating in this study. The possible benefits to participants may include an improvement in disease status. The possible benefits to humankind include finding an effective therapy for treatment of this disease.</p>	<p>U11 TR000445</p>	<p>Vanderbilt Clinical and Translational Science Award</p>	<p>\$7,200</p>	<p>Not Available</p>	<p>Not Available</p>	<p>Not Available</p>

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2:57 pm**

Year	Program Name	Brief Program Description	Funding Source #1	Grant Title	Funding Amount Granted	Patient Admissions	Patient Days	Outpatient Visits
July 3, 2013	MRI Biomarkers and Genetic Risk Factors for Alzheimer Disease	Early identification of Alzheimer disease-related neuropathology is critical for the success of treatments aimed at delaying the onset or slowing the rate of worsening symptoms, thereby extending quality of life years and reducing healthcare costs. The non-invasive MRI scan sequences we will investigate in this project can detect this pathology but have not yet been applied in vivo for early, preclinical detection, when its use would have the largest impact. If successful, these methods could enable early screening and detection of preclinical Alzheimer pathology, early referral for treatment, and regular monitoring of disease progression. To date, there are only five FDA-approved drugs for the treatment of AD, which aim to temporarily slow worsening symptoms of the disease. All of these treatments are most effective in the earliest stages of disease. Therefore, early and accurate identification of persons at high risk for AD is of great importance. Likewise, clinical trials require sensitive biomarkers for measuring treatment efficacy. There are currently 90 experimental therapies that are in various stages of clinical testing and could benefit from such biomarkers. The MRI scan sequences we will investigate in this project could serve as novel, effective screening tools for early AD-related pathology, which could translate into very early identification of persons at high-risk of developing AD. In clinical trials, these MRI biomarkers could increase the power to detect treatment effects and reduce the required number of subjects, thereby enabling more rapid evaluation of clinical therapies and reducing time to market for those demonstrated effective.	UL1 TR000445	Vanderbilt Clinical and Translational Science Award	\$48,100	Not Available	Not Available	Not Available
July 16, 2013	Forest MEM-MD-68	Funding for this project will enable collection of substantial preliminary data, which will guide study design decisions and will be necessary for a successful RO1 application.	UL1 TR000445	Vanderbilt Clinical and Translational Science Award	\$15,120	Not Available	Not Available	Not Available
July 16, 2013	Forest MEM-MD-91	There are currently no FDA approved treatments for social and communication deficits associated with autism spectrum disorder. This study aims to determine if memantine can improve these core deficits.	UL1 TR000445	Vanderbilt Clinical and Translational Science Award	\$19,778	Not Available	Not Available	Not Available
July 16, 2013	MEM-MD-69	There is currently no FDA approved treatments for social and communication deficits associated with ASD. This study aims to determine if memantine can improve these core deficits.	UL1 TR000445	Vanderbilt Clinical and Translational Science Award	\$15,660	Not Available	Not Available	Not Available

Year	Program Name	Brief Program Description	Funding Source #1	Grant Title	Funding Amount Granted	Patient Admissions	Patient Days	Outpatient Visits
July 16, 2013	Open-Label, Single-Arm, Multi-center, Long-Term Follow-Up Study To Evaluate Safety and Efficacy of Brivaracetam Used as Adjunctive Treatment in Pediatric Subjects With Epilepsy (N01266)	This present study (N01266) will give subjects who have completed N01263 or will have completed other future BRV pediatric studies an opportunity to continue BRV treatment for at least 3 years, or until approval of BRV is granted for pediatric subjects in their age range, or until the investigational product development is stopped by the Sponsor. In addition, N01266 will gather additional long-term safety and tolerability data on BRV in pediatric subjects with epilepsy while providing access to BRV for subjects who may benefit from long-term treatment. The information gathered in this study will help determine the long-term safety and tolerability of brivaracetam in the pediatric population.	U11 TR000445	Vanderbilt Clinical and Translational Science Award	\$27,360	Not Available	Not Available	Not Available
February 25, 2016 2:57 pm	Sequential, two-period study to assess the pharmacokinetics, safety & tolerability of single and multiple oral doses of AFD056 in patients with FXS (Fragile X syndrome) aged 5-11 years (Cohort 1) and 3-4 years (Cohort 2)	Currently, there are no specific treatments for Fragile X syndrome. This represents the first study of an mGluR5 antagonist in children with Fragile X syndrome, to our knowledge. This study directly translates data on the use of mGluR5 antagonists in the mouse model of Fragile X syndrome into children with Fragile X syndrome. Support from the CRC will enable us to do a pharmacokinetic profile, as well as an evaluation of safety.	U11 TR000445	Vanderbilt Clinical and Translational Science Award	\$30,130	Not Available	Not Available	Not Available
July 22, 2013	A Randomized Controlled Trial of Glutamine Dipeptide in Severe Trauma	Trauma is the leading cause of death in the United States for adults under age 45, and survivors of severe injury face many obstacles in their struggle to recover. Early prophylaxis against the metabolic sequelae of trauma represents a promising, efficient approach to improve care. Of the 'metabolic prophylaxis' agents studied to date, the amino acid glutamine shows the most promise to improve care of trauma victims and potentially other critically ill patients. Animal studies and preliminary work in humans suggests that glutamine dipeptide may provide important benefits following severe trauma, including improved survival and reduced infection rates. The proposed project will begin the process of more rigorously evaluating glutamine dipeptide, with the goal of translating the aforementioned findings into clinical practice.	U11 TR000445	Vanderbilt Clinical and Translational Science Award	\$40,716	Not Available	Not Available	Not Available
July 26, 2013	VICHEM1336 - A Randomized, Blinded, Placebo-Controlled, Dose Finding Study to Assess the Safety and Efficacy of the Oral Thrombopoietin Receptor Agonist, Eltrombopag, Administered to Subjects with Acute Myelogenous Leukemia (AML) Receiving Induction Chemotherapy	To assess the safety and tolerability of eltrombopag versus placebo in subjects receiving standard induction therapy for acute myeloid leukemia (AML). The secondary objectives are to compare the following in subjects treated with eltrombopag versus placebo: 1) plasma PK parameters of daunorubicin and daunorubicinol; 2) the effects on blood counts including platelets, absolute neutrophil count (ANC), and haemoglobin; 3) the incidence and severity of haemorrhagic events; 4) the effect on AML disease control; and 5) off-treatment medical resource utilization.	U11 TR000445	Vanderbilt Clinical and Translational Science Award	\$3,465	Not Available	Not Available	Not Available

SUPPLEMENTAL #1

Year	Program Name	Brief Program Description	Funding Source #1	Grant Title	Funding Amount Granted	Patient Admissions	Patient Days	Outpatient Visits
July 29, 2013	Effects of Cerebral Hypoperfusion and its Reversal on Late-Life Depression	There is substantial evidence linking vascular risk factors and vascular disease with depression occurring in older adults. It is important to examine potential mechanisms underlying these relationships as this may inform studies testing the utility of existent pharmaceuticals that target those mechanisms. This proposal will examine vascular dysregulation and cerebral hypoperfusions as mechanisms that contribute to late-life depression and may predict poor response to conventional antidepressants. The project is directly applicable to elderly populations. It will provide important information on the mechanisms underlying the relationship between vascular disease and depression. These funds will provide important pilot data examining the role of vascular dysregulation in contributing to depression but also examine how reversal of hypoperfusion may result in improved depression outcomes.	UL1 TR000445	Vanderbilt Clinical and Translational Science Award	\$22,939	Not Available	Not Available	Not Available
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July 31, 2013	Estrogen and cholinergic effects on cognition in higher and lower performing post-menopausal women	Estrogen has, historically, produced mixed effects on cognition with improvements, impairments, and no effects prevalent in previous research. Objective measures of cognitive function may be able to predict who will, and will not, benefit from estrogen treatment. We are examining the circumstances at which estrogen is beneficial to cognitive and brain function in post-menopausal women, specifically determining whether cognitive performance after menopause can serve as a biomarker for probable improvement with estrogen treatment. Our findings will guide clinicians, in the future, when approached by post-menopausal patients who are considering hormone replacement. Space and nursing support at the CRC is vital to our data collection and safety of our subjects.	National Institutes of Health RO1AG021476	Estrogen Effects on Cholinergic Function in Older Women	\$510,426	Not Available	Not Available	Not Available
August 1, 2013	(VTEU 01-2013) A Phase II Open-Label Study in Healthy Pediatric Populations to Assess the Safety, Reactogenicity, and Immunogenicity of an Intramuscular Unadjuvanted Subvirion Monovalent Inactivated Influenza H3N2 Variant (H3N2v) Vaccine (DMID 12-0016)	This is a Phase II open-label study in approximately 240 (up to 400) healthy males and non-pregnant females, 6 months to 17 years old, inclusive. This study is designed to assess the safety, reactogenicity, and immunogenicity of an unadjuvanted subvirion monovalent inactivated influenza H3N2 variant (H3N2v) vaccine (MIV) manufactured by sanofi pasteur. Funding allocated to this study will help physicians become better prepared in combating the recent emergence of novel influenza A viruses in human populations (including subtypes H5N1, H7N7, H7N9, H9N2 and 2009 H1N1).	National Institutes of Health / Division of Microbiology HHSN272200800007 C	Vaccine and Treatment Evaluation Unit	\$22,895,748	Not Available	Not Available	Not Available

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Year	Program Name	Brief Program Description	Funding Source #1	Grant Title	Funding Amount Granted	Patient Admissions	Patient Days	Outpatient Visits
August 2, 2013	Medtronic Early Feasibility Clinical Study of Gastric Electrical Stimulation (GES) for the Treatment of Obesity using the Exilis _{ac} System	Despite growing evidence of the benefits of bariatric surgery and a rapid rise in procedure volumes over the past two decades, only a small percentage of obese patients who are candidates for bariatric surgery under the standard criteria ¹ (BMI \geq 40, or 35% \leq BMI <40 with an obesity-related comorbidity) ² will ever undergo bariatric surgery. A likely reason for this is that patient acceptance is limited by the 10-20% rates of serious complications reported for AGB and RYGB surgeries, the potential for permanent adverse side effects (e.g., chronic vomiting, GERD, dumping syndrome, nutrient deficiencies), and the fact that the alterations in anatomy associated with these procedures are difficult or impossible to reverse in response to a poor outcome. Sensory-based amplitude titration experience gained in this study will guide procedures for setting amplitude in subsequent studies and will inform decisions about whether or not blinding can be properly managed with clinicians and subjects. This Early Feasibility study has multiple purposes. These include providing first-in-human experience with the Exilis ³ system, collecting initial human safety data, and gaining an understanding of how to use any sensations subjects report during in-office programming to identify device settings that will be comfortable for chronic daily treatment.	UL1 TR000445	Vanderbilt Clinical and Translational Science Award	\$7,475	Not Available	Not Available	Not Available
August 7, 2013	Vanderbilt Assessment of Shed ALCAM in Urogenital Cancers (Vansa)	Our inability to predict recurrence, monitor treatment response and detect relapse prior to overt clinical manifestations is among the top challenges faced in our battle to cure cancer. For this reason, there is a push to discover biomarkers that have the ability to diagnose, predict, and monitor cancer progression. Fluid biomarkers, if implemented correctly, have the capability of providing diagnostic, prognostic and treatment response feedback to the clinician in order to better direct patient care. This project directly translates to patient care in that, if successful, this urinary biomarker will direct patient care by allowing improved assessment of treatment response and early detection of recurrence. The ultimate goal is to improve patient outcome and survival by identifying high risk patients long before recurrence.	National Institutes of Health K12CA090625	Vanderbilt Clinical Oncology Research Career Development Award	\$4,050,657	Not Available	Not Available	Not Available
August 22, 2013	VX12-809-104	This study will address the disease of Cystic Fibrosis, specifically those CFTR gene mutations associated with minimal CFTR function such as the delta F508 mutation. Approximately 47% of CF patients in the US have 2 copies of the DeltaF508 CFTR mutation. Developing a drug to help this patient population is of the utmost urgency. This study is industry funded but will require the use of CRC space and nursing assistance as well as centrifuge, freezer, etc. If the efficacy and safety are proven effective, this oral drug could result in a lengthened life span and improved quality of life for Cystic Fibrosis patients. The patients who currently take the FDA approved vacacitor have experienced dramatic improvements. It is the hope that this result can be expanded to patients with different genotypes.	UL1 TR000445	Vanderbilt Clinical and Translational Science Award	\$17,036	Not Available	Not Available	Not Available

Year	Program Name	Brief Program Description	Funding Source #1	Grant Title	Funding Amount Granted	Patient Admissions	Patient Days	Outpatient Visits
August 23, 2013 February 25, 2016 2:57 pm	SCUSF0901 (ACC10922) - A Phase II Placebo-Controlled Trial of Modafinil to Improve Neurocognitive Deficits in Children Treated for a Primary Brain Tumor	Pharmacological agents such as methylphenidate, extended-release methylphenidate, dextroamphetamine and atomoxetine hydrochloride have met with success outside of the cancer population to treat attention deficit disorder (ADD) and Alzheimer's disease. Cognitive-behavioral interventions have been successful in traumatic brain injury and in several trials in pediatric cancer survivors. Educational approaches, including those intended to improve memory, have been useful in patients with vasculopathy and strokes secondary to sickle cell disease. CRNCD likely shares some features of all these disorders, with declines in attention, decreased memory and progressive small-vessel vasculopathy from radiation.	UL1 TR000445	Vanderbilt Clinical and Translational Science Award	\$1,200	Not Available	Not Available	Not Available
September 3, 2013	VICCHEM1289 Phase III, Multicenter, Randomized, Trial of CPX-351 (Cytarabine: Daunorubicin) Liposome Injection Versus Cytarabine and Daunorubicin in Patients 60-75 Years of Age with Untreated High Risk (Secondary) AML	High risk (secondary) leukemia means that the participant has a history of one of these conditions or treatments in addition to your leukemia: 1) prior chemotherapy or radiation for an unrelated disease; 2) prior history of MDS (myelodysplasia- a group of diseases in which the bone marrow does not make enough healthy blood cells; also called preleukemia and smoldering leukemia). 3) prior history of CMML - a slowly progressing type disease in which too many myelomonocytes (a type of white blood cell) are in the bone marrow, crowding out other normal blood cells, such as other white blood cells, red blood cells, and platelets (also called CMML). 4) newly diagnosed leukemia with certain differences in the appearance of your chromosomes (also known as karyotypic abnormalities). Through this study, we plan to learn how safe CPX-351 is and how effective it is on the participant's disease. The possible benefits to participants may include an improvement in disease status. The possible benefits to humankind include finding an effective therapy for treatment of this disease.	UL1 TR000445	Vanderbilt Clinical and Translational Science Award	\$4,620	Not Available	Not Available	Not Available
September 3, 2013	A Phase I open-label trial to evaluate the safety and immunogenicity of an HIV-1 subtype C gp 140 vaccine with MF59 adjuvant in healthy, HIV-1-uninfected adult participants previously primed or unprimed with HIV-1 subtype B envelope subunit vaccines with MF59 (HVTN 088)	One of the major challenges in HIV vaccine development has been to develop a vaccine regimen that can elicit broadly reactive neutralizing antibodies against heterologous primary HIV-1 isolates. Recent data from the Thai trial RV144 suggests that functional antiviral activities conferred by binding antibodies should be a focus of further study. This study will test experimental vaccines. If responses are good, this concept will be applied to much larger human trials. The CRC space is needed to see the participants.	National Institutes of Health / Fred Hutchinson Cancer Research Center	HVTN PIF Funds	\$2,647,930	Not Available	Not Available	Not Available
September 9, 2013	A prospective, single-blind, randomized, phase III study to evaluate the safety and efficacy of Fibrin Sealant Grifols (FS Grifols) as an adjunct to hemostasis during parenchymous tissue open surgeries	This is a prospective, single-blind, randomized, phase III study to evaluate the safety and efficacy of FS Grifols as an adjunct to hemostasis during parenchymous tissue open surgical procedures (i.e. hepatic resections). The study aims to evaluate if FS Grifols is non-inferior in achieving hemostasis when compared with SurgicelA®.	UL1 TR000445	Vanderbilt Clinical and Translational Science Award	\$0	Not Available	Not Available	Not Available

SUPPLEMENTAL #1

Year	Program Name	Brief Program Description	Funding Source #1	Grant Title	Funding Amount Granted	Patient Admissions	Patient Days	Outpatient Visits
September 19, 2013	Immune Responses in Healthy Blood Donors	This proposal requests the acquisition of healthy adult blood donors as a control group to establish novel assays and methods to compare immune responses and immune regulation between infant, children and adults. This project isolates immune cells and immune regulatory cells for functional studies from human intestinal tissue from preterm infants with and without necrotizing enterocolitis and children with and without inflammatory bowel disease. As a control we will isolate immune cells from cord blood and -specifically for this proposal- from peripheral blood of healthy adult blood donors. These studies will provide answers to the currently unknown development of intestinal immune regulation and can lead to new mechanisms of prevention and treatment.	UL1 TR000445	Vanderbilt Clinical and Translational Science Award	\$1,375	Not Available	Not Available	Not Available
February 25, 2016 2:57 pm	A Phase 2, Open-Label, Dose-Escalation Study in Subjects with Pulmonary Arterial Hypertension (PAH, WHO Group 1) and Pulmonary Hypertension Secondary to Idiopathic Pulmonary Fibrosis (PH-IPF WHO Group 3) Using Inhaled NITROSYL???	To identify the minimally effective dose (MinED) and the maximum effective dose (MaxED) (dose beyond which no further effect on PVR is seen) of inhaled nitric oxide using the GENO NITROSYL System compared to placebo. Secondary To assess the safety and tolerability of nitric oxide generated by the GENO NITROSYL System in subjects with WHO Group 1 PAH and WHO Group 3 PH-IPF. To evaluate the pharmacokinetics of total nitrates/nitrites and methemoglobin produced following inhalation of GENO NITROSYL. Nitric oxide has substantial therapeutic potential in various disease states, in particular among diseases involving the pulmonary vascular system. The beneficial effects of reducing pulmonary arterial pressures and improving oxygenation lead to approval of inhaled nitric oxide by the United States (US) Food and Drug Administration (FDA) in 1999 and the European Medicines Agency and European Commission in 2001 for the treatment of term and near term neonates with hypoxemia and PH.	UL1 TR000445	Vanderbilt Clinical and Translational Science Award	\$4,404	Not Available	Not Available	Not Available
September 19, 2013	A phase 1 randomized, double-blind, placebo controlled clinical trial to evaluate the safety and immunogenicity of an HIV-1 vaccine regimen of DNA prime and NYVAC boost with 3 different HIV-1 envelope inserts (Nat-B env, CON-S env, and Mosaic env) in healthy, HIV-1 ^{seroneg} uninfected adults	Through a bioinformatics approach, polyvalent mosaic antigens have been designed in silico to broaden cellular immune responses to globally circulating HIV-1 strains, and this approach utilizes the sequences of known HIV strains and then computationally derives the best set of complementary antigens, that is, those likely to elicit the broadest immune response against known HIV isolates. The mosaic concept has yet to be studied in humans, and this trial will determine the immune responses elicited utilizing the DNA prime NYVAC boost vaccination strategy. The Mosaic env and consensus inserts will each be compared to Nat-B env inserts to evaluate which antigen approach elicits the broadest immune response, and these data have the potential to fundamentally shape future HIV antigen design across delivery platforms. This study will test experimental vaccines. If responses are good, this concept will be applied to much larger human trials. The CRC space is needed to see the participants.	National Institutes of Health UM1A1069439	Clinical Trials Unit	\$11,928,141	Not Available	Not Available	Not Available
September 25, 2013	A MULTI-CENTER, RANDOMIZED, DOUBLE-BLIND, 12-WEEK, PARALLEL GROUP, PLACEBO-CONTROLLED PROOF OF CONCEPT STUDY TO INVESTIGATE THE EFFICACY AND SAFETY OF RO5285119	Autism Spectrum Disorders are a group of neurodevelopmental disorders that are characterized by impairment in social interaction, communication and repetitive or unusual behavior. There are currently no pharmacological treatments for these core deficits of ASD and those treatments that are available only address associated behavioral problems. As such, there is an unmet medical need for treatments of these key deficits.	UL1 TR000445	Vanderbilt Clinical and Translational Science Award	\$16,080	Not Available	Not Available	Not Available

SUPPLEMENTAL #1

Year	Program Name	Brief Program Description	Funding Source #1	Grant Title	Funding Amount Granted	Patient Admissions	Patient Days	Outpatient Visits
September 2013	IN INDIVIDUALS WITH AUTISM SPECTRUM DISORDERS (ASD)		UL1 TR0000445	Vanderbilt Clinical and Translational Science Award	\$68,226	Not Available	Not Available	Not Available
September 2013	Metabolic optimization of patients with left ventricular assist devices (VADs) implantation	We expect that this study will lead to a better understanding of the impact of mechanical circulatory support (VAD) on bioenergetics in heart failure (HF), and provide objective pilot data to guide management of patients with VADs awaiting heart transplantation.	UL1 TR0000445	Vanderbilt Clinical and Translational Science Award	\$4,332	Not Available	Not Available	Not Available
October 2013	Assessment of dynamic cardiac repolarization response in patients with hypertrophic cardiomyopathy	Patients with HCM are at substantial risk of sudden cardiac death from malignant ventricular arrhythmias. However, the mechanisms that initiate such events in these patients are poorly understood. Recent pre-clinical data suggests that dynamic abnormalities of cardiac repolarization may underlie arrhythmic events in such hearts; this protocol proposes to compare the dynamic repolarization response (=QT interval on surface ECG) of HCM patients with that of patients without HCM.	UL1 TR0000445	Vanderbilt Clinical and Translational Science Award	\$4,256	Not Available	Not Available	Not Available
October 9, 2013	A Multicenter, Randomized, Double-Blind, Placebo-Controlled, Phase 2 Study of the Safety and Efficacy of BMS-986020 in Subjects with Idiopathic Pulmonary Fibrosis.	Idiopathic pulmonary fibrosis (IPF) is a fatal, chronic, progressive fibrosing interstitial pneumonia of unknown cause. The clinical course of the disease is progressive dyspnea and irreversible loss of lung function, with an estimated median survival of 2 to 5 years. To date, no therapies had been shown to impact the progression of IPF.	UL1 TR0000445	Vanderbilt Clinical and Translational Science Award	\$22,895,748	Not Available	Not Available	Not Available
October 9, 2013	(VTEU 2013.05) A Phase II Randomized, Double-Blinded, Controlled Study in Healthy Adults to Assess the Safety, Reactogenicity, and Immunogenicity of a Monovalent Influenza A/H7N9 Virus Vaccine Administered at Different Dosages Given With and Without AS03 and MF59 Adjuvants (DMID 13-0033)	This Phase II randomized, double-blinded, controlled study in up to 1000 males and non-pregnant females, 19 to 64 years old, inclusive, who are in good health and meet all eligibility criteria is designed to provide data on an A/H7N9 vaccine made with HA antigen derived from the influenza A/Shanghai/2/2013 virus. The study aims to address several critical questions, including the safety, reactogenicity, and immunogenicity of a monovalent influenza A/H7N9 virus vaccine manufactured by sanofi pasteur in healthy adults: 1) two doses administered at different dosages (3.75, 7.5, or 15 mcg of HA/0.5 ml dose) given with AS03 adjuvant manufactured by GlaxoSmithKline Biologicals or without adjuvant (15 mcg of HA/0.5 ml dose and 45 mcg of HA/0.75 ml dose); 2) a combination of two doses of the A/H7N9 vaccine (15 mcg of HA/0.5 ml dose) each administered with a different adjuvant (AS03 or MF59 adjuvant manufactured by Novartis Vaccines and Diagnostics); and 3) two doses administered at 15 mcg of HA/0.5 ml dose given with MF59 adjuvant manufactured by Novartis Vaccines and Diagnostics. H7N9 is a new and potentially deadly virus. Originally H7N9 was transferred from animal to human with approximately 44 known deaths. Recently, the virus mutated from animal-human transmission, to human to human transmission, with one known death. Currently, there is no treatment for this virus. Information gained from this study may provide doctors with valuable information in preventing the spread of this virus.	National Institutes of Health / Division of Microbiology HHSN272200800007C	Vaccine and Treatment Evaluation Unit	\$165	Not Available	Not Available	Not Available
October 10, 2013	A Multicenter, Open-label BMN 110 US Expanded Access Program (BMN 110 US EAP) to Provide BMN 110 to Patients Diagnosed with	Morquio syndrome is a rare lysosomal storage disorder. There is currently no standard accepted treatment other than supportive care. This study aims to provide a treatment for this condition.	UL1 TR0000445	Vanderbilt Clinical and Translational Science Award		Not Available	Not Available	Not Available

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Year	Program Name	Brief Program Description	Funding Source #1	Grant Title	Funding Amount Granted	Patient Admissions	Patient Days	Outpatient Visits
October 25, 2016 February 25, 2016 2:57 pm	MPS IVA	A Randomized Trial of Metformin as Adjunct Therapy for Overweight Adolescents with Type 1 Diabetes	UL1 TR000445	Vanderbilt Clinical and Translational Science Award	\$9,693	Not Available	Not Available	Not Available
October 14, 2013	A phase 1b clinical trial to evaluate the safety and immunogenicity of different combinations of DNAHIV-PT123, NVVAC-HIV-PT1 and NVVAC-HIV-PT4, and AIDSVAXA® B/E in healthy, HIV uninfected adult participants	The RV144 efficacy trial demonstrated a 31% reduction in HIV infection in vaccines who received ALVACA®-HIV vaccine VCP1521 expressing Env, Gag, and Pro and boosted with a gp120 protein, AIDSVAXA® B/E, compared to placebo and provided valuable insights into the potential importance of binding antibody (Ab) responses in preventing acquisition. These results suggest further evaluation and understanding of prime-boost regimens that include HIV-1 envelope antigens are warranted. In addition, the results underscore the need to develop vaccine regimens that will provide durable immune protection, which likely will entail the induction of long-lived B- and T-cell memory. This study will test experimental vaccines. If responses are good, this concept will be applied to much larger human trials. The CRC space is needed to see the participants.	National Institutes of Health UM1A1069439	Vanderbilt HIV Clinical Trials Unit	\$11,928,141	Not Available	Not Available	Not Available

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Year	Program Name	Brief Program Description	Funding Source #1	Grant Title	Funding Amount Granted	Patient Admissions	Patient Days	Outpatient Visits
<p>October 29, 2013</p> <p>February 25, 2016 2:57 pm</p>	<p>The Endogenous Renin-Angiotensin-Aldosterone System and Glucose Metabolism</p>	<p>Impaired glucose metabolism results in type 2 diabetes mellitus (T2DM), is newly diagnosed in over 7 million people worldwide each year. Based on preliminary data in humans and in mice, this proposal will test the hypothesis that the endogenous renin-angiotensin-aldosterone system (RAAS) impairs insulin secretion and glucose homeostasis in humans.</p> <p>Identifying approaches that prevent the development of diabetes in high-risk individuals, such as those with metabolic syndrome (MetSyn) or impaired glucose tolerance (IGT), could have a major health impact.</p> <p>Based on published clinical trials and our preliminary data, we propose that inappropriately elevated aldosterone promotes diabetes in humans by impairing beta cell function and insulin sensitivity and targeting this system may provide a strategy for improving insulin secretion, insulin sensitivity, and reducing hepatic glucose production in subjects with metabolic syndrome. We have demonstrated in animal models and in preliminary studies in humans that aldosterone and RAAS activation decrease insulin secretion. Funding of this project will help test whether mineralocorticoid receptor antagonism will improve insulin secretion, and potentially reduce the risk of development of type 2 DM.</p>	<p>National Institutes of Health RO1 DK096994</p>	<p>Endogenous Aldosterone and Glucose Homeostasis</p>	<p>\$422,541</p>	<p>Not Available</p>	<p>Not Available</p>	<p>Not Available</p>
<p>October 31, 2013</p>	<p>A5318 $\alpha\epsilon$ Long-Term Effects of Antiretroviral Therapy on Change in Bone Mineral Density in HIV-Infected Subjects (The LEACH Study)</p>	<p>A5318 is designed to obtain longer-term data on change in BMD in HIV-infected individuals and to compare these changes to those that occur in similar populations of HIV-uninfected individuals. With the aging of the HIV-infected population in the United States and elsewhere, osteoporosis will likely become an increasingly common problem facing HIV-infected individuals. While it is known that HIV-infected individuals have increased rates of osteoporosis and osteopenia compared with uninfected individuals, there are limited data on the trajectory of and contributing factors to bone loss and on how the changes in bone loss compare to those that occur in uninfected individuals.</p>	<p>National Institutes of Health UM1A1069439</p>	<p>Vanderbilt HIV Clinical Trials Unit</p>	<p>\$11,928,141</p>	<p>Not Available</p>	<p>Not Available</p>	<p>Not Available</p>
<p>October 31, 2013</p>	<p>VICCTH1353 $\alpha\epsilon$ A Phase I, Open-Label, Multicentre Study to Assess the Safety, Tolerability, Pharmacokinetics and Preliminary Anti-tumour Activity of Ascending Doses of AZD9291 in Patients with Advanced Non Small Cell Lung Cancer who have Progressed Following Prior Therapy with an Epidermal Growth Factor Receptor Tyrosine Kinase Inhibitor Agent (AURA).</p>	<p>AZD9291 is an experimental treatment for patients with NSCLC, whose lung cancer is due to mutations in the Epidermal Growth Factor Receptor (EGFR). Patients who have NSCLC with a mutation in EGFR, can be treated with specific drugs called EGFR Tyrosine Kinase Inhibitors (EGFR TKIs). Unfortunately, after a period of therapy with EGFR TKIs, a significant number of tumors will develop resistance to this treatment due to a second EGFR mutation called T790M.</p>	<p>UL1 TR000445</p>	<p>Vanderbilt Clinical and Translational Science Award</p>	<p>\$13,140</p>	<p>Not Available</p>	<p>Not Available</p>	<p>Not Available</p>

SUPPLEMENTAL #1

Year	Program Name	Brief Program Description	Funding Source #1	Grant Title	Funding Amount Granted	Patent Admissions	Patent Days Available	Outpatient Visits
November 2013	Insulin Detemir in Obesity Management	Our overarching hypothesis is that insulin serves beneficial functions in the CNS by regulating the activity of neurons such as those found in the mediodorsal hypothalamus as well as dopaminergic midbrain neurons to regulate reward. Determine if low dose basal insulin detemir improves dopamine signaling by measuring dopamine transporters and receptors by PET imaging and functional magnetic resonance imaging. Firstly, dopamine neurotransmission underlies reward. Several high visibility studies in humans provide proof-of-principle data supporting the hypothesis that defects in dopamine homeostasis contribute to the pathophysiology of obesity (40, 41). By PET imaging, dopamine D2 receptor availability (radioligand binding potential) was reduced in a BMI dependent fashion, i.e. with increased body mass, less dopamine D2 receptor is available in the brain for dopamine signaling (leading to reduced dopamine signaling; hypodopaminergia). Similarly, brain activation, as measured by functional MR imaging (using techniques similar to those utilized herein), was reduced in obese individual who possess polymorphisms in genes regulating dopamine signaling. This work, together with an ever expanding body of preclinical work indicates that obesity is a chronic state of reduced dopamine signaling, or hypodopaminergia; indeed this condition has been termed hypodopaminergic reward deficiency syndrome. As our preliminary data supports dopamine neurotransmission is under regulatory influence by insulin; insulin regulates intracellular trafficking of the transporter (analogous to insulin regulation of glucose transporter trafficking), and this trafficking is required to maintain the fidelity of dopamine signaling via the D2 receptor	UL1 TR0000445	Vanderbilt Clinical and Translational Science Award	\$291,467	Not Available	Not Available	Not Available
November 15, 2013	Parental Perceptions of Pharmacogenetic Testing in Children	This study will determine the aspects of pharmacogenetic testing that are acceptable to parents and those aspects that concern parents. This information will inform the development future study protocols to account for parental concerns. This project determines parental views toward pharmacogenetic testing in their children, even prenatally. The support by VICTR will allow for assistance with recruitment and the administrative aspects of the study which is being conducted on a K23.	National Institutes of Health K23HD000001	MTRNRI Amnioglycoside Otorotoxicity Outcomes and Parental Perceptions of Testing	\$527,760	Not Available	Not Available	Not Available
November 11, 2013	Energy Expenditure and Fatigability in Aging	Fatigue or persistent and unexplained tiredness is a common problem among older people with or without chronic disease and a key component to definitions of frailty. Fatigability is a construct that normalizes fatigue in a context of physical or cognitive activity with which the fatigue is associated. This study will establish preliminary criteria for measuring fatigability by simultaneous measurement of energy, amount of physical activity, and self-reported perceived fatigability induced by performing standardized physical activity tasks of various intensity in a rigorously controlled environment of a whole-room indirect calorimeter.	UL1 TR0000445	Vanderbilt Clinical and Translational Science Award	\$8,000	Not Available	Not Available	Not Available
November 11, 2013	Modafinil and Cognitive Function in Postural Tachycardia Syndrome: A Pilot Study	POTS is one of the most frequent forms of chronic orthostatic intolerance in the general population, affecting an estimated 500,000 people in the United States alone. While mental clouding is an almost universal complaint among these patients, the precise nature of the cognitive deficits and the optimal treatment strategies for this disease have not been described.	UL1 TR0000445	Vanderbilt Clinical and Translational Science Award	\$93,150	Not Available	Not Available	Not Available

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Year	Program Name	Brief Program Description	Funding Source #1	Grant Title	Funding Amount Granted	Patient Admissions	Patient Days	Outpatient Visits
November 21, 2013	Fibromyalgia Activity with TENS (FAST) BRE 12116- An Open-Label, Phase I Study of ARN-810 in Postmenopausal Women with Locally Advanced or Metastatic Estrogen Receptor Positive Breast Cancer	<p>Pain associated with fibromyalgia interferes with daily function, work, and social activities resulting in a decreased quality of life. In addition people with fibromyalgia have a significant amount fatigue and a fear of movement. Exercise interventions have similar effect sizes to drugs, though a significant barrier to their use is poor compliance. Poor compliance is thought to be related to pain during exercise and post-exertional malaise. A reduction in pain during exercise would reduce fear of movement and ultimately result in increased physical function and quality of life. Thus, one of the main treatments for patients with fibromyalgia must focus on pain relief during exercise to allow the person to benefit from improved fitness and to function more effectively both at home and at work. Transcutaneous electrical nerve stimulation (TENS) is a modality used by health professionals that delivers electrical stimulation through the skin for pain control. TENS activates descending inhibitory pathways from the midbrain and brainstem to inhibit excitability of nociceptive neurons in the spinal cord. Since TENS reduces central excitability and increases central inhibition of pain this treatment addresses the mechanisms thought to be central to the pain of people with fibromyalgia. Although TENS is effective for several pain conditions, its effectiveness in treatment of people with fibromyalgia is virtually unknown. While TENS is in itself not a novel treatment, the study design is novel. Specifically, for the first time we will examine pain not only at rest but also during movement, examine effects of TENS on physical activity levels, function and quality of life. We are using an experimental design for this trial similar to that used in clinical trials for assessment of pharmacological interventions that generally include pain, self-reported function and quality of life. In addition, we have added functional tasks that will be completed in the laboratory to directly assess function and are not commonly used in clinical trials. The use of these direct functional tests will give an additional measure of function and will provide the ability to validate self-reported function measures. These functional tests are commonly used in physical therapy practice and thus help to translate results to the clinic. Thus, using multiple outcomes to assess effectiveness and potential underlying mechanisms will overcome shortcomings in prior trials on TENS and assess the utility of a variety of outcome measures in people with fibromyalgia to examine definitively if TENS is effective in this patient population.</p> <p>To determine the maximum tolerated dose (MTD) and/or recommended Phase II dose (RP2D) and assess the safety of ARN-810 in postmenopausal women with locally advanced or metastatic ER+ (HER2-) breast cancer</p>	<p>National Institutes of Health UM1-AR-063381-01A1 This is a new multisite clinical trial with Dr. Crofford as co-PI and site-PI. Will be funded as a sub-contract from University of Iowa.</p>	Fibromyalgia Activity with TENS (FAST) Study	\$267,814	Not Available	Not Available	Not Available

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Year	Program Name	Brief Program Description	Funding Source #1	Grant Title	Funding Amount Granted	Patient Admissions	Patient Days	Outpatient Visits
November 25, 2013	Pilot Study of Extended-release Exenatide to Improve Glucose Control and Reduce Systemic Inflammation in Diabetic, HIV-infected Adults on Antiretroviral Therapy	HIV-infected persons on combination antiretroviral therapy have an approximately 2-fold higher risk of myocardial infarction and 4-fold higher risk of diabetes compared to age and sex-matched controls, in addition to a high prevalence of lipid disorders and lipodystrophy. Previous studies have shown that high levels of persistent systemic inflammation predict the development of cardiovascular and metabolic diseases in HIV-infected persons. Bydureon has demonstrated potent anti-inflammatory effects in prior studies of non-HIV infected individuals, and some data suggests favorable effects on lipid levels and maintenance of normal fat distribution, which may make it a unique and preferred medication for the treatment of insulin resistance in HIV-infected adults. The proportion of deaths due to non-AIDS related conditions now exceeds AIDS deaths among HIV-infected adults in the US, and complications of cardiovascular and metabolic diseases are a leading cause. The prevention of these long-term treatment complications has been identified as a research and funding priority by NIAID. This pilot study will yield data on the value of GLP-1 therapy to reduce systemic inflammation and potentially reduce the incidence of non-AIDS related conditions. The requested VICTR funds will permit a range of additional evaluations of the effect of GLP-1 treatment on body composition, metabolic parameters, and vascular function.	National Institutes of Health P30 AI045999	Vanderbilt Center for AIDS Research / Meharry Medical College / Career Development	\$7,047,080	Not Available	Not Available	Not Available
November 25, 2013	Early Anti-inflammatory Treatment in Patients with Acute ACL Tear and Painful Effusions	This study will evaluate whether Kenalog will reduce preoperative pain from ACL rupture.	UL1 TR000445	Vanderbilt Clinical and Translational Science Award	\$330	Not Available	Not Available	Not Available
December 2, 2013	Cognitive Aging Prevention Study (CAPS)	As the population continues to age, cognitive decline and dementia are becoming increasing public health issues. Previous research examining ways to attenuate or prevent abnormal cognitive aging has shown that lifestyle modifications like engaging in a regular exercise program can have a positive impact on cognition, particularly in areas dealing with executive function. Findings from the proposed project will advance knowledge regarding the role that exercise plays in brain aging. Our study's novelty lies in examining the effect that different types of exercise conditions have on brain aging. Such insights will contribute to novel strategies to delay or prevent progression from normal cognitive aging to mild cognitive impairment or dementia. The rapidly aging population and increasing prevalence of abnormal cognitive aging highlights the importance of developing novel insights and additional preventative measures for this major public health issue.	UL1 TR000445	Vanderbilt Clinical and Translational Science Award	\$74,320	Not Available	Not Available	Not Available
December 6, 2013	BOTOX® DB Upper Limb (191622-101)	To evaluate the safety and efficacy of a single treatment of 2 doses (6 U/kg and 3 U/kg) of BOTOX with standardized OT for the treatment of pediatric patients with Upper limb spasticity caused by cerebral palsy or stroke.	UL1 TR000445	Vanderbilt Clinical and Translational Science Award	\$25,800	Not Available	Not Available	Not Available

Year	Program Name	Brief Program Description	Funding Source #1	Grant Title	Funding Amount Granted	Patient Admissions	Patient Days	Outpatient Visits
December 13, 2013	Inflammation in CKD and CVD—the Role of Genetics and IL-1ra	There is strong evidence that chronic inflammation is highly prevalent in CKD patients and markers of inflammatory response is associated with cardiovascular (CV) outcomes and CKD progression in this patient population. Pro-inflammatory cytokines are known to have properties that can lead to accelerated progression of kidney disease and atherosclerosis. An imbalance between the circulating cytokines and their inhibitors, especially IL-1 and its inhibitor, might play a crucial role in this process. Recent studies support the active role of the inflammasome Nlrp3 and dependent cytokines such as IL-1 beta and IL-18 in CKD progression. Studies have shown that IL-1 blockade with the administration of interleukin 1 receptor antagonist effectively controlled the inflammatory response of advanced CKD 54. While certain kidney diseases such as diabetic nephropathy and glomerular diseases tend to have a higher prevalence of exaggerated inflammatory response, inflammation is a common aspect of most, if not all, moderate to advanced CKD patients regardless of the etiology. This intervention is direct patient care related.	Veterans Administration Career Development Award	VA/PA: Bockstiegel-Krembel, Anne (CH&R&D Merit Award—Hung)	\$23,413	Not Available	Not Available	Not Available
December 16, 2013	A Randomized, Double-blind, Pilot Study of PINTA 745, an Anti-myostatin Peptibody, in Patients with End Stage Renal Disease who Require Maintenance Hemodialysis and have Protein Energy Wasting	This is a pilot study to determine the optimal dose range, safety, pharmacokinetics and efficacy of PINTA 745, an anti-myostatin peptibody, in patients with end stage renal disease (ESRD) who have protein energy wasting (PEW) and are undergoing maintenance hemodialysis (MHD). The primary objectives are as follows: • To evaluate the safety, dose-limiting toxicities (DLTs), maximum tolerated dose (MTD) and pharmacokinetics of PINTA 745 • To evaluate percentage change in LBM relative to baseline at 12 weeks in the group receiving PINTA 745 at the MTD (or if no MTD is reached, at the recommended phase 2 dose)	ULL TR000445	Vanderbilt Clinical and Translational Science Award	\$36,672	Not Available	Not Available	Not Available

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Year	Program Name	Brief Program Description	Funding Source #1	Grant Title	Funding Amount Granted	Patient Admissions	Patient Days	Outpatient Visits
December 23, 2013	December 23, 2013 February 25, 2016 2:57 pm Cerebral Blood Volume Mapping of the Hippocampal Formation in Psychotic Disorders	The goal of this project is to identify the brain regions, differentially targeted by schizophrenia, using a high-resolution functional magnetic resonance imaging (fMRI) in patients in the first episode of psychosis and matched healthy controls. We will employ an imaging protocol similar to a recently published study of regional Cerebral Blood Volume (rCBV) mapping in psychosis (Schobel et al. 2009). In the future, we plan to integrate this rCBV method of imaging hippocampal subfields along with our behavioral, structural, and functional neuroimaging data. This will facilitate a comprehensive understanding of neural correlates of emerging psychoses. We are currently studying the neural substrates of relational memory in patients with schizophrenia (IRB # 060175; IRB # 081176, and IRB # 090016). Recent developments of high resolution fMRI offer superior anatomical resolution to detect functional activities in small subregions of the brain, implicated in schizophrenia, especially in the hippocampal formation. The CA1 subfield of the HF has been implicated in consolidation of contextual (non-relational) memory (Daumas et al., 2005). An increased differential CA1 activity at baseline by using rCBV measurement and an abnormal hippocampal recruitment during a relational memory task might provide a better understanding of an abnormal cortico-hippocampal-thalamic interaction in schizophrenia. We are now proposing to explore abnormal CA1 subfield activity, as measured by rCBV, as the neural substrate of relational memory deficits in first episode psychosis.	National Institutes of Health R01MH070560	Imaging Hippocampal Function in Psychosis	\$495,294	Not Available	Not Available	Not Available
January 7, 2014	A Three-Part, Phase 3, Randomized, Double-blind, Placebo-Controlled, Four-Arm, Discontinuation Study to Evaluate the Efficacy and Safety of Subcutaneous Injections of BMN 165 Self Administered by Adults With Phenylketonuria	Study BMN 165-302 is a three-part, Phase 3 study. Part 1 is an open-label run-in period designed to stabilize the dosing regimen of subjects who enroll from a previous BMN 165 study. Part 2 is a double-blind, placebo-controlled, four-arm, discontinuation study designed to compare the blood Phe concentrations of subjects who continue administration with BMN 165 versus those of subjects who temporarily receive placebo. Part 3 is a long-term, open-label extension study designed to evaluate the long-term efficacy and safety of BMN 165 and to provide long-term access to BMN 165.	UL1 TR0000445	Vanderbilt Clinical and Translational Science Award	\$75,330	Not Available	Not Available	Not Available
January 14, 2014	BOTOX® OL Upper Limb (191622-105)	The purpose of this study is to further investigate the safety of BOTOX treatment in pediatric cerebral palsy patients with upper limb spasticity. The aim is to support a change in labeling by the FDA for the use of Botox to treat muscle spasticity in children.	UL1 TR000445	Vanderbilt Clinical and Translational Science Award	\$58,100	Not Available	Not Available	Not Available

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Year	Program Name	Brief Program Description	Funding Source #1	Grant Title	Funding Amount Granted	Patient Admissions	Patient Days	Outpatient Visits
January 16, 2014	A Prospective, Randomized, Double-Blind, Placebo-Controlled Study to Evaluate the Safety and Effectiveness of Intranasal Carbetoicin in Subjects with Prader Willi Syndrome (PWS)	The neurohypophysial hormone, oxytocin, previously thought to only be responsible for milk ejection and uterine contraction during labor, has recently been identified as an important neurotransmitter and key modulator of behavior. Numerous non-clinical and clinical studies, including a small, single-dose, pilot study in PWS patients suggest that oxytocin delivered via the nasal route will provide therapeutic benefit in treating both hyperphagia and negative behaviors in PWS.	UL1 TR0000445	Vanderbilt Clinical and Translational Science Award	\$34,500	Not Available	Not Available	Not Available
January 16, 2014 February 25, 2016 2:57 pm	Changes in HIV-1 Immune Responses Associated with Pregnancy	Women comprise an increasing proportion of all HIV-infected persons, and most of these women are of child-bearing age. We have shown in a previous study that HIV-infected women taking antiretroviral therapy had a lower risk of HIV disease progression. The immunologic mechanism that may explain these findings are unknown and the interaction of immunologic factors such as generalized immune activation and regulatory T cells (Tregs) with HIV infection, HAART, and pregnancy have not been explored. The results of this project will be directly translational to humans in that it will provide an improved understanding of the impact that pregnancy has on HIV infection. This has broad implications for the clinical care of HIV-positive pregnant women, both during pregnancy and postpartum. Further understanding of the immunologic changes that occur during pregnancy in both HIV positive and HIV negative women could also have an impact on HIV vaccine design. This study will not be possible without support from VICTR. Funding will provide the necessary supplies, core services, and patient recruitment materials that will allow us to accomplish the aims of this project.	UL1 TR0000445	Vanderbilt Clinical and Translational Science Award	\$18,596	Not Available	Not Available	Not Available
January 17, 2014	Treatment of Children With Autism Spectrum Disorders and Epileptiform EEG With Divalproex Sodium	Epilepsy and epileptiform EEG abnormalities are common co-morbidities in Autism Spectrum Disorders (ASD) that can be considered important biomarkers of cortical dysfunction in these disorders. Epileptiform discharges are associated with deficits in attention, language and behavior, we believe that they may represent an important and novel treatment target in this population. The proposed study investigates the efficacy of using an anticonvulsant medication with spike suppression capabilities (valproate [VPA]) in the form of divalproex sodium) to treat children with ASD and isolated epileptiform EEGs.	UL1 TR0000445	Vanderbilt Clinical and Translational Science Award	\$60,575	Not Available	Not Available	Not Available
January 23, 2014	VICCPH1342 - A Phase 1, First-in-Human Study Evaluating the Safety, Tolerability, and Pharmacokinetics of AMG 337 in Adult Subjects with Advanced Solid Tumors.	AMG 337 is a small molecule drug, which is taken by mouth as a tablet. AMG 337 has the potential to block a receptor called c-Met which is located on cells within the body and tumor. It is hoped that blocking c-Met receptors may help stop tumor spread and growth. In laboratory studies, AMG 337 has been shown to block the c-Met receptor and tumor growth in mice. The purpose of this study is to help to understand whether the AMG 337 study drug can be given safely to humans who have advanced solid tumors. This study will also help determine the best dose or doses of AMG 337 to use in this study and in future studies involving AMG 337.	UL1 TR0000445	Vanderbilt Clinical and Translational Science Award	\$3,360	Not Available	Not Available	Not Available

Year	Program Name	Brief Program Description	Funding Source #1	Grant Title	Funding Amount Granted	Patient Admissions	Patient Days	Outpatient Visits
January 28, 2014	Validation of computational modeling in dialysis grafts	Hemodialysis access grafts are prone to thrombosis due to unnatural blood flow patterns caused by intimal thickening. We will be using CFD to gain a better understanding of the flow characteristics present in these grafts. By eventually applying machine learning algorithms to the flow data, we hope to develop a new technique for predicting Imminent graft failure.	UL1 TR000445	Vanderbilt Clinical and Translational Science Award	\$6,500	Not Available	Not Available	Not Available
February 25, 2014 2:57 pm	Effect of Exenatide on Body Weight in Patients with Hypothalamic Obesity	Hypothalamic obesity occurs in up to 60% of patients with brain tumors in the hypothalamic region. Brain tumor survivors who develop obesity have greater morbidity and mortality than normal weight survivors. This study will characterize the metabolic phenotype of patients with hypothalamic obesity and study the effects of exenatide on body weight and glucose control. This study will test the effectiveness of an available medication, exenatide, on glucose control and weight loss in patients with hypothalamic obesity.	UL1 TR000445	Vanderbilt Clinical and Translational Science Award	\$50,057	Not Available	Not Available	Not Available
February 5, 2014	Mitochondrial Dysfunction in Chronic Kidney Disease	Patients undergoing maintenance hemodialysis (MHD) are more susceptible to cardiovascular morbidity and mortality. Factors such as systemic inflammation and increased oxidative stress may play a role in accelerated atherosclerosis in these patients. Mitochondria are sources of reactive oxygen species (ROS) and oxidative stress. Mitochondrial dysfunction, by increasing oxidative stress and inflammation, has been implicated in the pathogenesis of atherosclerosis in the general population, and it has been described in patients on MHD. Despite the high incidence of cardiovascular events in hemodialysis patients, no therapeutic intervention has proven to be effective in reducing the cardiovascular mortality and morbidity in end-stage renal disease. Reduction of oxidative stress and inflammation by restoring mitochondrial function is a promising therapeutic approach to decrease the cardiovascular risk in this population.	National Institutes of Health K23 DK100533	Mitochondrial Dysfunction in Chronic Kidney Disease	\$761,150	Not Available	Not Available	Not Available
February 7, 2014	A RANDOMIZED, PLACEBO-CONTROLLED STUDY TO INVESTIGATE THE EFFICACY AND SAFETY OF CIRCADIN? TO ALEVIATE SLEEP DISTURBANCES IN CHILDREN WITH NEURODEVELOPMENTAL DISABILITIES NEU_CH_7911 (Sponsor: Neurim Pharmaceuticals)	This is a randomized placebo-controlled study in children diagnosed with autism spectrum disorders (ASD) and related neurodevelopmental disorders. This population has a high incidence of insomnia. The effect on caregiver's sleep quality will also be assessed as well as the child's social functioning improvements. The time release of this natural hormone that induces sleep may help children who have difficulty maintaining sleep as well as sleep onset difficulties. Improvements to caregiver's sleep quality translates into improved family functioning.	UL1 TR000445	Vanderbilt Clinical and Translational Science Award	\$4,090	Not Available	Not Available	Not Available
February 12, 2014	A Randomized, Double-Blind, Placebo-Controlled, Phase 3 Trial of Tadalafil for Duchenne Muscular Dystrophy	Availability of a pharmacological approach to treat DMD which targets pathophysiological mechanisms downstream from dystrophin deficiency, independent of individual genotype and potentially applicable to the broader populations of boys with DMD, would represent a substantial improvement in the care of boys with DMD. This clinical trial has already been translational to humans, and is now available for study as a possible treatment for boys with DMD.	UL1 TR000445	Vanderbilt Clinical and Translational Science Award	\$13,310	Not Available	Not Available	Not Available

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Year	Program Name	Brief Program Description	Funding Source #1	Grant Title	Funding Amount Granted	Patient Admissions	Patient Days	Outpatient Visits
February 12, 2014	BOTOX [®] DB Lower Limb (191622-111)	The primary objective of the study is to assess the safety and tolerability of ascending doses of IV PDA001 infused every other week for 8 weeks (5 total infusions) in subjects with CD with colonic involvement who are refractory to one or more of the following: oral corticosteroids, immunosuppressants and/or biologic agents. Traditional treatment for CD has focused on non-specific anti-inflammatory or immunosuppressive agents. More recently, biological therapies that target some of the specific immunological pathways responsible for CD pathogenesis have become available. For example, the anti-TNF agent infliximab has offered an important advance in therapy for some patients with CD. Unfortunately, a considerable proportion of patients is still unresponsive or loses response to therapy. Therefore there is a need for additional therapies to improve treatment for patients with CD. It is hypothesized that treatment with PDA001 will suppress the aberrant immune/inflammatory reactions involved in the pathogenesis of CD, thereby resulting in a decrease in CD symptoms and an increase in quality of life for individuals with CD.	U11 TR000445	Vanderbilt Clinical and Translational Science Award	\$39,000	Not Available	Not Available	Not Available
February 17, 2014	Metabolic intervention on the Right Ventricle in Pulmonary Arterial Hypertension	Metabolic abnormalities are common in patients with PAH and preliminary data suggest insulin resistance and lipid deposition lead to RV dysfunction in this population. Insulin resistance may therefore represent a therapeutic target in PAH but little is known about the metabolic phenotype of the RV. This study aims to define the metabolic phenotype of the RV in PAH in order to develop a mechanistic understanding of RV failure in PAH and guide the testing or development of metabolic therapies.	U11 TR000445	Vanderbilt Clinical and Translational Science Award	\$43,177	Not Available	Not Available	Not Available
February 18, 2014	A phase 3, randomized, double-blind, placebo-controlled, parallel-group, multicenter study to evaluate the safety and efficacy of ustekinumab induction therapy in subjects with moderately to severely active Crohn's disease	to evaluate the efficacy of IV induction regimens of ustekinumab in inducing clinical remission to evaluate the efficacy of IV induction regimens of ustekinumab in improving disease-specific health-related quality of life to evaluate the pharmacokinetics, pharmacodynamics of ustekinumab therapy	U11 TR000445	Vanderbilt Clinical and Translational Science Award	\$1,250	Not Available	Not Available	Not Available
February 18, 2014	BOTOX OL Lower Limb (191622-112)	The purpose of this study is to further investigate the safety of BOTOX treatment in pediatric cerebral palsy patients with lower limb spasticity. The aim is to support a change in labeling by the FDA for the use of Botox to treat muscle spasticity in children.	U11 TR000445	Vanderbilt Clinical and Translational Science Award	\$58,100	Not Available	Not Available	Not Available

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Year	Program Name	Brief Program Description	Funding Source #1	Grant Title	Funding Amount Granted	Patient Admissions	Patient Days	Outpatient Visits
February 2014	Determinants of Enuresis in Children and Adults with Sickle Cell Disease	Children and adults with sickle cell disease struggle with nocturnal enuresis more than the general population, negatively affecting their quality of life and detracting from their ability to participate in educational and social activities. Although several theories have been proposed, the mechanism of this increased prevalence of nocturnal enuresis is unknown. In order to study this problem, it is important to establish the physiology of sleep nights during which enuresis occurs and elucidate possible correlations.	UL1 TR000445	Vanderbilt Clinical and Translational Science Award	\$10,068	Not Available	Not Available	Not Available
February 2014 February 25, 2016 2:57 pm	Role of Ghrelin in the Improvement of Insulin Resistance after Roux-en-Y Gastric Bypass Surgery	It is widely known that bariatric surgery, especially Roux-en-Y gastric bypass (RYGB), results in substantial, sustainable weight loss, especially in the excessively obese (BMI >40kg/m ²). Data indicate that diabetes and insulin resistance improve within the first week after RYGB, before apparent weight loss. We hypothesize that changes in metabolic hormones, specifically ghrelin, contribute to the early improvements in insulin resistance resultant from RYGB. Ghrelin contributes to the regulation of food intake and energy balance. In the obese, ghrelin levels are low, likely reflecting a positive energy balance. We have observed that ghrelin levels actually begin to decline during the RYGB operation, continuing to decrease after for about a month before returning to preoperative levels around 6 months post-operatively. This, along with research showing that infusing ghrelin into humans promotes insulin resistance, suggests that the immediate decline in ghrelin post-RYGB might contribute to improvements in insulin sensitivity independent of weight loss. Because more than 1/3 of American adults are obese and the costs of this problem are astronomical, elucidating mechanisms that contribute to the resolution of obesity and insulin resistance is of extreme importance.	UL1 TR000445	Vanderbilt Clinical and Translational Science Award	\$119,905	Not Available	Not Available	Not Available

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Year	Program Name	Brief Program Description	Funding Source #1	Grant Title	Funding Amount Granted	Patient Admissions	Patient Days	Outpatient Visits
February 27, 2014	<p>AS317 - Effects of Telmisartan on Fibrotic and Inflammatory Contributors to End-Organ Disease in HIV-Infected Patients Well Controlled on Antiretroviral Therapy</p>	<p>Therapeutic interventions other than ART are needed to improve clinical outcomes in chronically HIV-infected patients. ART has dramatically improved clinical outcomes and survival in individuals infected with HIV [1]. However, diseases of inflammation, including cardiovascular disease, diabetes, malignancies, and hepatic disease are emerging as leading causes of morbidity and mortality in HIV-infected individuals [1-4]. Similarly, markers of systemic inflammation (interleukin-6 [IL-6], C-reactive protein [CRP] and soluble CD14 [sCD14]), coagulation pathway activation (D-dimer), and increased fibrosis (hyaluronic acid) are independent predictors of all-cause mortality in HIV infection [5-7]. Telmisartan has numerous potential benefits in HIV-infected patients: Telmisartan therapy is associated with greater metabolic benefits than other ARBs, earning it the nickname "diabetic-sparing" [34]. In HIV-uninfected subjects, telmisartan has been shown to decrease visceral adipose tissue (VAT) volume and cardiovascular mortality; improve surrogate markers of atherosclerotic disease; improve fasting lipid and glucose parameters; and improve markers of vascular inflammation, endothelial, and renal function [8, 35-39]. The range of benefits associated with this drug is likely related to the systemic role of the RAS and the wide distribution of PPAR-γ receptors. In the setting of HIV infection, ritonavir-boosted protease inhibitors (PIs) have been associated with RAS activation [40], making telmisartan a candidate to improve cardiovascular risk in HIV-infected patients via both traditional and HIV-specific pathways. The biopsy procedure needs to be carried out in an outpatient setting with the ability to set up a sterile field with access to cautery equipment. Without core services provided by the CRC we would have to schedule for a surgery center which is cost prohibitive and we would not be able to take part in this important study.</p>	National Institutes of Health UM1A1069439	Vanderbilt HIV Clinical Trials Unit	\$11,928,141	Not Available	Not Available	Not Available
February 27, 2014	<p>Evaluating Cardiac Biomarkers in Healthy Children</p>	<p>Neuregulin is a growth factor that can be used as a marker of fitness in young adults and a marker of heart failure in patients with cardiomyopathy. It also has significant potential as a therapeutic for patients with cardiomyopathy. Before it can be used in the assessment or treatment of pediatric patients with cardiomyopathy, investigators must acquire a better understanding of neuregulin levels in healthy children. This project will allow serum biomarkers evaluated in research laboratories, including neuregulin, brain-derived neurotrophic factor, and osteopontin in patients with DMD, to be evaluated in patients with clinical disease. A comparison group of healthy children is integral to the assessment of serum biomarker levels. This study will provide money for the collection of extensive cardiac data (adding a VO2 to the exercise test to better evaluate fitness and provide an approximation of cardiac output) as well as blood samples in healthy children referred for exercise testing.</p>	UL1 TR000445	Vanderbilt Clinical and Translational Science Award	\$7,849	Not Available	Not Available	Not Available
February 27, 2014	<p>(VVRP 2013.02) A Study to Assess Persistence of the Immune Response after Vaccination with a Stephylococcus Aureus 4-Antigen (SA4Ag) Vaccine (B3451014 Pfizer)</p>	<p>Pfizer is developing SA4Ag vaccine for the prevention of ISA disease in at-risk patient populations. Currently there is no licensed vaccine indicated for prevention of ISA disease. A vaccine capable of preventing the most serious manifestations of S. aureus disease could achieve meaningful reductions in this disease burden in many at-risk populations while also reducing both the cost to healthcare systems and the global dependence on a limited number of antibiotics effective against MRSA infections.</p>	UL1 TR000445	Vanderbilt Clinical and Translational Science Award	\$1,125	Not Available	Not Available	Not Available

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Year	Program Name	Brief Program Description	Funding Source #1	Grant Title	Funding Amount Granted	Patient Admissions	Patient Days	Outpatient Visits
March 5, 2014	HVTN 505	This study will test the immunogenicity and potential protective efficacy of an Adenovirus vector expressing HIV antigens. We will be recruiting adenovirus-seronegative Gay men at high risk for HIV infection. This study will test the relationship between induced immune responses and control of viremia in subjects who become HIV infected over the course of the trial.	VUMC36217(UMIA1068614)	HVTN 505	\$2,059,840	Not Available	Not Available	Not Available
March 6, 2014	A PROSPECTIVE, RANDOMIZED, DOUBLE-BLIND, SHAM-CONTROLLED, MULTICENTER, PHASE 3 STUDY OF OTO-201 GIVEN AS A SINGLE INTRATYMPANIC INJECTION FOR INTRA-OPERATIVE TREATMENT OF MIDDLE EAR EFFUSION IN PEDIATRIC SUBJECTS REQUIRING TYMPANOSTOMY TUBE PLACEMENT	Otitis media (OM) is the most common infection for which antibiotics are prescribed to children in the United States (AAP, AAPF 2004). Otorrhea following TT placement may be attributed in part to incomplete eradication of infectious organisms at the time of surgery. For this reason, a course of topical antibiotic ear drops is often used following TT placement, despite the fact that these antibiotic ear drops are not approved for this indication. Thus, there is an unmet medical need for an approved, sustained-release antibiotic therapy that can be administered once by the pediatric otolaryngologist at the time of TT placement, thereby eliminating the need for repeat administration and providing sufficient exposure to effectively treat middle ear effusion in pediatric subjects requiring TT placement.	UL1 TR0000445	Vanderbilt Clinical and Translational Science Award	\$100	Not Available	Not Available	Not Available
March 6, 2014	Epileptiform Discharges and its Relation to Cognition and Behaviors in Children with Autism Spectrum Disorders	We will collect comprehensive 21-channel overnight sleep EEGs and behavioral data in a cohort of at least 60 children with ASD, ages 3-7 years, who represent a broader ASD population with average or below average IQ and epileptiform or non epileptiform EEGs.	National Institutes of Health UAS3MC11054	Epileptiform Discharges and its Relation to Cognition and Behavior in Children with Autism Spectrum Disorders	\$120,548	Not Available	Not Available	Not Available
March 11, 2014	VX12-809-105: A Phase 3, Roll-over Study to Evaluate the Safety and Efficacy of Long-term Treatment With Lumacator in Combination With Ivacaftor in Subjects Aged 12 Years and Older With Cystic Fibrosis, Homozygous or Heterozygous for the F508del-CFTR Mutation	We will define unique phenotypes of children with ASD which will form the basis of an NIH interventional trial in which ASD children will be treated with sodium valproate to determine if abolishment or amelioration of sleep LEDs improves sleep, daytime behavior, or cognitive skills. This grant seeks to answer a common clinical question in autism clinics- If a child has epileptiform discharges on his EEG, is this associated with difficulties in learning, memory, receptive language, mood, and attention. How does sleep effect both of these parameters? These data will form the background necessary to apply for an R01 grant where we will suppress the epileptiform discharges with anti seizure medication and observe whether changes in sleep or suppression of the discharges changes behavior and cognitive skills, thus improving the ability to learn.	UL1 TR0000445	Vanderbilt Clinical and Translational Science Award	\$17,280	Not Available	Not Available	Not Available

Year	Program Name	Brief Program Description	Funding Source #1	Grant Title	Funding Amount Granted	Patient Admissions	Patient Days	Outpatient Visits
March 13, 2014	Testing Tissue Sodium Stores in CAPD Patients Receiving Icodextrin or Glucose-Based Dialysate, A Randomized Trial—Aims 1 & 2	Our overarching goal is to improve long-term outcomes for ESRD patients. In this study we focus specifically on patients receiving peritoneal dialysis (PD). Volume regulation in PD patients is related to hypertension, heart failure, nutritional status, and survival. Salt (NaCl) is the body's ion transport target to normally regulate volume via the kidneys; however, in hemodialysis (HD) patients the dialyser or in PD patients the peritoneal membrane, must serve that purpose. Determining volume status in PD patients is not easy and monitoring sodium (Na+) is more difficult still. We have developed a novel, noninvasive approach to this problem involving 23Na+ magnetic resonance imaging (Na-MRI). Na+ is stored bound to proteoglycans in mostly the skin. Our technique measures Na+ in skin and skeletal muscle. In this study, we propose to apply this novel technique to PD patients. Studies in this high risk population are likely to provide novel insights into risk factors for cardiovascular disease that apply to all human populations. This understanding may lead to novel therapies for patients with renal disease, as well as the general population.	UL1 TR000445	Vanderbilt Clinical and Translational Science Award	\$5,395	Not Available	Not Available	Not Available
March 13, 2014	Microbial Induction of CD4+ T cell dysfunction (CLEAR 2)	Sarcoidosis is a idiopathic, granulomatous disease characterized by progressive loss of pulmonary forced vital capacity (FVC) in ~ 50% of subjects. The mechanisms driving this loss are not clear; however, pathogenic mycobacteria visualized in sarcoidosis BAL may drive loss of CD4+ T cell function through inactivation of the tyrosine kinase, Lck. We have NIH support to conduct a Phase II, multicenter, randomized, placebo-controlled investigation of the effects of antimycobacterial therapy on sarcoidosis FVC and T cell function. We will conduct research bronchoscopies at study entry, as well as after completion of the regimen. With the BAL-derived T cells, we will assess the effects of antimycobacterial therapy on sarcoidosis T cell function, such as proliferation.	National Institutes of Health R01HL117074	Microbial Induction of sarcoidosis CD4+ T cell dysfunction	\$721,130	Not Available	Not Available	Not Available
March 13, 2014	Genomic Research of AIAT Deficiency and Sarcoidosis (GRADS)	Specific Aims: 1. To compare the lower respiratory tract microbiome and virome population diversity and content in age and GOLD stage matched PIZZ individuals not receiving augmentation therapy, PIZZ individuals on augmentation therapy, PIMZ individuals not receiving augmentation therapy, and PIMM individuals with COPD. 1.2. Determine correlations between bronchoalveolar lavage (BAL) and peripheral blood gene expression patterns and patterns in lung microbial and viral populations across all cohorts. 1.3. Correlate the presence or absence of computed tomography (CT) bronchiectasis and bronchiolectasis with patterns in the microbiome population diversity and content. 1.4. To identify and define novel molecular phenotypes of AATD based on computational integration of clinical, transcriptomic, and microbiome data. We are interested in the impact that microbial diversity has on loss of expiratory function in AIAT patients, as well as the lung phenotypes that are seen. Correlation with a specific microorganism may allow identification of antibiotic therapy that may alter disease progression or loss of lung function.	National Institutes of Health U01HL112694	Investigation of microbial heterogeneity to sarcoidosis and ATT clinical outcome	\$463,022	Not Available	Not Available	Not Available

Year	Program Name	Brief Program Description	Funding Source #1	Grant Title	Funding Amount Granted	Patient Admissions	Patient Days	Outpatient Visits
March 14, 2014	A PROSPECTIVE, RANDOMIZED, DOUBLE-BLIND, PLACEBO-CONTROLLED, MULTICENTER, PHASE 2b STUDY OF OTO-104 GIVEN AS A SINGLE INTRATYMPANIC INJECTION IN SUBJECTS WITH UNILATERAL MENIERE'S DISEASE	Meniere's disease is an idiopathic syndrome of endolymphatic hydrops (Committee on Hearing and Equilibrium, 1995). It is associated with a distinct pattern of clinical symptoms comprised of vertigo, hearing loss, tinnitus and aural fullness. It is more frequently unilateral than bilateral. Episodic vertigo is considered the most prominent symptom, with episodes typically lasting at least 20 minutes and resulting in significant patient morbidity. There continues to be an unmet medical need for therapies to address this debilitating disease. This is a randomized, double blind, placebo-controlled, multicenter 20-week Phase 2b study with participants receiving a single intratympanic injection of either 12 mg OTO-104 or placebo.	UL1 TR000445	Vanderbilt Clinical and Translational Science Award	\$5,325	Not Available	Not Available	Not Available
February 25, 2014 5:57 pm	Phosphodiesterase-5 inhibition and insulin signaling in skeletal muscle	Obesity and insulin resistance produces abnormalities in insulin-stimulated insulin receptor signaling in skeletal muscle. Insulin stimulation of the phosphatidylinositol 3-kinase (PI3-kinase) as measured by phosphorylation of the insulin receptor and IRS-1 and by IRS protein association with p85 and with PI3-kinase is impaired in obese subjects. Recent studies reported that phosphodiesterase-5 inhibition prevented the attenuation in insulin-mediated Akt phosphorylation in vascular tissue from high-fat compared with low-fat mice. In this sub-study, we will determine if prolonged PDE-5 inhibition exerts a favorable effect on insulin signaling pathways in skeletal muscle in subjects with impaired glucose tolerance.	UL1 TR000445	Vanderbilt Clinical and Translational Science Award	\$38,048	Not Available	Not Available	Not Available
March 31, 2014	(VVRP 2013.01) A Phase II, Multicenter, Randomized, Observer-Blind, Controlled Study to Evaluate Safety and Immunogenicity of a Trivalent Group B Streptococcus Vaccine in Healthy Pregnant Women (Novartis V98_12)	The aim of this phase II study is to evaluate the concentration of serotype-specific GBS antibodies in infants born to maternal subjects measured at birth, Day 42 and Day 90 of age. The safety and immunogenicity of the GBS trivalent vaccine in maternal subjects, when administered at 28 0/7 through 34 6/7 weeks of gestation, will also be evaluated.	UL1 TR000445	Vanderbilt Clinical and Translational Science Award	\$7,500	Not Available	Not Available	Not Available
April 1, 2014	: A5315 - A Phase I/II Study of Single Dose Romidepsin in HIV-Infected Adults with Suppressed Viremia on Antiretroviral Therapy to Assess Safety, Tolerability, and Activation of HIV-1 Expression	This study will explore the level of σ gA and IgG antibodies specific to the GBS capsular polysaccharides present in breast milk in the first 90 days postpartum, in maternal subjects who have been vaccinated with GBS vaccine at 28 0/7 through 34 6/7 weeks of gestation. With the knowledge learned from this study, it is anticipated to provide a FDA approved vaccine that is able to provide GBS protection to both the mother and infant.	National Institutes of Health UM1A10069439	Vanderbilt HIV Clinical Trials Unit	\$11,928,141	Not Available	Not Available	Not Available

Year	Program Name	Brief Program Description	Funding Source #1	Grant Title	Funding Amount Granted	Patient Admissions	Patient Days	Outpatient Visits
<p>April 1, 2014</p> <p>February 25, 2016 2:57 pm</p>	<p>Effect of Passive Immunization on the Progression of Mild Alzheimer's Disease: Solanezumab (LY2062430) Versus Placebo</p>	<p>Study H8A-MC-LZAX (LZAX) is a Phase 3, placebo-controlled study in mild AD patients. Study LZAX is designed to collect data on the long-term safety and efficacy of solanezumab, including cognitive outcomes, as well as functional outcomes, quality of life, resource utilization, and biomarker measures. Study Rationale: Alzheimer's disease (AD) is an age-related neurodegenerative disorder characterized by progressive decline in cognitive function and ability to perform activities of daily living, and ultimately can lead to death due to complications of the disease. The amyloid-β ($A\beta$) hypothesis for AD, which states that the production and deposition of $A\beta$ (later forming neuritic $A\beta$ plaques) is an early and necessary event in the pathogenesis of AD, suggests that treatments that slow the synthesis or deposition of $A\beta$, or that increase clearance, might be expected to slow the progression of AD.</p>	<p>UL1 TR0000445</p>	<p>Vanderbilt Clinical and Translational Science Award</p>	<p>\$48,000</p>	<p>Not Available</p>	<p>Not Available</p>	<p>Not Available</p>
<p>April 9, 2014</p>	<p>THN 1326-A Phase II, Multi-Centre, Randomized, Double-Blind, Placebo-Controlled Study Comparing The Efficacy and Safety of Clonidine Lauriad 50 μg and 100 μg Mucoadhesive Buccal Tablet (MBT) Applied Once Daily to Those of Placebo in the Prevention and Treatment of Chemoradiation Therapy Induced Oral Mucositis in Patients with Head and Neck Cancer</p>	<p>To demonstrate the efficacy of clonidine Lauriad, c 50 μg and 100 μg MBT versus placebo in the prevention and treatment of chemoradiation therapy induced oral mucositis. Study is looking to compare study drug to placebo to determine efficacy in order to use in patients with oral mucositis.</p>	<p>UL1 TR0000445</p>	<p>Vanderbilt Clinical and Translational Science Award</p>	<p>\$240</p>	<p>Not Available</p>	<p>Not Available</p>	<p>Not Available</p>
<p>April 14, 2014</p>	<p>RYGB and the Gastric Adipose Axis</p>	<p>Recent evidence has shown that specific gut hormones and peptides administered at physiological or pathophysiological concentrations can influence appetite via the CNS. Gut hormones and peptides have important physiological roles in postprandial satiety, appetite control and maintenance of energy homeostasis; therefore gut hormone signaling systems represent important pharmaceutical targets for potential future anti-obesity therapies. The role of the interruption of the stomach (via RYGB) in triggering early metabolic improvements has never been studied and is suggested by our preliminary data. It is clear from animal studies that inhibition of the ghrelin/GHS-R1a signaling pathway represents a potential approach for treating obesity in mice and rats. If proven successful, our work could lead to performance of less invasive surgical procedures in combination with pharmacologic manipulation of either ghrelin production (such as inhibiting GOAT), or development of selective blockers of acylated ghrelin.</p>	<p>National Institutes of Health R01DK091748</p>	<p>RYGB Improves Metabolism by Interrupting the Gastric Adipose Tissue Axis</p>	<p>\$591,043</p>	<p>Not Available</p>	<p>Not Available</p>	<p>Not Available</p>

Year	Program Name	Brief Program Description	Funding Source #1	Grant Title	Funding Amount Granted	Patient Admissions	Patient Days	Outpatient Visits
April 17, 2014	Effects of Age and Scopolamine on Multi-Sensory Integration and Learning	In healthy aging, the ability to learn new information and skills is impaired compared to young adults. At the foundation of these learning processes is the information that must be associated, information that is often specified across the different sensory modalities. The current study will determine whether cognitive impairments in aging are related to decline in multisensory processing and/or multisensory learning. We are examining a new hypothesis concerning the cause of cognitive impairments with age, impaired multi-sensory plasticity. Our findings will guide clinicians, in the future, when approached by nondemented, aged individuals experiencing declines in memory and attention. Space and nursing support at the CRC is vital to our data collection and safety of our subjects.	UL1 TR000445	Vanderbilt Clinical and Translational Science Award	\$28,273	Not Available	Not Available	Not Available
February 25, 2014 8:57 pm	Impact of Auditory Access on Sleep Quality of Individuals with Profound Hearing Loss	Individuals with profound hearing loss who use cochlear implants remove their cochlear implants during sleep and eliminate auditory access during sleep. As fully implantable cochlear implants become available, individuals will have auditory access when awake and asleep. It is unknown whether continuous auditory access is beneficial or detrimental to individuals with hearing loss. The purpose of this exploratory study is to examine the impact of auditory access on quality of sleep in individuals with profound hearing loss who typically do not have auditory access during sleep.	UL1 TR000445	Vanderbilt Clinical and Translational Science Award	\$6,483	Not Available	Not Available	Not Available
April 22, 2014	A Phase I double-blind, randomized, placebo-controlled, staggered, single and multiple ascending dose, multicenter study evaluating the safety, tolerability, pharmacokinetics and efficacy of GS-5745 in subjects with moderate to severe ulcerative colitis (Gilead GS-326-0101)	To assess the safety and tolerability of escalating single and multiple doses of GS-5745 in subjects with moderate to severe ulcerative colitis as assessed by adverse events and laboratory abnormalities	UL1 TR000445	Vanderbilt Clinical and Translational Science Award	\$5,050	Not Available	Not Available	Not Available
April 24, 2014	Synapdx Autism Spectrum Disorder Gene Expression Analysis (STORY) Study	Autism Spectrum Disorders (ASD) are pervasive developmental disorders that are being diagnosed at increasing rates likely due to increased sensitivity by clinicians and a true increase in frequency. With mounting evidence that behavioral therapy is effective and that the beneficial effects are likely associated with age at which therapy begins, the need for early diagnosis has intensified. Unlike most other areas of medicine, medical diagnostic tests are not available for making a diagnosis of ASD. Validating an RNA-based signature that can distinguish between ASD and other developmental disorders could enable a more rapid and accurate diagnosis. Earlier diagnosis facilitates earlier access to clinically important interventions and therapies that may have a profound impact on children's development.	UL1 TR000445	Vanderbilt Clinical and Translational Science Award	\$24,500	Not Available	Not Available	Not Available

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Year	Program Name	Brief Program Description	Funding Source #1	Grant Title	Funding Amount Granted	Patient Admissions	Patient Days	Outpatient Visits
April 29, 2014	VICCHEM1315 & "Open-label, uncontrolled Phase II trial of Intravenous PI3K inhibitor BAY 80-6946 in patients with relapsed, indolent or aggressive Non-Hodgkin's lymphomas	In general, treatment with standard agents rarely produces a cure in patients whose non-Hodgkin Lymphoma (NHL) has relapsed. Sustained remissions after relapse can often be obtained in patients with indolent lymphomas, but relapse will usually ensue. Considering the pre-clinical profile of the investigational drug, BAY 80-6946, it is expected that this compound will show anti-tumor activity also in patients with indolent and aggressive lymphomas. The study will provide data on the efficacy and safety of a new investigational drug that could potentially be used to treat people with relapsed or refractory NHL.	UL1 TR000445	Vanderbilt Clinical and Translational Science Award	\$7,881	Not Available	Not Available	Not Available
February 25, 2014	A Pilot Study of Perioperative Oral Nutrition Supplementation to Improve Nutritional Status and Clinical Outcomes in Patients Undergoing Radical Cystectomy	Surgical removal of the bladder (radical cystectomy) and urinary diversion for bladder cancer is a complex and morbid procedure with 25-64% of patients experiencing post-operative complications. Studies have shown that nutritional status in radical cystectomy patients is associated with morbidity and mortality. To date, there have been very few studies designed to improve the nutritional status of radical cystectomy patients and to determine if this will decrease complication rates thereby translating into decreased length of stay (LOS), readmission rates and LOS for readmission. The majority of these adverse events occur within the initial 30 day period post-operatively. Therefore the problem we seek to address is the 30d morbidity associated with radical cystectomy, specifically: the high incidence of post-operative complications, extended LOS, frequent readmissions and LOS for readmission.	UL1 TR000445	Vanderbilt Clinical and Translational Science Award	\$53,420	Not Available	Not Available	Not Available
April 29, 2014	Autonomic Evaluation in Obesity Associated Hypertension	We are trying to get a complete autonomic and metabolic profile of in obese hypertensives and controls to get a better understanding of why obese subjects develop endothelial dysfunction and sympathetic overactivity. This study will give us a way of developing better tools to target obesity associated hypertension.	National Institutes of Health K23HL095905	Sympathetic Nervous System and Nitric Oxide in Obesity Associated Hypertension	\$150,874	Not Available	Not Available	Not Available
May 7, 2014	Genetic, Hormonal, And Signaling Interactions in PAH	All phases of this project depend upon the correct phenotyping of all subjects enrolled. Certain subjects may have pre-clinical disease. The best, non-invasive, screening tool available to determine early onset pulmonary hypertension is the echocardiogram. Therefore, we want to be able to use this tool in evaluation of "at risk" family members who are carriers of a gene predisposing them to develop pulmonary arterial hypertension. The overall study is evaluating the interactions of sex hormones, metabolic syndrome and different signaling pathways, including BMP2 and CAV1, on the development of pulmonary hypertension. Accurate comparisons for all of the studies cannot be made without correctly phenotyping enrolled subjects. All three of the projects may lead to development of new treatment options for these patients and their families.	National Institutes of Health P01HL108800	Hormonal, Metabolic and Signaling Interactions in PAH	\$13,576,414	Not Available	Not Available	Not Available

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Year	Program Name	Brief Program Description	Funding Source #1	Grant Title	Funding Amount Granted	Patient Admissions	Patient Days	Outpatient Visits
May 13, 2014	Norepinephrine Transporter Blockade as a Pathophysiological Biomarker in Neurogenic Orthostatic Hypotension	Diseases of the autonomic nervous system may result in a drop in blood pressure on standing and may lead to fainting. Pure Autonomic Failure (PAF), Multiple System Atrophy (MSA) and Parkinson's Disease (PD) are disorders of the autonomic nervous system and present with very similar symptoms, making it difficult to determine an exact diagnosis. The purpose of the study is to find out if the blood pressure response from taking a single dose of atomoxetine can help in the diagnosis of these diseases. Based on our preliminary data, we propose that the effect of a NET blockade will depend on the level of the lesion. There is evidence that a single dose of atomoxetine acutely increases blood pressure in MSA, but not in PAF or PD. We propose a multi-center study to determine if our preliminary results will translate into an effective disease predictor biomarker for MSA, distinguishing this disorder from PAF and PD. Diagnosis of early forms of MSA is challenging particularly when individuals present with only neurogenic orthostatic without neurological symptoms. Detect patients in this early stage is paramount in the development of therapeutic agents which goal is to delay the progression of the disease. This study combines the use of pharmacologic agents and disease pathophysiology to develop a novel diagnostic tool that is simple and accessible to clinicians for the early detection of MSA.	National Institutes of Health US4NS065736	Autonomic Rare Diseases Clinical Research Consortium	\$1,250,002	Not Available	Not Available	Not Available
May 14, 2014	A Phase 2, randomized, double-blind, placebo-controlled study of AeroVanc for the treatment of persistent methicillin-resistant Staphylococcus aureus lung infection in cystic fibrosis patients	The primary objective of the study is to evaluate the efficacy of AeroVanc in reducing the quantity of methicillin-resistant Staphylococcus aureus (MRSA) colony forming units (CFU) in the sputum cultures of cystic fibrosis (CF) patients with persistent MRSA lung infection.	UL1 TR0000445	Vanderbilt Clinical and Translational Science Award	\$8,400	Not Available	Not Available	Not Available
May 20, 2014	Serum Manganese levels in patients with Restless Legs Syndrome versus controls	The purpose of the current proposed study is to draw blood from 10 adult RLS patients age 21 and over and 10 age and sex matched controls and determine the Mn and Fe levels in both groups by inductively coupled plasma-Mass Spectrometry (ICP-MS), at the University of Trondheim, Norway. Dr. Aschner has an established and ongoing collaboration with Professor Syversen at Trondheim (please see references). We will need < 1 ml of whole blood/subject that will be delivered to the laboratory of Dr. Aschner for analysis. Future studies could investigate whether altered Mn levels play a role in the pathology of RLS and whether altering blood Mn can improve the symptoms of RLS. There is already a counterpart for this as altering iron levels in RLS patients has been shown to improve symptoms.	UL1 TR0000445	Vanderbilt Clinical and Translational Science Award	\$278	Not Available	Not Available	Not Available

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Year	Program Name	Brief Program Description	Funding Source #1	Grant Title	Funding Amount Granted	Patient Admissions	Patient Days	Outpatient Visits
May 20, 2014	RENIN-ANGIOTENSIN AND FIBRINOLYSIS INTERACTION IN HUMANS; Effect of Long-Term PDES Inhibition on Glucos Homeostasis	The World Health Organization predicts seven million incident cases of Type 2 diabetes mellitus (T2DM) per year. Individuals who have impaired glucose tolerance are at increased risk for T2DM. Existing pharmacological interventions to prevent T2DM such as metformin or rosiglitazone may have negative renal or cardiovascular effect. Developing new strategies to prevent the development of T2DM are therefore needed. In this context, the proposed studies are aimed to provide new information relevant to the biology of increasing cGMP, particularly its effect on glucose homeostasis. Previous studies have showed that insulin resistance improves in obesity animal models by increasing cGMP availability with PD5-inhibitor, sildenafil. The current project aimed at studying the effect of chronic administration of sildenafil on glucose homeostasis in humans and determine its underlying mechanism (improvement in insulin resistance and/or beta cell function). With a number of new pharmacological strategies to increase cGMP emerging, these studies could have a major impact on the incidence of diabetes.	National Institutes of Health R01HL060906	Renin-Angiotensin and Fibrinolysis Interaction in Humans	\$1,658,543	Not Available	Not Available	Not Available
February 25, 2014 2:57 pm								
May 30, 2014	Oxidative Stress in Chronic Kidney Disease	The goals of this proposal are to develop enhanced understanding of how the loss of kidney function leads to increased oxidative stress, inflammation, endothelial dysfunction, and accelerated development of cardiovascular disease. SPECIFIC AIMS: (1) Characterize the inter-relationships between oxidative stress, inflammation, and endothelial dysfunction in patients with chronic kidney disease; (2) Determine prospectively whether increased oxidative stress, inflammation, and endothelial dysfunction are risk factors for cardiovascular events in patients with chronic kidney disease; (3) Determine prospectively whether progressive loss of kidney function over time influences oxidative stress, inflammation, endothelial dysfunction, and cardiovascular disease in patients with chronic kidney disease. The proposed project will explore the contribution of increased oxidative stress, inflammation, and endothelial dysfunction on the progression of cardiovascular disease in patients with chronic kidney disease. If this is the case, then strategies to prevent increased oxidative stress, inflammation, and endothelial dysfunction become even more important to prevent future development of cardiovascular disease.	UL1 TR000445	Vanderbilt Clinical and Translational Science Award	\$42,900	Not Available	Not Available	Not Available
June 5, 2014	Association between performance and perceived fatigue in adolescents with Crohn's disease	Crohn's disease is a type of inflammatory bowel disease (IBD), and the most common chronic gastrointestinal disease in children, often leading to chronic morbidity even as its activity waxes and wanes. The reported prevalence of fatigue in adults with quiescent IBD is >40%, and fatigue is a very common clinical symptom reported by adolescents with Crohn's disease that significantly diminishes their quality of life. Clinical symptoms of Crohn's disease range from quiescent to severe, and one measure of disease activity is the Pediatric Crohn's Disease Activity Index (PCDAI). We expect that this study would guide the development of interventions for preventing and/or treating fatigue in patients with Crohn's disease.	UL1 TR000445	Vanderbilt Clinical and Translational Science Award	\$9,260	Not Available	Not Available	Not Available

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Year	Program Name	Brief Program Description	Funding Source #1	Grant Title	Funding Amount Granted	Patient Admissions	Patient Days	Outpatient Visits
June 9, 2014	Capsid-targeting HIV-1 antivirals	This study will address the mechanism of what cellular component inhibits replication of PF74 resistant viruses 4Mut and 5Mut. It will also elucidate why PF74 is less potent in macrophages. The discovery of anti HIV-1 mechanism by PF74 enable people to develop a new class of anti HIV-1 inhibitor drug. Though bunch of cell lines have been tested for anti HIV-1 potency by PF74, the anti viral function in primary T cells have yet to be addressed. The mechanism of 4Mut and 5Mut replication deficiency in macrophages need also to be addressed. The fund will fulfill us to accomplish our aim.	National Institutes of Health R01AI089401	Capsid-Targeting HIV-1 Antivirals	\$2,908,963	Not Available	Not Available	Not Available
February 25, 2014 1:14 pm 2:57 pm	Cerebrospinal Fluid Markers of Post-Hemorrhagic Hydrocephalus	For SA2, L1CAM, NCAM-1, APP, brevican and other protein levels will be measured in CSF samples taken at the initiation of PHH treatment and again at TEA during the permanent CSF diversion procedure, if one is required. In addition, relevant clinical data points, including complications such as infection or repeat/revision neurosurgery, follow-up imaging findings, neurological morbidity, mortality, and other factors that may influence neurodevelopmental outcome will be collected to inform interpretation of the CSF marker data.	U11 TR000445	Vanderbilt Clinical and Translational Science Award	\$100	Not Available	Not Available	Not Available
June 12, 2014	Randomized, Double-Blind, Placebo Controlled, Phase 2a Trial of ZGN-440, a Novel Methionine Aminopeptidase 2 Inhibitor, in Obese Subjects with Hypothalamic Injury to Evaluate Weight Reduction and Safety Over 4 Weeks Followed by an Optional 4-Week Open-Label Extension	Hypothalamic obesity occurs in up to 60% of patients with tumors in the hypothalamic region and this obesity is associated with a 5-times greater overall mortality rate. Currently, there are no pharmacologic treatments for hypothalamic obesity. This study will test a novel drug that may lead to weight loss and decreased hunger in patients with this disorder.	U11 TR000445	Vanderbilt Clinical and Translational Science Award	\$15,100	Not Available	Not Available	Not Available
June 13, 2014	Genomic and Biomarker Studies in Sickle Cell Disease	This research is being done to better understand sickle cell disease and improve our ability to predict and effectively treat sickle cell disease. Genetic analysis will be performed as well as conduct RNA and biomarker analysis to investigate the relationship between the variations and the risk or progression of sickle cell disease. Residual samples and related data may be shared with colleagues studying sickle cell disease and related diseases, only when future investigators have received IRB approval for their research. We, as a society, have invested hugely in generating a resource infrastructure to enable more effective investigation of the relationship between biological markers, such as DNA, RNA and protein variation, and risk or progression of disease. In order to reap the benefits of these investments, it is necessary to develop large-scale sample collections that enable us to link clinical information on health and disease status and disease progression to biological samples allowing us to test a broad range of markers in proteomic and genomic investigations.	National Institutes of Health R01HL111656	Vascular-targeted Genomic and Genetic Strategies for Acute Chest Syndrome		Not Available	Not Available	Not Available

Year	Program Name	Brief Program Description	Funding Source #1	Grant Title	Funding Amount Granted	Patient Admissions	Patient Days	Outpatient Visits
June 13, 2014	Genes, fibrinolysis, and the human endothelium - Dialysis Aim 3	Patients with end stage renal disease are at significantly increased risk of cardiovascular events. The favorable effects of ACE inhibitors may be attenuated because of the proinflammatory effects of bradykinin during activation of the kallikrein-kinin system by hemodialysis. This study tests the hypothesis that ARBs will have a favorable effect compared to ACE inhibitors on progression of atherosclerosis as measured by carotid intima-media thickness. This study could lead to multicenter hard-outcomes trials in patients with end stage renal disease.	UL1 TR0000445	Vanderbilt Clinical and Translational Science Award	\$7,690	Not Available	Not Available	Not Available
February 25, 2016 11:14 2:57 pm	The Effect of Dipeptidyl Peptidase 4 Inhibition on Growth Hormone Secretion	This study promises to provide novel data regarding how this increasingly used class of anti-diabetic drugs affects the growth hormone insulin like growth factor-1 axis and could modulate vascular function. Growth hormone and IGF-1 levels are low in the setting of obesity and insulin resistance, and improve with weight loss. An alternative strategy to improve cardio-metabolic risk is to increase GH levels by preventing degradation of the primary stimulus of GH secretion, GHRH. A further study may evaluate the effect of chronic DPPIV inhibitor therapy in a population of patients with impaired GH secretion and increased cardio-metabolic risk. GH and IGF-1 secretion is also low in patients with obesity, insulin resistance, and hyperlipidemia. GH administration in these populations and others has been limited by side effects which include hyperglycemia. Exogenous GH therapy results in a steady level of GH which is not able to be regulated by IGF-1. Another strategy to increase GH and IGF-1 is to enhance the GH response to GH releasing hormone (GHRH) stimulation. To this end, a therapy that increases GH secretion has recently been approved by the FDA for the treatment of HIV-associated lipodystrophy. Tesamorelin is a GHRH analog stabilized against DPPIV degradation which augments pulsatile GH secretion while allowing physiologic negative feedback by IGF-1. Therapy is associated with a small though undesirable increase in hemoglobin A1c. An alternative strategy to increase endogenous GH and IGF-1 is by inhibiting DPPIV. DPPIV inhibition may increase GH and IGF-1 secretion by increasing the appropriate GHRH response to physiologic stimuli such as fasting and exercise and by lowering free fatty acids as well as post-prandial blood glucoses. We therefore propose that DPPIV inhibitor therapies are uniquely situated to enhance GH and IGF-1 secretion through a variety of mechanisms while improving glucose homeostasis and vascular function in specific at-risk patient populations. Aim 1A serves primarily as a novel proof of concept study to define the effect of pharmacologic acute DPPIV inhibition on stimulated GH secretion. Aim 1B investigates the mechanism underlying an increase in endothelium-dependent vasodilation; we hypothesize that it is GH and thus endothelium-dependent, and thus independent from GLP-1.	National Institutes of Health K23HL119602	Effect of Dipeptidyl Peptidase 4 Inhibition on Growth Hormone Secretion	\$152,415	Not Available	Not Available	Not Available

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Year	Program Name	Brief Program Description	Funding Source #1	Grant Title	Funding Amount Granted	Patient Admissions	Patient Days	Outpatient Visits
June 19, 2014	VICCPH11375 - PHASE 1 DOSE-ESCALATION, SAFETY, PHARMACOKINETIC AND PHARMACODYNAMIC STUDY OF BVD-523 IN PATIENTS WITH ADVANCED MALIGNANCIES	To define the safety and tolerability of BVD-523 in patients with advanced malignancies by determining the dose-limiting toxicities (DLT), the maximum tolerated dose (MTD), and the recommended Phase 2 Dose (RP2D). Participants may or may not receive a direct benefit from participating in this study. The possible benefits to participants may include an improvement in disease status. The possible benefits to humankind include finding an effective therapy for treatment of this disease.	U11 TR000445	Vanderbilt Clinical and Translational Science Award	\$15,762	Not Available	Not Available	Not Available
February 25, 2016 2:57 pm		The overall purpose of this study is to support the development of an oral formulation of BVD-523 for the treatment of patients with advanced cancers. BVD-523 is a highly potent, selective, and pharmacologically active inhibitor of ERK family kinases. The compound has demonstrated efficacy as a single agent in preclinical models of colon, pancreatic and melanoma cancers (Section 1.5.2), and has potential for application alone or in combination with existing cancer chemotherapeutics.						
June 24, 2014	Montelukast Trial in Sickle Cell Anemia	SCD is an autosomal recessive disorder that affects one of every 400 African-American newborns in the United States. The basis for SCD is a point mutation in the sixth codon of the β -globin gene. Under hypoxic conditions, the resulting hemoglobin S polymerizes inducing rigid, dense and deformed erythrocytes. In a multi-cellular process, sickle erythrocytes interact with non-sickle erythrocytes, leukocytes, platelets and endothelial cells causing recurrent microvascular occlusion, tissue ischemia and ultimately end-organ damage. Chronic vasculopathy is complicated by acute vaso-occlusive episodes, which are the pathogenic basis for the two most common morbidities in SCD, pain and acute chest syndrome (ACS) episodes. Hydroxyurea is the only FDA-approved drug for preventing vaso-occlusive episodes and has become standard medical care for most adolescents and adults with SCD. We are investigating montelukast as an adjuvant therapy with hydroxyurea. Individuals with asthma will be excluded from this study because the benefit of montelukast for the treatment of asthma is well established. Although the best therapy for individuals with SCD and asthma is not known, the present study is designed to evaluate the effect of montelukast on chronic vasculopathy and not on asthma-related morbidity.	National Institutes of Health R01FD04117	Project Title: Phase 2 Study of Montelukast for the Treatment of Sickle Cell Anemia	\$1,567,000	Not Available	Not Available	Not Available

Year	Program Name	Brief Program Description	Funding Source #1	Grant Title	Funding Amount Granted	Patient Admissions	Patient Days	Outpatient Visits
February 25, 2016 2:57 pm June 26, 2014	GI 13115 - A phase Ib/II multi-center, open-label, dose escalation study of LGX818 and cetuximab or LGX818, BYL719, and cetuximab in patients with BRAF mutant metastatic colorectal cancer	<p>Activating mutations of the BRAF gene are observed in up to 15% of patients with colorectal cancer. While the treatment of mCRC has improved significantly in patients whose tumors express wild-type KRAS, recent data indicate that patients with wild-type KRAS that also carry the BRAFV600E mutation have worse outcome (Van Cutsem et al 2011, Modest et al 2011), highlighting the need for new therapies in this patient population. Evidence of clinical activity of the selective BRAF inhibitor, vemurafenib, in patients with BRAF mutant mCRC, supports that BRAF is a therapeutic target for this disease. However, the clinical activity has been more modest than that observed in patients with BRAF mutant melanoma (Kopetz et al 2010), suggesting that additional factors may modulate the response to BRAF inhibitor in mCRC. Preclinical work from Corcoran et al. (2012a) and Prahalad et al. (2012) has shown that BRAF inhibition causes a rapid feedback activation of EGFR that supports continued proliferation of BRAF mutant CRC tumor cells, and can be effectively prevented by the combination of vemurafenib with anti-EGFR agents such as the small-molecule kinase inhibitor, erlotinib, or the monoclonal antibody, cetuximab. Interestingly, the constitutive activation of the PI3K/AKT signaling pathway was also shown to confer resistance to vemurafenib in BRAF mutant CRC cells (Yang et al 2012). These reports suggest that both activation of EGFR and aberrant PI3K pathway signaling may explain the limited therapeutic effect of BRAF inhibitor monotherapy in patients with BRAF mutant metastatic colorectal cancer. The effect of combining the selective BRAF inhibitor, LGX818, with the EGFR inhibitor cetuximab or erlotinib, or the PI3Kβ-specific inhibitor BYL719, resulted in a strong synergistic anti-tumor activity consistent with the recent published reports (Corcoran et al 2012a, Prahalad et al 2012, Yang et al 2012). Furthermore, the results suggested that additional benefit may be gained through the simultaneous combination of all three inhibitors. The triple combination of LGX818, BYL719, and cetuximab effectively suppressed both RAF/MEK/ERK and PI3K/AKT pathways, and inhibited proliferation to a greater degree in vitro than did any of the dual combinations. Similarly, the triple combination was more effective than the dual combinations at inhibiting the growth of a xenograft model in vivo (RD-2012-50088; RD-2012-50198). Together these data provide a strong rationale to evaluate the combination of LGX818 and cetuximab \pm BYL719 in patients with BRAF mutant metastatic colorectal cancer that have a poor clinical outcome, and for whom no targeted therapeutic strategies are effective after failure of standard chemotherapeutic regimens. Signs of clinical activity were observed in a patient who was unintentionally enrolled on this study with a non V600 BRAF mutation, D594G. The patient, who progressed despite standard therapy of FOLFOX plus avastin followed by an investigational combination treatment of a MEK inhibitor and Akt inhibitor, is currently receiving their fifth cycle of study treatment (dual combination α€” LGX818 and cetuximab) and has a best response of -19% tumor reduction of their target lesions. In consultation between the investigators and Novartis, select patients with non V600 BRAF mutations may be enrolled in phase Ib of this study.</p>	UL1 TR0000445	Vanderbilt Clinical and Translational Science Award	\$7,200	Not Available	Not Available	Not Available

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Year	Program Name	Brief Program Description	Funding Source #1	Grant Title	Funding Amount Granted	Patient Admissions	Patient Days	Outpatient Visits
June 30, 2014	A5331 - Modulation of Immune Activation by Aspirin	HIV-infected patients on ART with complete virologic suppression have an increased risk of non-infectious co-morbidities, most commonly ischemic cardiovascular disease, and also malignancy, liver and renal disease. The cause of this increased risk is unknown, but heightened immune activation and inflammation are thought to be major drivers. Aspirin is a low-cost and low-risk anti-platelet, anti-inflammatory, and immune-modulating therapy. We recently evaluated the platelet and immune effects of one week of open-label low-dose daily aspirin 81 mg in a prospective cohort of 25 HIV-infected subjects on ART with virologic suppression. HIV-infected subjects displayed heightened platelet and immune activation, which was attenuated after one week of low-dose daily aspirin. The proposed double-blind, randomized, placebo-controlled study will compare 2 different doses of aspirin to placebo for 12 weeks to test whether aspirin is immune modulating in this population.	National Institutes of Health UM1A1069439	Vanderbilt HIV Clinical Trials Unit	\$11,928,141	Not Available	Not Available	Not Available
February 25, 2016 2:57 pm		JoAnn Gottlieb, the CRC Research Ultrasound Technician is certified to perform the FMD brachial artery ultrasounds for the ACTG studies. Our site would not be eligible to take part in these site-limited studies without the VICTR resources which allow JoAnn to perform these tests for us.						
July 7, 2014	A phase 1b clinical trial to evaluate the safety and immunogenicity of different combinations of DNA-HIV-PT123 and AIDSVAXX [®] B/E in healthy, HIV uninfected adult participants	The RV144 efficacy trial demonstrated a 31% reduction in HIV infection in vaccines who received ALVACA [®] -HIV vaccine vCP1521 expressing Env, Gag, and Pro and boosted with a gp120 protein, AIDSVAXX [®] B/E, compared to placebo and provided valuable insights into the potential importance of binding antibody (Ab) responses in preventing acquisition. These results suggest further evaluation and understanding of prime-boost regimens that include HIV-1 envelope antigens are warranted. In addition, the results underscore the need to develop vaccine regimens that will provide durable immune protection, which likely will entail the induction of long-lived B- and T-cell memory. This study will test experimental vaccines. If responses are good, this concept will be applied to much larger human trials. The CRC space is needed to see the participants.	National Institutes of Health UM1A1069439	Vanderbilt HIV Clinical Trials Unit	\$11,928,141	Not Available	Not Available	Not Available
July 18, 2014	A Phase 2, Open-label, Sequential Cohort Dose-escalation Study of BMN 111 in Children with Achondroplasia	Achondroplasia (ACH), the most common form of disproportionate short stature or dwarfism, is an autosomal dominant genetic skeletal disorder caused by a gain-of-function mutation in the fibroblast growth factor receptor-3 gene (FGFR3), a negative regulator of endochondral bone formation. C-type natriuretic peptide (CNP) and its receptor, NPR-B, are key regulators of skeletal growth. Alteration in CNP/NPR-B signaling leads to skeletal-related phenotypes.	UL1 TR000445	Vanderbilt Clinical and Translational Science Award	\$74,895	Not Available	Not Available	Not Available

SUPPLEMENTAL #1

Year	Program Name	Brief Program Description	Funding Source #1	Grant Title	Funding Amount Granted	Patient Admissions	Patient Days	Outpatient Visits
July 18, 2014	Effect of Drinking Water on the Pressor Response to Pseudoephedrine in Patients with Autonomic Failure (Project 1, Aim 3.1)	The clinical picture of autonomic failure is dominated by disabling orthostatic hypotension. We previously determined that water produces a dose-related pressor effect in autonomic failure patients with impaired baroreflex function. The blood pressure-raising effects of agents that increase sympathetic nervous system tone, such as pseudoephedrine, may be potentiated by water drinking. Results from this study will provide information on the interaction between pressor effects of water and pseudoephedrine. This information may be used to more effectively treat orthostatic hypotension in autonomic failure patients and to warn individuals about a possibly dangerous pressor response related to the combination of water and pseudoephedrine. Due to its use in the illicit manufacture of methamphetamine, legislators in Tennessee have restricted sales of pseudoephedrine. Knowledge about potential dangers or benefits associated with the pressor effects of pseudoephedrine may contribute to the risk/benefit analysis of this medication. Because these patients must be withdrawn from their medications for study, they will be fall risks and need to be studied as inpatients. Catecholamine analyses will provide valuable information on the mechanism of pressor responses.	National Institutes of Health P01HL056693	Autonomic Cardiovascular Regulation	\$9,951,249	Not Available	Not Available	Not Available
July 22, 2014	Dysfunctional HDL in Chronic Kidney Disease	The study addresses the high occurrence of cardiovascular disease in patients with end stage renal disease who are receiving hemodialysis. We propose to assess the innovative hypothesis that rather than the level of HDL, it is the functionality of this lipoprotein and its transporters, which play a key role in excess CVD in this population. Studies in this high risk population are likely to provide novel insights into risk factors for cardiovascular disease that apply to all human populations. This understanding may lead to novel therapies for patients with renal disease, as well as the general population.	National Institutes of Health P01HL116263	HDL Function in Human Disease	\$2,337,895	Not Available	Not Available	Not Available

**February 25, 2014
2:57 pm**

Year	Program Name	Brief Program Description	Funding Source #1	Grant Title	Funding Amount Granted	Patient Admissions	Patient Days	Outpatient Visits
July 23, 2014	Metabolic and CD4+ T Cell Dysregulation in Post-Transplant Diabetes Mellitus	Post-transplant diabetes mellitus (PTDM) is a common complication following allogeneic hematopoietic stem cell transplantation (HCT) that negatively affects patient survival. We propose that understanding the immunology and the metabolic abnormalities generating PTDM will promote rapid improvements in the care of HCT recipients, while also uncovering new modes of intervention for type 1 and type 2 diabetes mellitus. Allogeneic hematopoietic stem cell transplant (HCT) recipients are at significant risk for developing new-onset post-transplant diabetes mellitus (PTDM), which in turn confers inferior survival. The initiating events and mechanisms that culminate in PTDM development remain understudied, and formal recommendations for screening and treatment are lacking. In this protocol, we will 1) use oral glucose tolerance testing (OGTT) to define patients at risk for developing PTDM, this test could be used as a future screening procedure for HCT recipients analogous to gestational diabetes screening in pregnant women, 2) we will determine the mechanisms involved with abnormal glucose homeostasis after HCT via insulin clamps, which will then be translated into future therapeutic clinical trials targeting either peripheral or hepatic insulin resistance, and 3) we will investigate T cell subsets involved with metabolic inflammation thereby exploring immune-mediated pathways for the prevention or treatment of important transplant complications. The modulation of inflammatory metabolic disorders with pharmacologic or immunologic treatments could represent an important new therapeutic objective to improve transplant outcomes and limit HCT morbidity and mortality. The oral glucose tolerance testing and the euglycemic hyperinsulinemic clamps described in this proposal will be performed using resources and funding from VICTR and the Vanderbilt Clinical Research Center (CRC). With assistance from the CRC and VICTR, data from this proposal will be translated into clinical intervention targeting newly defined pathways involved with PTDM generation or developing standardized screening procedures. With the preliminary data generated from this proposal and additional training from my submitted Mentored-Patient-Oriented Research Career Development Award (K23), I will develop a RO1-funded independent research program focused on treating and preventing metabolic complications after HCT.	National Institutes of Health K23HL122143	Metabolic and CD4+ T Cell Dysregulation in Post-Transplant Diabetes Mellitus	\$124,500	Not Available	Not Available	Not Available
July 25, 2014	A Randomized, Double-blind, Placebo-controlled Multi-center Study to evaluate the safety and efficacy of Eculizumab in subjects with refractory generalized myasthenia gravis (GMG) (PROTOCOL ECU-MG-301)	There is a cohort of patients, with Myasthenia Gravis, who continue to have marked generalized weakness and bulbar signs and symptoms of the disease despite adequate dosing of immunosuppressant therapy. For these patients, there is a medical need for alternative treatment strategies targeting different pathophysiological aspects of the disease. This is a clinical research trial involving human subjects living with a diagnosis of refractory generalized myasthenia gravis. With the use of some of the infrastructure of refractory generalized resources, we can help determine the safety and efficacy of eculizumab in the treatment of this disease.	UL1 TR000445	Vanderbilt Clinical and Translational Science Award	\$8,800	Not Available	Not Available	Not Available

SUPPLEMENTAL #1

Year	Program Name	Brief Program Description	Funding Source #1	Grant Title	Funding Amount Granted	Patient Admissions	Patient Days	Outpatient Visits
July 28, 2014	Biomarkers for Aspirin Resistance	<p>More widely applicable and robust biomarkers with which to assess platelet reactivation in vivo in humans are clearly required to further research on platelet-related diseases and their prevention/treatment. The need for improved biomarkers of in vivo platelet activation was emphasized in a report of the NHLBI Working Group on Translational and Clinical Research in Thrombosis and Hemostasis. The proposed investigation intends to define the kinetics of the rate of platelet removal by a novel method that does not require ex vivo manipulation of platelets and the confounding introduced thereby. It will provide a basis for initiating investigations in diseases associated with arterial thrombosis and in therapeutic interventions. In particular, this novel method for assessing the rate of platelet removal will be evaluated as an approach to determining whether initial aspirin treatment of essential thrombocythemia has achieved normalization of platelet turnover, and thereby provide a basis for decisions about the necessity for adding a second antiplatelet agent. The current strategy is to make that decision based on whether aspirin has been successful in preventing thrombosis.</p> <p>The investigations are oriented to understanding the participation of platelet activation in human diseases in general, also including patients undergoing surgery for coronary artery disease, primary pulmonary hypertension, sickle cell disease, and other diseases in which such perturbations in platelets participate in the pathophysiology. The pilot studies will lay the basis for future studies of aspirin resistance.</p>	UL1 TR000445	Vanderbilt Clinical and Translational Science Award	\$14,656	Not Available	Not Available	Not Available
July 28, 2014	A phase 2b, dose-ranging, randomized, double-blind, placebo-controlled trial evaluating the safety and efficacy of GS-6624, a monoclonal antibody against Lysyl Oxidase-Like 2 (LOXL2), in subjects with compensated cirrhosis secondary to non-alcoholic steatohepatitis (NASH) Gilead GS-US-321-0106	<p>The primary objective of this study is as follows: • To evaluate whether GS-6624 can reverse cirrhosis in subjects with cirrhosis due to NASH.</p> <p>The secondary objectives of this study are as follows: • To assess the safety of GS-6624 in subjects with compensated cirrhosis due to NASH; • To assess the immunogenicity of GS-6624 in this population; • To assess whether baseline LOXL2 levels are predictive of response to GS-6624 therapy (active arms) and/or prognostic for disease progression (placebo arm); • To compare different efficacy assessment tools in this population; • To determine whether non-invasive measures of fibrosis can predict regression of fibrosis and reversal of cirrhosis in this population.</p>	UL1 TR000445	Vanderbilt Clinical and Translational Science Award	\$27,000	Not Available	Not Available	Not Available
July 29, 2014	Genetic Modifier of CMT	<p>The aims of this study are:</p> <ol style="list-style-type: none"> 1) To characterize the phenotypic expression in patients with a late-onset neuropathy of CMT2A; 2) To test the hypothesis that levels of Mfn-1 expression are lower in patients with the early-onset CMT2A than that in patients with the late-onset CMT2A. 3) To test if any copy number variance encoding the junction protein genes would be associated with different phenotypic severities in patients with CMT. 	UL1 TR000445	Vanderbilt Clinical and Translational Science Award	\$9,725	Not Available	Not Available	Not Available

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Year	Program Name	Brief Program Description	Funding Source #1	Grant Title	Funding Amount Granted	Patient Admissions	Patient Days	Outpatient Visits
February 25, 2014 2:57 pm		Estrogen has, historically, produced mixed effects on cognition with improvements, impairments, and no effects prevalent in previous research. Women reporting cognitive complaints following menopause have few treatment options, but may be a select group whose cognitive and brain function benefit from estrogen treatment. We are examining the circumstances at which estrogen is beneficial to cognitive and brain function in post-menopausal women, specifically determining whether subjective report of cognitive decline since menopause can serve as a biomarker for probable improvement. Our findings will guide clinicians, in the future, when approached by post-menopausal patients who complain of cognitive difficulties. Space and nursing support at the CRC is vital to our data collection and safety of our subjects.	National Institutes of Health R01AG021476	Estrogen Effects on Cholinergic Function in Older Women	\$510,426	Not Available	Not Available	Not Available
August 5, 2014	CAFO056B2278- An open-label study to evaluate the long-term safety and tolerability of AFQ056 in adolescent patients with Fragile X Syndrome	Fragile X Syndrome causes significant cognitive and behavioral impairment, including intellectual disability, repetitive behavior, social dysfunction, and irritability/agitation in many patients. There are currently no specific treatments for Fragile X Syndrome in humans. This project would translate mouse genetic findings into the human population, providing a huge benefit for patients with Fragile X syndrome and their families.	UL1 TR000445	Vanderbilt Clinical and Translational Science Award	\$20,575	Not Available	Not Available	Not Available
August 5, 2014	An open-label study to evaluate the long-term safety, tolerability, and efficacy of AFQ056 in adult patients with Fragile X Syndrome	There are no current specific treatments for Fragile X Syndrome, which leads to lifelong disability from intellectual impairment and aberrant behavior. The mouse model of Fragile X Syndrome shows dramatic improvement of behavior and brain function with mGluR5 antagonists, including AFQ056. Initial data from a randomized, controlled trial suggests that AFQ056 is safe and tolerable in adults with Fragile X Syndrome, and that it may improve aberrant behavior, although long-term safety, tolerability, and sustained benefit has not been evaluated. This project directly translates mouse model findings to individuals with Fragile X syndrome. If effective, it could transform the lives of individuals with Fragile X Syndrome and their families.	UL1 TR000445	Vanderbilt Clinical and Translational Science Award	\$27,220	Not Available	Not Available	Not Available
August 7, 2014	Autonomic Assessment of a 15 year old Girl with a Congenital Absence of Norepinephrine	Norepinephrine and epinephrine are critical determinants of blood pressure. Due to a congenital absence of the enzyme, dopamine beta-hydroxylase, patients with dopamine beta-hydroxylase deficiency, also known as norepinephrine deficiency, have no norepinephrine or epinephrine but elevated dopamine levels. Norepinephrine deficiency can affect not only blood pressure and autonomic function but also sleep, metabolism, brain function and other processes that require norepinephrine.	UL1 TR000445	Vanderbilt Clinical and Translational Science Award	\$15,198	Not Available	Not Available	Not Available
August 8, 2014	GGF2-CV-1007 A Double-Blind Pharmacokinetic Interaction Study Evaluating the Effect of a Single IV Infusion of GGF2 or Placebo on Midazolam Pharmacokinetics in Patients with Heart Failure	GGF2 is an investigational biologic being developed as a potential therapeutic for congestive heart failure. Non-clinical studies of GGF2 and related neuregulins demonstrate that it can protect cardiomyocytes in vitro and in vivo from various stressors. In vivo studies demonstrate that GGF2 can restore cardiac function in animal models of heart failure	UL1 TR000445	Vanderbilt Clinical and Translational Science Award	\$78,386	Not Available	Not Available	Not Available

SUPPLEMENTAL #1

Year	Program Name	Brief Program Description	Funding Source #1	Grant Title	Funding Amount Granted	Patient Admissions	Patient Days	Outpatient Visits
August 8, 2014	Low Resource Diagnostics Development Cohort (LRDDC) Study	Shifting clinical diagnostic tasks from centralized reference laboratories to the point of care is an attractive approach to reduce program costs, improve linkage to and retention in care and treatment programs, and to improve patient outcomes in infectious, tropical, and neglected diseases. We propose to collect and utilize primary human biospecimens as biologically relevant reagents to refine molecular and biochemical diagnostic approaches and prototype device designs and validate these experimental clinical diagnostics against standard of care tests. Biospecimens collected at Vanderbilt can accurately represent clinical specimens collected in the field without actually going to a low resource setting, a convenient and cost-effective alternative leading up to field trials.	National Institutes of Health Vanderbilt Zambia Innovations in Global Health Technology (VZNIIGHT) - D43TW093448	Low Resource Extraction and Processing of Biological Samples Using Surface Tension Valves	\$1,999,664	Not Available	Not Available	Not Available
February 25, 2014 2:57 pm								
August 11, 2014	Treatment of Resistant Hypertension by Prevention of T-Cell Co-stimulation	This study will determine if inhibition of T cell co-stimulation reduces blood pressure and improves vascular function in patients with resistant hypertension. It will be the first to address the role of inflammation and adaptive immunity in human hypertension. We propose that addition of abatacept therapy to conventional treatment of subjects with resistant hypertension will result in a greater decrease in blood pressure at 24 weeks compared to treatment with placebo and conventional drugs.	UL1 TR000445	Vanderbilt Clinical and Translational Science Award	\$89,600	Not Available	Not Available	Not Available
August 12, 2014	PHI 1435: First-In-Human Dose-Escalation Study of TEW-7197 Monotherapy in Subjects with Advanced Stage Solid Tumors	The primary objective of the trial is to evaluate the safety and tolerability of TEW-7197 monotherapy, by defining the maximum tolerated dose (MTD), and determining the recommended Phase-2 dose (RP2D) in subjects with advanced stage solid tumors. Patients are being asked to consider taking part in a clinical research study to test TEW-7197 for subjects with advanced types of cancer. They are being asked to take part in this research study because they have a type of cancer that is appropriate for treatment with TEW-7197. The main purpose of this study is to evaluate the safety of TEW-7197 as a treatment for advanced cancers. Other purposes of this study include evaluating the following: the types of side effects caused by TEW-7197, how the body breaks down and eliminates TEW-7917, any effect of TEW-7197 on the size of their cancer, and whether any substances in their blood can provide information about how TEW-7197 works. TEW-7197 is an investigational drug, which means that it has not been approved by the Food and Drug Administration (FDA) for the treatment of advanced cancers. TEW-7197 has not been approved by any Health Authority, and has not been tested in people before.	UL1 TR000445	Vanderbilt Clinical and Translational Science Award	\$19,296	Not Available	Not Available	Not Available
August 15, 2014	Finding Longitudinal Indicators of Cardiovascular Risk in Kidney Transplant Recipients (FLICKER)	The goal of this proposal is to develop an enhanced understanding of how kidney transplantation impacts cardiovascular disease (CVD) risk through abnormal glucose metabolism, and how genetic variability affects this risk. The additional pathways oxidative stress, inflammation, and endothelial dysfunction and their relation to CVD and abnormal glucose metabolism will also be studied. The study is conducted using DNA and blood markers from kidney transplant patients with the long-term goal of gaining information essential to develop personalized therapies and drug dosing strategies designed to improve glucose metabolism, alleviate oxidative stress, reduce inflammation, and reduce cardiovascular morbidity and mortality in kidney transplant recipients.	National Institutes of Health K23GM1100183	Pharmacogenomics of Tacrolimus and New Onset Diabetes After Kidney Transplant	\$188,460	Not Available	Not Available	Not Available

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Year	Program Name	Brief Program Description	Funding Source #1	Grant Title	Funding Amount Granted	Patient Admissions	Patient Days	Outpatient Visits
August 21, 2014	Study of Oxytocin in Autism to Improve Reciprocal Social Behaviors (SOARS-B)	There is currently no approved pharmacological treatment for the core symptoms of ASD. Difficulties in social orienting is a key problem across the lifespan in ASD. If proven to be effective, intranasal oxytocin could provide a new form of treatment to help reduce some of the primary social deficits found in ASD.	National Institutes of Health U01HD073984	Study of Oxytocin in Autism to Improve Reciprocal Social Behaviors (SOARS-B)	\$153,240	Not Available	Not Available	Not Available
February 25, 2014 14:44 2:57 pm	An Open-Label Safety Study of USL261 in the Outpatient Treatment of Adolescent and Adult Subjects with Seizure Clusters (protocol P261-408)	Seizure clusters can evolve into prolonged seizures with worsening epileptogenesis if treatment is not prompt and effective. Many treatment options rely on intervention by emergency medical personnel and therefore delay treatment while the patient is transported to a medical facility. The development of an easily administered outpatient treatment of seizure clusters may reduce emergency medical intervention and decrease seizure cluster duration. An approved treatment is needed that effectively terminates seizure cluster activity, has a rapid onset of action, and is easily administered in an outpatient setting.	UL1TR000445	Vanderbilt Clinical and Translational Science Award	\$500	Not Available	Not Available	Not Available
September 3, 2014	Quantitative Assessment of Cardiac Disease in Duchenne Muscular Dystrophy	Studies have demonstrated that early cardiac therapy can have a significant impact on morbidity and mortality in patients with Duchenne muscular dystrophy (DMD). However, it is unclear when this medical therapy should be begun and also unclear what tests should be used to monitor its efficacy. In addition, the complex relationship between skeletal and cardiac myopathy is poorly understood; clarifying this relationship is critical as new treatment methods improve skeletal function with little effect on the myocardium. We propose to study advanced serum and imaging biomarkers and compare those with clinical progression of disease in the hopes of clarifying the relationship between skeletal and cardiac disease and identifying biomarkers that can improve DMD morbidity and mortality. This study will have a direct effect on patients with Duchenne muscular dystrophy (DMD). It will help with monitoring and the information gleaned can be used to follow the effects of current and new medical therapies. The translational portion involves measuring advanced serum biomarkers (NRG, markers of fibrosis) in patients with DMD and correlating those with advanced imaging methods of detecting fibrosis.	National Institutes of Health 5K23HL123938-02	Quantitative Assessment of Cardiac Disease in Duchenne Muscular Dystrophy	\$762,010	Not Available	Not Available	Not Available
September 3, 2014	Decreasing Adrenergic or Sympathetic Hyperactivity After Severe Traumatic Brain Injury: A Pilot Randomized Clinical Trial Using Propranolol and Clonidine	The full spectrum of sympathetic hyperactivity after TBI has not been systematically described nor intervened upon, though the benefits of ??-blockers and ??2-agonists have been reported in small studies. In this proposal, we will utilize our actively accruing, single-center, double-blinded, placebo-controlled, randomized clinical trial (RCT) - the DASH (Decreasing Adrenergic or Sympathetic Hyperactivity) After TBI Study - to determine the effect of combined adrenergic blockade using propranolol and clonidine on 1) short-term (physiological, behavioral, and cognitive) and 2) long-term neuropsychological outcomes after severe TBI. Using this prospective cohort, we expect to develop an in-hospital risk prediction model for long-term functional and quality of life impairment after TBI. If the DASH After TBI Study results in positive trends, this could provide pilot evidence for an entire class of neuroprotective agents and open doors for a larger multicenter RCT. If there is no effect of therapy, this trial will still provide a robust prospective description of sympathetic hyperactivity after TBI. With a NINDS K23 award, this VICTR amendment would co-sponsor the IDS (study drugs) and CRC (catecholamine endpoints) costs of expanding the	National Institutes of Health K23 Re-Submission to NINDS for July 12, 2013.	DASH (Decreasing Adrenergic or Sympathetic Hyperactivity) After TBI Study	Pending re-submission	Not Available	Not Available	Not Available

Year	Program Name	Brief Program Description	Funding Source #1	Grant Title	Funding Amount Granted	Patient Admissions	Patient Days	Outpatient Visits
<p>February 25, 2016 2:57 pm</p>		<p>latter 36-month accrual (2013 - 2015) for 60 patients.</p>						
<p>September 4, 2014</p>	<p>Treatment of Overweight Induced by Antipsychotic Medication in Young People with ASD</p>	<p>Atypical antipsychotics are the only medications approved by the FDA for use in children with autism. A common side effect of these drugs is weight gain. In adult populations, multiple studies have found that metformin may stop or reverse weight gain from atypical antipsychotics. Metformin is a biguanide anti-diabetic drug that acts by increasing insulin sensitivity and decreasing intestinal glucose absorption and hepatic glucose production. Since atypical antipsychotic medications are commonly used and effective in children with autism, there is a pressing need to test whether metformin can ameliorate the weight or weight gain and metabolic symptoms commonly associated with these drugs in children with autism. Our study will add to the published literature by extending into a younger age group that has yet to be studied in this population, focusing solely on children with ASD who are less able to communicate potential adverse events, which merits a separate assessment of safety in this population, and finally, since the large ongoing study is single-blinded and lacks a placebo comparator, our study will be only the second pediatric randomized, placebo-controlled trial to test metformin for treatment of weight gain due to atypical antipsychotic medications.</p>	<p>National Institutes of Health U43MH11054</p>	<p>Treatment of Overweight Induced by Antipsychotic Medication in Young People with ACD</p>	<p>\$430,055</p>	<p>Not Available</p>	<p>Not Available</p>	<p>Not Available</p>
<p>September 8, 2014</p>	<p>Mesocorticolimbic Function in Parkinson Disease</p>	<p>Patients on dopaminergic therapy can develop a behavioral side effect known as Impulse Control Disorder (ICD), a disorder more prevalent in Parkinson Disease patients treated with dopamine agonists. Since dopamine agonists preferentially target D2-like mesocortical and mesolimbic receptors, alterations to the mesocorticolimbic network may account for this behavioral side effect. We have shown alterations in risk and reward behavior in patients with ICD. This study will assess, using D2-like receptor PET and fMRI, mesocorticolimbic changes that result from dopamine agonist use in patients with and without ICD. This project will result in better ways to identify patients susceptible to ICD. Also, it will enable us to characterize the fundamental biological changes that occur in the development of ICD, and guide future disease modifying therapies.</p>	<p>National Institutes of Health K23NS080988</p>	<p>Dopamine Effects on Mesocorticolimbic Function in Parkinson Disease</p>	<p>\$179,739</p>	<p>Not Available</p>	<p>Not Available</p>	<p>Not Available</p>

SUPPLEMENTAL #1

Year	Program Name	Brief Program Description	Funding Source #1	Grant Title	Funding Amount Granted	Patient Admissions	Patient Days	Outpatient Visits
September 2014	A Randomized, double-blind, active-controlled study to evaluate the effect of various fixed-dose leucine and metformin combinations (ns-0100) versus standard metformin monotherapy on glycemic control in subjects with type 2 diabetes	The goal of this protocol is to demonstrate that metformin's metabolic effects can also be enhanced in humans by the addition of leucine in a fixed-dose combination (FDC) product (NS-0100) as an adjunct to diet and exercise to improve glycemic control in individuals with type 2 diabetes mellitus. This study will evaluate the comparative efficacy of various fixed-dose combinations of leucine and low-dose metformin versus standard metformin monotherapy. Metformin, a biguanide, is the first-line oral agent for the management of type 2 diabetes (T2DM). Studies examining clinical use of metformin have shown dose-related adverse gastrointestinal effects are common and of sufficient severity to cause drug discontinuation in 5-10% of patients and to limit dose-titration to suboptimal levels in ~30% of patients. The combination of metformin and leucine may provide a better tolerated first-line of treatment for T2DM providing better glycemic control for subjects not previously able to obtain adequate glycemic control	UL1 TR000445	Vanderbilt Clinical and Translational Science Award	\$14,610	Not Available	Not Available	Not Available
February 25, 2014 2:57 pm	COSMIC HF - A Double-blind, Randomized, Placebo-controlled, Multicenter, Dose Escalation Study to Select and Evaluate an Oral Modified Release Formulation of Omeacamtiv Mecarbil in Subjects with Heart Failure and Left Ventricular Systolic-AMG423-20010151	Study Phase: 2 Indication: Heart failure Primary Objectives: The primary objectives of this study are (i) to select an oral modified release (MR) formulation and dose of omeacamtiv mecarbil for chronic twice daily (BID) dosing in subjects with HF and left ventricular systolic dysfunction and (ii) to characterize its pharmacokinetics (PK) after 12 weeks of treatment. Secondary Objectives: • to evaluate the safety and tolerability of oral omeacamtiv mecarbil • to measure changes in systolic ejection time (SET), stroke volume, left ventricular end-systolic diameter (LVESD), left ventricular end-diastolic diameter (LVEDD), and heart rate after 12 weeks of oral dosing with omeacamtiv mecarbil • to evaluate the effect of 12 weeks of oral dosing with omeacamtiv mecarbil on N-terminal pro-B-type natriuretic peptide (NT-proBNP) • to evaluate the PK of omeacamtiv mecarbil metabolites with oral omeacamtiv mecarbil dosi	UL1 TR000445	Vanderbilt Clinical and Translational Science Award	\$78,740	Not Available	Not Available	Not Available

SUPPLEMENTAL #1

Year	Program Name	Brief Program Description	Funding Source #1	Grant Title	Funding Amount Granted	Patient Admissions	Patient Days	Outpatient Visits
September 17, 2014	The Effects of Pallidal Deep Brain Stimulation on Sleep in Parkinson's Disease	<p>February 25, 2016 2:57 pm</p> <p>There are two anatomical targets approved for the use of DBS in treating the motor symptoms (tremor, stiffness, slowness) of Parkinson's disease. There is now some data available that the STN target can also help sleep disturbances in Parkinson's which is a common problem. There is no good data looking at the GPI target. Our study will look at sleep changes in the GPI target pre and post surgery to assess for efficacy in comparison to the STN target. DBS is becoming an increasingly more common treatment for Parkinson's disease patients. As the volume is increasing, it is becoming more important to tailor the therapy as much as possible to individual patients to maximize outcomes. Sleep disturbance is a major problem for Parkinson's disease patients that may be augmented by the surgery. The VICTR funds will allow us to initiate a study of GPI patients using overnight sleep studies pre and post DBS surgery. This will hopefully be in the setting of an overall study looking at both STN and GPI patients pre and post surgery for which we will obtain funding through external sources.</p>	UL1 TR000445	Vanderbilt Clinical and Translational Science Award	\$15,597	Not Available	Not Available	Not Available
September 17, 2014	The Combined Effects of Obesity and HIV Infection on Systemic Inflammation and Cellular Immune Activation	<p>HIV-infection and obesity are independently associated with increased innate and adaptive immune activation, a commonality which may underlie the higher age and sex-adjusted rates of cardiovascular and metabolic disease observed in both conditions. Obesity is also associated with reduced CD4+ lymphocyte recovery on ART, a finding potentially linked to a higher percentage of activated CD4+ and CD8+ lymphocytes in these patients. The overarching goal of the proposed studies is to investigate the effect of high adipose tissue stores on systemic inflammation, relevant to the development of cardiovascular and metabolic disease, and cellular immune activation, relevant to immune reconstitution on ART, among HIV-infected individuals. As the proportion of obese HIV-infected patients approaches parity with the general population, the prevalence and associated health care costs of several cardiovascular and metabolic diseases associated with both excess adiposity and long-term HIV infection or ART use are expected to rise. This study will investigate several known biomarkers relevant to cardiovascular/metabolic disease development and immune reconstitution, with the expectation that these data will inform future intervention trials in obese, HIV-infected patients to improve treatment outcomes.</p>	National Institutes of Health K23AI100700	The Role of Obesity Adipocytes in Immune Activation on Antiretroviral Therapy	\$600,161	Not Available	Not Available	Not Available

SUPPLEMENTAL #1

Year	Program Name	Brief Program Description	Funding Source #1	Grant Title	Funding Amount Granted	Patient Admissions	Patient Days	Outpatient Visits
September 2014	Clinical Study of Tetanus Toxoid, Reduced Diphtheria Toxoid, and Acellular Pertussis Vaccine (Tdap) Safety in Pregnant Women (CISA Task III)	Motivated by the need to combat the resurgence of pertussis and its grave impact on young infants, ACP now recommends Tdap administration to all pregnant women, regardless of history of prior Tdap receipt. Data are currently being collected through the Vaccine Adverse Event Reporting System (VAERS) and the Vaccine Safety DataLink (VSD); however, data compilation and analysis will take several years to complete. Further, neither of these surveillance systems will provide detailed clinical data on reactogenicity following repeated Tdap administration during pregnancy, particularly during the implementation phase of the new recommendation.	Centers for Disease Control VU Contract #200-2012-50430	Clinical Immunization Safety Assessment (CISA)	\$23,700,303	Not Available	Not Available	Not Available
February 25, 2014 2:57 pm		Thus a prospective observational assessment of Tdap administration, in accordance with the new ACP recommendation, to assess short-term maternal outcomes (reactogenicity) and longer-term pregnancy outcomes (preterm birth, SGA) is warranted. Knowledge gained from this study will help doctors to better understand the pertussis connection between infants and mothers that receive Tdap injections.						
September 18, 2014	Neural and Behavioral Response to Sucrose and Sucralose in Pediatric Obesity	Artificially sweetened beverage consumption, compared with nutritive sweetened beverage consumption, is associated with increased acute energy consumption and equivalent long-term weight change among children. While numerous hypotheses may explain these observations, artificial sweeteners may be associated with increased hedonic (reward) brain activation and food intake. We will investigate the association of artificial sweetened beverages (sucralose) compared to nutritive sweetened beverages (sucrose) on subsequent food intake and brain activation in both healthy weight and obese children (age 8 - 10 years old).	UL1 TR0000445	Vanderbilt Clinical and Translational Science Award	\$22,307	Not Available	Not Available	Not Available
September 18, 2014	Cardiovascular Effects of Angiotensin-(1-7) in Essential Hypertension	Hypertension is a major public health problem associated with increased risk for cardiovascular disease and stroke, but the mechanisms underlying this disease are not fully understood. In this regard, pharmacologic approaches to increase levels or actions of the vasodilatory peptide angiotensin-(1-7) are currently in development for the treatment of hypertension, based on findings from animal studies. There are limited and contradictory clinical studies, however, and it is unclear if this peptide even contributes to blood pressure regulation in humans. These studies will provide new insight into the potential for targeting angiotensin-(1-7) in human hypertension. In addition, findings from these studies will improve our understanding of hypertension mechanisms in general to improve targeted treatment approaches in this disease. These funds are critical to obtain preliminary data regarding angiotensin-(1-7) cardiovascular effects in hypertensive subjects for extramural funding applications.	UL1 TR0000445	Vanderbilt Clinical and Translational Science Award	\$31,120	Not Available	Not Available	Not Available

SUPPLEMENTAL #1

Year	Program Name	Brief Program Description	Funding Source #1	Grant Title	Funding Amount Granted	Patient Admissions	Patient Days	Outpatient Visits
September 2014	A5314 - Effect of Reducing Inflammation with Low Dose Methotrexate on Inflammatory Markers and Endothelial Function in Treated and Suppressed HIV Infection	<p>1. To evaluate the safety of LDMTX therapy in individuals with treated and virally suppressed HIV infection (see section 9.2.1.1 for primary endpoint).</p> <p>2. To demonstrate that treatment with LDMTX improves endothelial function (brachial artery FMD) in treated and virally suppressed HIV-infected individuals (see section 9.2.1.2 for primary endpoint). Although ART prolongs life, it does not fully restore health. For reasons that remain controversial, HIV-infected individuals doing well on therapy have a higher than expected risk of a number of Æœnon-AIDS conditions, including premature CVD. Many factors likely contribute to this excess risk of CVD, including chronic inflammation. Chronic inflammation may also contribute to the premature onset of other non-AIDS conditions, including kidney disease, bone disease, and neurologic complications [4]. Thus, therapeutic strategies to target inflammation in the setting of HIV infection may be beneficial in reducing not only CVD risk, but other non-AIDS events resulting in improved mortality.</p> <p>Without the core services available through the CRC it would be difficult, if not impossible, for our site to take part in studies that have 24 hour PK sampling and vascular ultrasound evaluations.</p>	National Institutes of Health UM1A1069439	Vanderbilt HIV Clinical Trials Unit	\$11,928,141	Not Available	Not Available	Not Available
September 24, 2014	K23 MTRNR1 Aminoglycoside induced hearing loss	<p>Although the role of MTRNR1 mutations in aminoglycoside induced hearing loss has been demonstrated in adults, no studies have examined the role of these mutations in infants and children. If hearing loss also occurs in infants and children with MTRNR1 mutations, this will allow for avoidance of this class of medications in those found to be at risk, avoiding prelingual hearing loss in this population. The results will also allow for the development of audiologic screening guidelines in at-risk infants who have already received aminoglycosides.</p> <p>It will describe the safety of prepopak in children through a collection of adverse events, clinical laboratory tests, and physical exams.</p> <p>It will describe the completion of prep as directed to colon cleansing by Prepopak in preps for colonoscopies, as compared to local standard of care prep. It will evaluate pharmacokinetic (PK) characteristics in children 9-16.</p>	National Institutes of Health K23HD000001	MTRNR1 Aminoglycoside Otolotoxicity Outcomes and Parental Perceptions of Testing	\$527,760	Not Available	Not Available	Not Available
September 30, 2014	A Randomized, Assessor-Blind, Multicenter, Dosing-Ranging Study Comparing the Safety and Efficacy of Prepopak versus Polyethylene Glycol (Local Standard of Care) in Children Aged 9 Years to 16 Years.	<p>It will describe the safety of prepopak in children through a collection of adverse events, clinical laboratory tests, and physical exams.</p> <p>It will describe the completion of prep as directed to colon cleansing by Prepopak in preps for colonoscopies, as compared to local standard of care prep. It will evaluate pharmacokinetic (PK) characteristics in children 9-16.</p>	UL1 TR000445	Vanderbilt Clinical and Translational Science Award	\$2,068	Not Available	Not Available	Not Available

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2:57 pm**

Year	Program Name	Brief Program Description	Funding Source #1	Grant Title	Funding Amount Granted	Patient Admissions	Patient Days	Outpatient Visits
October 1, 2014	Immune Modulation by Misoprostol	Misoprostol has immunomodulatory effects, though the extent to which it lowers resistance to gynecological infection (and whether this is affected by the route of administration) remains unanswered. Because intravaginal misoprostol continues to be used for a number of ob/gyn indications, it is important to resolve controversies over its putative effect on mucosal/local vs. systemic immunity. Planned Parenthood, the largest provider of medical abortions in the USA, changed from using vaginal misoprostol to buccal misoprostol in light of infections of the female reproductive tract that it thought might be due to vaginal misoprostol. Subsequent data published by Planned Parenthood showed that infectious complications of abortion had fallen after this change in the route of administration of misoprostol but their study was controversial because they simultaneously implemented the use of prophylactic antibiotic administration in women receiving mifepristone plus misoprostol. Thus, the actual impact of misoprostol's route of administration on infection risk is unclear.	UL1 TR000445	Vanderbilt Clinical and Translational Science Award	\$5,625	Not Available	Not Available	Not Available
October 2, 2014	An Open-label Phase 2 Study to Assess Safety and Clinical Effects of UX007 in Subjects with Long-Chain Fatty Acid Oxidation Disorders (LC-FAOD)	Long-chain fatty acid oxidation disorders (LC-FAOD) are caused by defects in the metabolic pathway that converts fatty acids into energy, leading to deficiencies in energy metabolism. The deficiency of energy metabolism can cause depletion of energy sources, resulting in serious muscle-specific clinical manifestations including hypotonia, rhabdomyolysis, liver dysfunction and severe hypoglycemia, and cardiomyopathy (CM). These clinical problems are not sufficiently controlled in many patients by current standard of care, usually consisting of avoidance of fasting, low-fat/high-carbohydrate diet, dietary medium chain triglycerides (MCT oil) and/or carnitine supplementation.	UL1 TR000445	Vanderbilt Clinical and Translational Science Award	\$43,416	Not Available	Not Available	Not Available
October 6, 2014	Prevention of Cystic Fibrosis-Related Diabetes	Patients with CF have a high prevalence of CF related diabetes (CFRD). Patients with CFRD have a significantly higher mortality, up to 6-fold higher, than CF patients without diabetes. A new drug, sitagliptin, might be an ideal agent for CF patients with high risk prediabetes as it markedly enhances insulin secretion in the presence of hyperglycemia by preventing the degradation of the incretins, glucagon-like peptide-1 (GLP-1) and gastric insulinotropic polypeptide (GIP) thus helping to prevent development of diabetes in CF patients. A reduction in hyperglycemia through treatment with sitagliptin should reduce hyperglycemia-induced oxidative stress and inflammation, the associated progression of pulmonary disease, and the subsequent development of CF diabetes in CF subjects with high risk prediabetes. If successful, this would be the first treatment modality available to prevent the development of CFRD, a serious and life shortening complication of CF. The funds provided by VICTR would enable the sponsor to document and recommend the use of the medication as a treatment to help prevent diabetes in CF patients.	Food and Drug Administration & Emory University (Primary) Sponsor Number: 010508 & 010017	Prevention of Cystic Fibrosis Diabetes	\$57,760	Not Available	Not Available	Not Available

Year	Program Name	Brief Program Description	Funding Source #1	Grant Title	Funding Amount Granted	Patient Admissions	Patient Days	Outpatient Visits
October 8, 2014	A multi-center, randomized, prospective, open-label phase III study to evaluate the efficacy, safety and pharmacokinetics of hepatitis C immune globulin (HClG) in orthotopic liver transplant recipients	Proportion of subjects with unquantifiable HCV RNA (LLOQ <43 IU/ml), as measured quantitatively by PCR, at 4, 14 and 34 weeks post-OLT treated with HClG compared to control group (not treated and currently considered standard of care). 1. Biochemical response rates at 12, 22 and 34 weeks post-transplant. The proportions of subjects with normal ALT, AST, total bilirubin and alkaline phosphatases at 12 and 22, and 34 weeks. If this treatment is successful we would be able to offer treatment for HCV at transplant as a standard of care.	UL1 TR0000445	Vanderbilt Clinical and Translational Science Award	\$52,155	Not Available	Not Available	Not Available
October 8, 2014 February 25, 2014 2:57pm	A Multi-Center, Randomized, Controlled, Double-Blind Study of the Effects of an Antioxidant-Enriched Multivitamin Supplement on Inflammation and Oxidative Stress in Cystic Fibrosis Patients	To determine the effects of 16 weeks of treatment with AQUADEKS - 2 on induced sputum myeloperoxidase (MPO) levels. this is a study supported by the CF Foundation to directly benefit the CF patients	UL1 TR0000445	Vanderbilt Clinical and Translational Science Award	\$370	Not Available	Not Available	Not Available
October 14, 2014	Actigraphy to Measure Intensive Care Unit Activity (AMERICA)	Instruments that better quantify the overall "dose" of physical activity during critical illness are needed for clinical practice and to measure the effects of future interventions. Tiny, unobtrusive accelerometers have revolutionized physical activity measurement by accurately quantifying the amount, intensity, frequency and duration of activity. Accelerometry, however, has not been widely studied to measure of activity in the ICU. Enhanced, detailed measurement of physical activity during critical illness will advance knowledge of the associations between activity and long-term outcomes for survivors; allow between study comparisons of activity, and eventually, become a quality indicator of ICU care.	UL1 TR0000445	Vanderbilt Clinical and Translational Science Award	\$2,000	Not Available	Not Available	Not Available
October 23, 2014	VICCPH113113 "A" Multicenter Phase 1A/1B Ascending Dose Study of DCC-2701 to Assess Safety, Tolerability, Pharmacokinetics, and Pharmacodynamics in Patients with Advanced Solid Tumors.	Determine the safety and tolerability of oral DCC-2701. Determine the maximum tolerated doses (MTD) of oral DCC-2701. Determine the pharmacokinetic (PK) profiles of oral DCC- Assess the effect of food on the PK profile and safety of oral DCC-2701. Investigate the effects of DCC-2701 on selected pharmacodynamic (PD) biomarkers. Additive anti-tumor activity has been observed in vivo with DCC-2701 combined with biologic and/or chemotherapeutic agents such as bevacizumab, Irinotecan, and paclitaxel. DCC-2701 substantially enhanced the efficacy of bevacizumab in two orthotopic GBM ICV xenograft models, as well as in a colorectal cancer xenograft model in combination with bevacizumab and Irinotecan. These data with DCC-2701 combined with commonly used anticancer agents form the scientific basis for the combination use of DCC-2701 with selected biological therapies and chemotherapeutic drugs in patients with cancer, including bevacizumab. Document preliminary evidence of antitumor response to DCC-2701.	UL1 TR0000445	Vanderbilt Clinical and Translational Science Award	\$17,936	Not Available	Not Available	Not Available
October 23, 2014	Safety, Efficacy and Pharmacokinetics of NNC-0156-0000-0009 in Previously Treated Children with Haemophilia B	The rationale for performing this trial is to investigate safety, efficacy and PK of N9-GP in the treatment of haemophilia B patients >=12 years. we cannot process and ship samples without the use of the CRC	UL1 TR0000445	Vanderbilt Clinical and Translational Science Award	\$45	Not Available	Not Available	Not Available

Year	Program Name	Brief Program Description	Funding Source #1	Grant Title	Funding Amount Granted	Patient Admissions	Patient Days	Outpatient Visits
October 4, 2014	Peripheral Mechanisms of Fatigue in Inflammatory Arthritis	Unknown mechanisms contribute to skeletal muscle dysfunction in RA and other forms of inflammatory arthritis, such as ankylosing spondylitis (AS), and its relationship with fatigue is unrevealed. The overall goal of this project is to identify potentially remediable peripheral mechanisms associated with fatigue in patients with RA and AS. Our proposed model predicts that circulating TNF α (or other pro-inflammatory cytokines) stimulates local production of IL-1 β and/or TNF α , SMase/ceramides, nNOS-derived NO and mitochondrial ROS leading to skeletal muscle fatigability and clinical fatigue. It has been shown, that anti-oxidants including L-NAME, SOD, and catalase correct TNF-induced reductions in specific force in mice (32). It follows that treatment strategies affecting these pathways may improve muscle function and exercise capacity in patients with RA and other forms of inflammatory arthritis such as AS. Our studies will lay the groundwork to propose targets and clinical measures for potential adjunct treatments of patients with inflammatory arthritis.	UL1 TR000445	Vanderbilt Clinical and Translational Science Award	\$26,900	Not Available	Not Available	Not Available
February 25, 2016 2:57 pm	(VTEU 2014.01) A Phase II Randomized, Partially-Blinded, Controlled Trial in Healthy Adults Aged 65 Years and Older to Assess the Safety, Reactogenicity, and Immunogenicity of an MF59-Adjuvanted, Monovalent Inactivated Influenza A/H7N9 Virus Vaccine Administered Intramuscularly at Different Intervals and Dosages (DMID 13-0034)	This is a Phase II randomized, partially-blinded, controlled trial in 360 (up to 600) males and females, 65 years of age and older, who are in good health and meet all eligibility criteria. This clinical trial is designed to assess the safety, reactogenicity, and immunogenicity of a monovalent inactivated Influenza A/H7N9 virus vaccine manufactured by Sanofi Pasteur administered intramuscularly at different intervals and dosages (3.75, 7.5, or 15 mcg of HA/0.5 ml dose) given with MF59 adjuvant manufactured by Novartis Vaccines and Diagnostics. The inactivated A/H7N9 vaccine was derived from the influenza A/Shanghai/2/2013 virus. Knowledge gained from this study will further help doctors become better prepared to treat H7N9 infections in the worldwide population.	National Institutes of Health HHSN272200800007C	Vaccine and Treatment Evaluation Unit	\$22,895,748	Not Available	Not Available	Not Available
November 4, 2014	A5326 - Safety, Pharmacokinetics and Immunotherapeutic Activity of an Anti-PD-L1 Antibody (BMS-936559) in HIV-1 Infected Participants on Suppressive cART: A Phase 1, Double-Blind, Placebo-Controlled, Ascending Single Dose Study	In patients who are effectively treated with combination antiretroviral therapy (cART), HIV-1 persists in latently-infected resting CD4+T-cells and possibly other tissues or cellular reservoirs. Elimination of latently infected cells with replication competent virus is necessary to cure HIV-1 infection. The overall goal of this exploratory study is to identify single doses of BMS-936559, an anti-PDL-1 mAb, that are safe and well-tolerated in HIV-infected participants suppressed on cART, measure pharmacokinetics, receptor occupancy, HIV-1 specific immune responses and determine whether BMS-936559 impacts low level viremia or virus expression in CD4+ T-cells. If this goal is achieved, the next step will be a phase II, multiple-dose study of BMS-936559, to assess safety, tolerability, immune responses and virologic impact.	National Institutes of Health UM1A1069439	Vanderbilt HIV Clinical Trials Unit	\$11,928,141	Not Available	Not Available	Not Available
V/CTR funding allows our site to take part in these Phase I safety trials. Because this study requires infusion of an experimental drug with a 12 hour PK sampling and observation of the participant, the CRC setting with the trained nursing staff and necessary equipment provides us with a safer environment for accomplishing these procedures.								

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Year	Program Name	Brief Program Description	Funding Source #1	Grant Title	Funding Amount Granted	Patient Admissions	Patient Days	Outpatient Visits
November 2014	The Measurement of Insulin Resistance in Peritoneal Dialysis Patients	<p>The overarching goal of this proposal is to examine the relevance of insulin resistance in PD patients and means to improve this metabolic derangement. In order to achieve these goals, we propose the following specific aims through a prospective randomized study using Icodextrin as an alternate dialysate solution to routine glucose-based dialysate.</p> <p>1. To determine the degree of insulin sensitivity in peritoneal dialysis patients. Hypothesis: The glucose loading associated with PD leads to impairment in insulin sensitivity in peritoneal dialysis patients</p> <p>2. To compare insulin sensitivity measured by Hyperinsulinemic Euglycemic Clamp Study (HIEC - gold standard) to the more readily available methods including Homeostatic Model Assessment (HOMA), and oral glucose tolerance test (OGTT) in peritoneal dialysis patients. Hypothesis: The degree of insulin resistance is dependent on the basal metabolic state (fasting versus stimulated) in peritoneal dialysis patients.</p> <p>3. To evaluate the influence of a non glucose-based dialysate (Icodextrin) on basal and stimulated insulin resistance in PD patients. Hypothesis: Replacement of conventional dialysate with glucose-sparing dialysate preparations will improve insulin resistance and associated metabolic disturbances in peritoneal dialysis patients.</p>	U11 TR000445	Vanderbilt Clinical and Translational Science Award	\$100,520	Not Available	Not Available	Not Available
November 12, 2014	Inflammation and the Heart	<p>Specific Aim 1: Will test the hypothesis that structural and functional myocardial dysfunction as revealed by cardiac MRI is present in patients with rheumatoid arthritis compared to controls and is related to inflammation. Specific Aim 2: Will test the hypothesis that disease modifying drug therapy for RA improves structural and functional myocardial measures in patients with RA as revealed by cardiac MRI. We anticipate that control of inflammation in RA will improve myocardial function, but that methotrexate and anti-TNF therapy may have different effects, particularly on left ventricular mass. Identification of early cardiac changes may allow medical therapy aimed at attenuating inflammatory mediated remodeling.</p>	U11 TR000445	Vanderbilt Clinical and Translational Science Award	\$51,263	Not Available	Not Available	Not Available
November 14, 2014	Assessment, Serial Evaluation, and Subsequent Sequelae in Acute Kidney Injury (ASSESS-AKI)	<p>The Assessment, Serial Evaluation, and Subsequent Sequelae in Acute Kidney Injury (ASSESS-AKI) Consortium has been established and includes Clinical Research Centers (CRCs) led by Kaiser Permanente of Northern California, Yale University, Vanderbilt University, and University of Washington as well as a Data Coordinating Center at The Pennsylvania State University and representatives from NIDDK. The ASSESS-AKI Consortium will address the Specific Aims listed above through the initiation and follow-up of a long-term prospective cohort of participants with and without evidence of acute kidney injury (AKI) based on serum creatinine-based criteria. The proposed project will explore the contribution of acute kidney injury on the progression of chronic kidney disease. If this is the case, i.e. AKI events contributing to faster progression of CKD, then strategies to prevent AKI becomes even more important to prevent future development CKD.</p>	National Institutes of Health Health U01DK082192	Impact of Acute Kidney Injury on Kidney Disease Progression	\$2,395,141	Not Available	Not Available	Not Available

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Year	Program Name	Brief Program Description	Funding Source #1	Grant Title	Funding Amount Granted	Patient Admissions	Patient Days	Outpatient Visits
November 2014	Risk and Resiliency for Youth with Autism During the Transition to Adulthood	Given the surge of children and adolescents with autism spectrum disorders preparing to exit the school system in the next decade, it is critical to understand the factors that promote a successful transition to adulthood. This project is the most comprehensive effort to date to understand the range of factors (biological, behavioral, and environmental) placing individuals with ASD at risk for a poor transition to adulthood. If the aims are achieved, this project will add markedly to our knowledge of how to optimize the transition to adulthood for youth with autism spectrum disorders, as well as open the possibility of developing and studying interventions to address those factors which are malleable.	National Institutes of Health K01 MH092598	Risk and resiliency for youth with autism during the transition to adulthood	\$142,194	Not Available	Not Available	Not Available
November 2014	Comparative effects of rapid release aspirin and NHP-544C on basal and bradykinin-stimulated prostacyclin production	Aspirin causes irreversible inhibition of platelet cyclooxygenase (COX)-1, the enzyme catalyzing the conversion of arachidonic acid to thromboxane A2, which is rapidly converted to thromboxane B2 which prevents aggregation for the life of the platelet. However, immediate release aspirin in doses over 80 mg also inhibits peripheral prostacyclin which promotes clotting. NHP-544C is a unique dosage form that provides low exposures to aspirin and salicylic acid peripherally (so as to spare prostacyclin) while providing adequate exposures in the portal vein to inhibit platelet COX-1 and thus, platelet thromboxane B2 production. Aspirin is one of the key drugs in our armamentarium against cardiovascular disease. Developing a slow release form of aspirin that had better anti-thrombotic and vascular protective properties could have a huge impact.	U11 TR0000445	Vanderbilt Clinical and Translational Science Award	\$59,245	Not Available	Not Available	Not Available
November 19, 2014	Peripheral and brain manganese, and other metals, in patients with Restless Legs Syndrome versus controls.	In Overall Project Aim 1, we will test the hypothesis that RLS patients will exhibit elevated brain and/or serum Mn levels influenced by the patients Fe status and inheritance of genetic risk factors (e.g. common variants of MEIS1 and BTBD9). In Overall Project Aim 2, we will test the hypothesis that lymphocytes isolated from RLS patients will exhibit Fe-deficiency related phenotypes and alteration in cellular Mn levels modulated by their RLS genetic risk status. The planned studies will provide insight into both basic biology and the mechanistic events leading to RLS, develop techniques that will provide opportunities to understand and reduce RLS, and assesses genomic information to make better-supported individual decisions about diagnosis and treatment that are tailored to the biology of the specific patient.	National Institutes of Health / Albert Einstein Medical College ES010563	Mechanisms of Manganese Neurotoxicity	\$644,834	Not Available	Not Available	Not Available
November 21, 2014	Characterization of the Sleep Phenotype in Adolescents and Adults With Autism Spectrum Disorders	Sleep problems affect as many as two-thirds of children with autism spectrum disorders (ASD), however little is known about these problems in adolescence and young adults. In adolescents with typical development circadian phase shifting, associated with changes in melatonin production, occurs resulting in a delayed sleep phase. Individuals with ASD are thought to have lower melatonin levels than those of typical development. How this translates to the adolescents with ASD and their sleep is not known. We will investigate both sleep and melatonin in adolescents in this study. There is a lack of information regarding the sleep patterns in adolescents and young adult with ASD. Analysis of the Autism Treatment Network database showed sleep problems due Research This study will provide the foundation for future interventional trials to improve sleep and behavior in ASD.	U11 TR0000445	Vanderbilt Clinical and Translational Science Award	\$23,500	Not Available	Not Available	Not Available

Year	Program Name	Brief Program Description	Funding Source #1	Grant Title	Funding Amount Granted	Patient Admissions	Patient Days	Outpatient Visits
November 2014	Dysmetabolism of Chronic Kidney Disease and Vascular Health--Aim 1	The ultimate goal of this proposal is to understand the relative and combined impact of obesity and CKD on the generation and maintenance of insulin resistance and their impact on cardiovascular health. Specific Aim 1: To characterize the metabolic disturbances that arise from the intersection of increased adiposity and decreased clearance of insulin and adipokines in obese patients with moderate CKD. S.A.1.a: To compare the extent of insulin resistance between patients with and without CKD and the degree to which this is modified by obesity. The primary outcome will be glucose disposal rate measured by hyperinsulinemic euglycemic clamp (HEGC) studies. S.A.1.b: To examine if LAR will more accurately reflect the metabolic state of obesity in the setting of moderate CKD compared to conventional measures of insulin resistance validated against HEGC. S.A.1.c: To evaluate if LAR is a determinant of systemic inflammation, oxidative stress, endothelial dysfunction and atherosclerosis in patients with obesity and moderate CKD.	Veterans Administration	VA/IPA: Whitehead, Jack	\$25,039	Not Available	Not Available	Not Available
December 8, 2014	Pediatric Anesthesia NeuroDevelopment Assessment Study (PANDAS)	Our specific aim is to compare neurocognitive functions in sibling pairs: one of whom had exposure to general anesthesia during inguinal hernia surgery before 36 months of age and who is between 8 and 15 years of age at the time of the study period (exposed cohort group) and the other who never had any exposure to anesthesia or surgery and who is between 8 and 15 years of age at the time of the study period (unexposed cohort group). Sibling pairs will be within 36 months of age from each other. Identification of potential neurocognitive risks associated with anesthesia exposure has the potential to alter clinical practice in ways that minimize such risks.	UL1 TR000445	Vanderbilt Clinical and Translational Science Award	\$6,000	Not Available	Not Available	Not Available
December 11, 2014	Early-onset obesity and cognitive impairment in children with pseudohypoparathyroidism	Children with PHP1a have cognitive impairment and early-onset obesity, but the mechanism behind these impairments is poorly understood. Understanding the eating behaviors and degree of cognitive impairment in children with PHP1a will inform future clinical trials for treatment of obesity in this population.	National Institutes of Health K23DK101689	Early onset obesity and cognitive impairment in children with pseudohypoparathyroidism	\$153,852	Not Available	Not Available	Not Available

Year	Program Name	Brief Program Description	Funding Source #1	Grant Title	Funding Amount Granted	Patent Admissions	Patent Days	Outpatient Visits
December 23, 2014	Ischemic Brain Injury and Cognitive Impairment in Adolescents and Young Adults with Congenital Heart Disease	Since the advent of neonatal repair for complex congenital cardiac lesions in the 1970s, an estimated 85% of patients now survive into adult life, thus the number of adults with congenital heart disease (CHD) in the United States is rising exponentially and now exceeds 1,000,000 and in the next decade, almost 1 in 150 young adults will have some form of CHD. The current proposal will provide the obligatory data required to determine the prevalence of ischemic brain injury in adolescents and young adults with surgically treated CHD, as well as the impact of brain injury on cognition and behavior. In addition, we plan to test a computerized method of screening for cognitive impairment that could better identify which patients require a full, costly, cognitive testing battery. If we can demonstrate a high frequency of ischemic brain injury and that cognitive impairment is present in adolescents and adults with CHD, this would make a strong argument for clinically-indicated neuroimaging. Similarly, if computer-based screening in the clinic could identify those at highest risk for cognitive problems, then this also would directly translate to clinical practice and improved care for patients.	U11 TR0000445	Vanderbilt Clinical and Translational Science Award	\$23,411	Not Available	Not Available	Not Available
December 23, 2014	Nicotinic Treatment of Age-Related Cognitive Decline in Down Syndrome: An Open Label Pilot Trial	An additional consequence of the gene triplication that causes Down Syndrome is early development of Alzheimer's disease by age 60, in more than 50% of affected persons. Thus the age-related cognitive impairment and changes pose an urgent public health concern. With this study, we aim to explore the strategy of nicotinic stimulation to stabilize or improve cognitive functioning in adults with DS. This study will ascertain whether nicotine is safe and tolerable in DS patients, help with dose-ranging of nicotine in DS, look for evidence of enhancements in cognitive functioning, and establish evidence for biological and behavioral correlates of nicotinic stimulation effects. The knowledge gained from the translational aspects of this project may also guide the application of new nicotinic drugs in DS and generate, for the first time, data on the importance of nicotinic receptor changes in the development of cognitive impairment in DS adults.	U11 TR0000445	Vanderbilt Clinical and Translational Science Award	\$10,422	Not Available	Not Available	Not Available
December 23, 2014	Advancing Treatment for Pediatric Craniopharyngioma: Prospective Pilot Study Identifying Clinically Relevant Biological Targets for Medical Therapy	Over a 36 month period, we will complete a multicenter pilot study that includes member institutions of POETC as well as selected additional sites. We will analyze 35 samples of snap frozen pediatric CPA using advanced biological techniques. We will concomitantly collect clinical data that will be correlated with the biological characteristics of each subject's tumor tissue. Lastly, because of the unique quality of life burden that CPA imposes, we will pilot an electronically based method for the assessment of short-term academic and behavioral outcomes in these patients. This project will inform the design of a subsequent clinical trial of medical antitumor therapy as well as establish a multicenter working group for the ongoing study of children with CPA. The VICTR funding will allow for the successful shipment of the blood and tissue specimen to the laboratory of Dr. Nicholas Foreman at UC-AMC.	U11 TR0000445	Vanderbilt Clinical and Translational Science Award	\$130	Not Available	Not Available	Not Available

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Year	Program Name	Brief Program Description	Funding Source #1	Grant Title	Funding Amount Granted	Patient Admissions	Patient Days	Outpatient Visits
December 2014	A Multinational, Open-Label, Non-Controlled Trial on Safety, Efficacy and Pharmacokinetics of NNC 0129-0000-1003 in Previously Treated Paediatric Patients with Severe Haemophilia A	This trial will document the safety, including immunogenicity, efficacy and pharmacokinetics of N8-GP in PTPs below 12 years of age with severe haemophilia A (FVIII <1%), we cannot process and ship samples without the use of the CR	UL1 TR000445	Vanderbilt Clinical and Translational Science Award	\$52	Not Available	Not Available	Not Available
February 25, 2016 2:57 pm	Dysmetabolism of Chronic Kidney Disease and Vascular Health-Aim 2	The ultimate goal of this proposal is to understand the relative and combined impact of obesity and CKD on the generation and maintenance of insulin resistance and their impact on cardiovascular health. Specific Aim 2: To study the effects of metformin, an AMPK activator, on metabolic disturbances associated with obesity and moderate CKD. - S.A.2.a: To test if metformin will improve LAR in obese patients with moderate CKD compared to placebo. - S.A.2.b: To test if metformin will improve markers of systemic inflammation, oxidative stress, endothelial dysfunction in obese patients with moderate CKD compared to placebo. - S.A.2.c: To test if metformin will improve atherosclerosis markers and reduce clinical CVD events in obese patients with moderate CKD compared to placebo.	Veterans Administration	VA/PA: Bockstiegel-Krembel, Anne (CHR&D Merit Award--Hung)	\$23,413	Not Available	Not Available	Not Available

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Year	Program Name	Brief Program Description	Funding Source #1	Grant Title	Funding Amount Granted	Patient Admissions	Patient Days	Outpatient Visits
January 7, 2015	Oral Docosahexanoic Acid supplementation in cystic fibrosis	Aim 1: To determine changes in serum fatty acid profiles and inflammatory byproducts of fatty acids (as measured in urine and exhaled breath condensates) before and after two periods of oral DHA supplementation at different doses in comparison to a placebo period. Aim2: To determine if oral DHA supplementation produces improvement in clinical markers such as number of pulmonary exacerbations and spirometry components (when applicable based on ability to perform testing). The background for this study is based on previous studies of DHA supplementation in a cfr-/- mouse model. The CF mouse model demonstrates dilation of pancreatic ducts and ileal hypertrophy, as well as lipid imbalances that paralleled those seen in human CF patients, including decreased levels of DHA and increased levels of AA. Oral administration of DHA to these mice resulted in correction of the pancreatic ductal dilation and the ileal hypertrophy to patterns seen in wild type mice. The DHA supplementation in the mouse model also resulted in diminished neutrophil concentrations in the BAL fluid in response to Pseudomonas aeruginosa. Multiple clinical trials have been conducted in human patients to evaluate for benefit from supplementation with DHA, EPA, or a combination of the two. Supplements have been administered for various lengths of time, ranging from 1 month to 1 year. Pulmonary function tests have been main clinical parameter that has been followed in the studies, and improvement was seen in only one study. Decreased antibiotic use was also demonstrated in this study. It is possible that the lack of clinical improvement in the previous studies has been due to lack of power to find such changes and inadequate length of supplementation or follow-up time. Using a biomarker of oxidative stress may show clinical improvement in the patients supplemented with DHA which then would support the development of larger scale trials to evaluate the clinical benefits. This funding will help support a study investigating an alternate outcome measure, exhaled breath 8-isoprostane, as well as analysis of fatty acid biochemistry after DHA supplementation in cystic fibrosis. The data gathered may support future grant applications and also the development of larger scale, longer term trials.	UL1 TR0000445	Vanderbilt Clinical and Translational Science Award	\$13,269	Not Available	Not Available	Not Available
January 7, 2015	Genetics of PFAPA	PFAPA is the most common periodic fever syndrome in children, but no candidate genes that cause the syndrome have been identified. Our preliminary studies suggest that many patients with PFAPA have family members with the syndrome. We aim to identify candidate genes for PFAPA by sequencing family members of patients with PFAPA. Because PFAPA is currently a clinical diagnosis, the diagnosis is often delayed. If candidate genes are found, the diagnosis of PFAPA may expedite through genetic testing, and the pathogenesis of the syndrome can be better understood which will provide additional therapeutic benefits.	UL1 TR0000445	Vanderbilt Clinical and Translational Science Award	\$1,985	Not Available	Not Available	Not Available
January 8, 2015	A STUDY OF THE EFFECTS OF WEIGHT LOSS FOLLOWING GASTRIC BYPASS SURGERY ON THE PLASMA NATRIURETIC PEPTIDE RESPONSE TO SALINE INFUSION	Natriuretic peptides are hormones produced by the heart to maintain its structure and function. Natriuretic peptides also help regulate salt and water balance in the body. Overweight people have much lower levels of natriuretic peptides than people who are not overweight and the reasons for this relationship are unclear. The results of this research study may advance our understanding of how obesity and weight loss affect the heart.	National Institutes of Health R01 HL102780	Obesity, salt-sensitivity, and the natriuretic peptides.	\$576,739	Not Available	Not Available	Not Available

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Year	Program Name	Brief Program Description	Funding Source #1	Grant Title	Funding Amount Granted	Patient Admissions	Patient Days	Outpatient Visits
January 15, 2015	Acetaminophen for the Reduction of Oxidative Stress in Severe Sepsis	Severe sepsis is common and carries a high mortality in adults; however there are currently no therapies directed at the underlying pathophysiology of this condition. Cell-free hemoglobin is present in patients with sepsis and is associated with poor clinical outcomes and lipid peroxidation, as measured by F2-isoprostanes. Acetaminophen is an inhibitor of hemoprotein-mediated lipid peroxidation and may be beneficial to patients with severe sepsis. As the mortality associated with sepsis is high and there are no specific therapies directed toward the underlying pathophysiology of this condition, there is a critical need for studies of novel therapies that might improve outcomes. A therapy such as acetaminophen is an attractive option since practitioners have decades of experience with this drug, it is well tolerated by patients, it is safe at multiple dosing strengths, is inexpensive, and can be given by multiple routes. Evidence that acetaminophen reduces oxidative stress in patients with sepsis is the first step towards potential development of acetaminophen as a desperately needed therapeutic that would be easily integrated into the care of sepsis patients.	UL1 TR0000445	Vanderbilt Clinical and Translational Science Award	\$28,386	Not Available	Not Available	Not Available
January 20, 2015	Racial Differences in Vagal Control of Glucose Homeostasis	African American women(AAW) have reduced insulin sensitivity compared with white women which increased their risk for the development of T2DM. We will test the hypothesis that decreased parasympathetic activity in obese AAW contributes to reduced insulin sensitivity and oxidation in this population. The project is entirely performed in human subjects. At the end of the project, we are planning to contact African American community leaders to share the findings of our study.	UL1 TR0000445	Vanderbilt Clinical and Translational Science Award	\$128,568	Not Available	Not Available	Not Available
January 29, 2015	Antithymocyte Globulin (ATG) and pegylated granulocyte colony stimulating factor (G-CSF) in New Onset Type 1 Diabetes (TN19)	At the time of diagnosis, a person with type 1 diabetes still has residual beta cells sufficient to produce significant amounts of insulin. Preserving beta cells in new onset T1D enhances diabetes management and reduces the frequency of hypoglycemia. If this therapy is shown to preserve beta cells after the diagnosis of T1D, it will be studied for its ability to prevent the onset of T1D in individuals with islet inflammation and impending diabetes. The incidence of T1D has been increasing by 3-5% each year. The burden of this disease initially falls on the young. Whereas the peak incidence remains between 10 and 15 years of age, the rise in new cases is greatest among the 1-4 year old age group. The outcome of these studies will not only inform us on how to prevent the development of T1D in vulnerable populations, but could also provide insight into the cure/reversal of established T1D.	National Institutes of Health U01DK085465	Vanderbilt University: Clinical Center Application, Type 1 Diabetes TrainNet	\$2,283,788	Not Available	Not Available	Not Available
February 6, 2015	A multi-site RCT comparing regional and general anaesthesia for effects on neurodevelopmental outcome and apnoea in infants	This trial will compare outcome in infants receiving a) general anaesthesia with the volatile general anaesthetic sevoflurane plus regional nerve blockade with the local anaesthetic bupivacaine, or b) awake regional anaesthesia using regional nerve blockade with bupivacaine alone. This study will provide useful data on the frequency and clinical significance of post-operative apnoea using RA and GA with modern anaesthesia techniques.	National Institutes of Health R01HD06	A Multi-Site Randomized Controlled Trial Comparing Regional and General Anesthesia for Effects on Neurodevelopment Outcome and Apnea in Infants (GAS)	\$62,835	Not Available	Not Available	Not Available

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Year	Program Name	Brief Program Description	Funding Source #1	Grant Title	Funding Amount Granted	Patient Admissions	Patient Days	Outpatient Visits
February 16, 2015	A Phase 3, Two-Arm, Rollover Study to Evaluate the Safety of Long-Term Vacafor Treatment in Subjects 6 Years of Age and Older with Cystic Fibrosis and a Non-G551D CTR Mutation	There is a well acknowledged need for an HIV vaccine. Of major concern is the failure of vaccine candidates studied in three large efficacy trials, two based on the use of recombinant bivalent HIV Env gp120 (A10SVAXA [®] B/B and B/E) and the third (æcøSTEPæ study) based on the use of a replication-deficient Ad5 vectored vaccine encoding gag, pol and nef antigens [4-6]. For some time the results of these trials suggested that protecting against infection with HIV or suppressing viral replication following infection were goals that would be difficult to achieve in humans. However, over the past several years some important advances have generated considerable optimism that these goals are more readily achievable than previously thought. This study will test experimental vaccines, if responses are good, this concept will be applied to much larger human trials. The CRC space is needed to see the participants.	U11 TR0000445	Vanderbilt Clinical and Translational Science Award	\$4,100	Not Available	Not Available	Not Available
February 18, 2015	AN EXTENSION OF PROTOCOL NS-0100-01 TO EVALUATE THE SAFETY AND EFFECT OF VARIOUS FIXED-DOSE LEUCINE AND METFORMIN COMBINATIONS (NS-0100) VERSUS STANDARD METFORMIN MONOTHERAPY ON GLYCEMIC CONTROL IN SUBJECTS WITH TYPE 2 DIABETES	NuSirt Biopharma has demonstrated that the essential amino acid L-leucine converges on the same signaling pathway (AMPK and Sirt 1) that is activated by metformin to increase insulin sensitivity. Consequently, adding L-leucine to metformin results in a novel synergistic interaction that has enabled an 80% dose reduction of metformin with no loss of efficacy, or in some doses, improved efficacy when compared to standard metformin doses in two mousemodels of diabetes. It is hoped the drug combination of leucine and metformin will effect more normalized fasting plasma glucose, insulin secretory rates, fasting plasma insulin and lipids, HbA1c among other markers of diabetes, will prove safe and tolerable and with few gastrointestinal symptoms than with metformin alone. The funds are necessary to fund the resources for the conduct of the study.	U11 TR0000445	Vanderbilt Clinical and Translational Science Award	\$10,600	Not Available	Not Available	Not Available
March 6, 2015	A phase 2, multi-center, multi-national, randomized, double-blind, placebo-controlled parallel-group clinical trial to evaluate the efficacy and safety of RRC4046 in adolescent and adult subjects with eosinophilic esophagitis	To characterize the effects of RRC4046 on clinical symptoms of EOE To characterize the effects on EOE endoscopic score To characterize the effects on esophageal histologic findings.	U11 TR0000445	Vanderbilt Clinical and Translational Science Award	\$1,095	Not Available	Not Available	Not Available

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Year	Program Name	Brief Program Description	Funding Source #1	Grant Title	Funding Amount Granted	Patient Admissions	Patient Days	Outpatient Visits
March 9, 2015	Genetically Determined Response to Atenolol in Patients with Persistent Atrial Fibrillation	Atrial fibrillation, the most common sustained heart rhythm disorder, is frequently treated with beta-blockers, which control the ventricular rate and prevent tachycardia-induced symptoms and heart failure. In patients with atrial fibrillation, there is a great deal of inter-individual variability in the response to beta-blockers, which is thought to be due in part to genetic variation. We plan to study the role of genetic polymorphisms in the response to beta-blockers in patients with atrial fibrillation. This study will provide important insights into the genetic determinants of response to beta-blocker therapy in patients with atrial fibrillation. The results of this study will potentially help genetic variants that identify patients who might not benefit from beta-blocker therapy. This information might help clinicians choose more effective therapies for their patients with atrial fibrillation, potentially leading to improved outcomes, decreased adverse events, and decreased cost.	UL1 TR0000445	Vanderbilt Clinical and Translational Science Award	\$60,838	Not Available	Not Available	Not Available
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March 11, 2015	Resveratrol in metabolic syndrome	Resveratrol is a phytoalexin found in grapes that has anti-inflammatory, cardiovascular protective and chemopreventive properties. We will examine whether it has the ability to improve parameters of metabolic syndrome, such as platelet activation, which have been associated with adverse outcomes.	UL1 TR0000445	Vanderbilt Clinical and Translational Science Award	\$50,959	Not Available	Not Available	Not Available
March 16, 2015	NN104 Rhapsody	Ischemic stroke patients who are eligible to receive tPA are the most likely patient population to benefit from a neuroprotectant like 3K3A-APC, due to the need for recanalization. Circulating tPA is cleared quickly from the body and levels are expected to be nearly undetectable by the time 3K3A-APC will be administered. An evaluation of the effect of 3K3A-APC on all (symptomatic and asymptomatic) bleeding will be determined by MRI at Day 7 and Day 30. This study aims to investigate a neuroprotective agent for use in acute ischemic stroke patients. If it is found to be safe and effective, then stroke patients will benefit in terms of reduced brain damage and improved functional outcomes. The CRC will play a valuable role in this study by allowing clinical follow up and phlebotomy for the subjects participating in the trial.	National Institute of Health / National Institute of Neurological Disorders and Stroke / Cedars-Sinai: U01NS088312-01; Clinical Coordinating Center (CCC): U01NS77179-01; Data Coordinating Center (DCC): U01NS077352	The Vanderbilt Stroke Trials Network Regional Coordinating Center for Tennessee	\$1,175,418	Not Available	Not Available	Not Available

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Year	Program Name	Brief Program Description	Funding Source #1	Grant Title	Funding Amount Granted	Patient Admissions	Patient Days	Outpatient Visits
March 17, 2015	Nutrition, Inflammation and Insulin Resistance in End Stage Renal Disease-Aim 2	There are more than 350,000 patients receiving chronic hemodialysis (CHD) therapy in United States. CHD patients display a unique type of metabolic and nutritional derangement, which can be collectively termed as protein energy wasting (PEW) of kidney disease. PEW is primarily characterized by increased protein breakdown in the skeletal muscle compartment compared to protein anabolism. Although the etiology and the mechanism leading to increased PEW in hemodialysis patients are complex, two well recognized and interrelated metabolic abnormalities, insulin resistance (IR) and chronic inflammation, are likely to play a critical role in the pathogenesis of this condition. Assessment of protein and energy turnover by stable isotope tracer techniques in CHD patients with different levels of inflammatory response and insulin resistance can elucidate the influence of these metabolic derangements on protein homeostasis, as well as substrate metabolism and oxidation. The combined dual glucose and amino acid (AA) clamp technique, first developed by Abumrad et al was devised to compensate for the confounding reduction in plasma amino acids with insulin administration due to its suppressive effect on protein breakdown, providing the most precise estimation of components of protein homeostasis. We will take advantage of this novel approach to determine amino acid sensitivity in a cohort of CHD patients in order to elucidate the relative effects of inflammation and insulin resistance on skeletal muscle protein turnover.	Veterans Administration Merit Award	VA/PA: Cindy Booker	\$141,481	Not Available	Not Available	Not Available
March 17, 2015	Tissue Sodium in Pre-hypertensive Patients	We believe that the accumulation of salt in the interstitium and inside cells represents a neglected risk factor, which initiates a pro-inflammatory state, chronically increases blood pressure, and leads to systemic energy imbalance. We will explore the concept that Na+ storage in the skin and in muscle is associated with increased blood pressure, a pro-inflammatory state, and reduced insulin sensitivity. Our goal is to identify Na+ storage as a novel unexpected risk factor for aging-associated cardiovascular disease. We hope to demonstrate that Na+ storage can be reduced by dietary intervention or by drug treatment. Our results could eventually progress to end-point trials on long-term tissue Na+ accumulation prevention to reduce cardiovascular disease risk. This intervention is direct patient care related.	UL1 TR000445	Vanderbilt Clinical and Translational Science Award	\$435,035	Not Available	Not Available	Not Available
March 18, 2015	Effects of bromocriptine on dopamine-dependent cognitive and reward processes	Individual differences in baseline dopamine function affects individual responses to dopaminergic drugs and thus the efficacy of treatments for dopaminergic disorders. This study will examine the role of baseline dopamine receptor levels on individual responsiveness to a dopaminergic agonist. This study will also assess the potential of eye blink rates as a proxy for dopamine function given its association to the dopamine system. The findings from this proposal will have implications both for the development of targeted interventions for dopamine disorders as well as the development of targeted interventions for at risk individuals. It may additionally prove relevant for understanding positive and negative treatment effects for a number of disorders in which dopaminergic agonists are given, such as Parkinson's disease and restless leg syndrome. Furthermore, eye blink rates cost significantly less to measure than PET imaging and may be a useful tool for indexing dopamine function in clinical settings. This study's findings will speak to the strength of eye blink rates as a proxy for dopamine function.	UL1 TR000445	Vanderbilt Clinical and Translational Science Award	\$24,090	Not Available	Not Available	Not Available

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Year	Program Name	Brief Program Description	Funding Source #1	Grant Title	Funding Amount Granted	Patient Admissions	Patient Days	Outpatient Visits
2015	Role of Sympathetic Activity and Splanchnic Capacitance in Obesity Hypertension: Specific Aim 1 and 2	Sympathetic nervous system activation contributes to obesity hypertension, but the mechanisms underlying this phenomenon are not fully understood. Our preliminary data showed that sympathetic withdrawal with the ganglionic blocker trimethaphan normalizes blood pressure in these patients by decreasing stroke volume and cardiac output with no change in vascular resistance, suggesting that a sympathetically mediated reduction in venous capacitance may play a major role. In this study, we will test the hypothesis that sympathetic activation in obesity contributes to hypertension through a reduction in splanchnic capacitance, the main venous capacitance bed. Our goal is to assess the contribution of the abdominal veins and the sympathetic nervous system to the high blood pressure in obesity. This is a novel mechanism of hypertension that has not been studied in humans because of the limitations of previous techniques. We believe that we can overcome these limitations with our experimental approach. More importantly, this knowledge may open possibilities for the development of new treatments, such as denervation of abdominal sympathetic nerves. Our research approach can also be used to determine the effect of medications (e.g. antihypertensives) on abdominal veins. This can guide the treatment of patients with certain forms of hypertension and be particularly useful in patients with both hypertension and orthostatic hypotension. Finally, our studies will provide a novel non-invasive tool to assess sympathetic tone in the splanchnic vasculature, and sympathetically mediated changes in splanchnic capacitance in other conditions such as acute decompensated heart failure	UL1 TR000445	Vanderbilt Clinical and Translational Science Award	\$17,504	Not Available	Not Available	Not Available
2013	Assessing Bone Fracture Resistance with Reference Point Indentation	There are currently no clinical tools to directly assess the fracture resistance of bone. The Reference Point Indentation (RPI) instrument has the potential to do so, but the relationship of its measurement to fracture resistance is not well characterized. The proposed study aims to validate the use of RPI in discriminating fragile bone (old) from robust bone (young). Funds are being requested to purchase the RPI instrument in order to validate its use as a direct indicator of bone's resistance to fracture. The RPI instrument can test human bone in vivo and ex vivo. If the proposed study finds that RPI can assess the age-related deterioration of fracture resistance of bone using cadaveric tissue, then in vivo application of RPI will likely identify individuals who are at risk of a bone fracture. The proposed project will provide the findings necessary to acquire extramural funding to achieve our long-term goals: to perform a prospective clinical studies that determine whether novel measures of bone quality (i.e., RPI-derived indentation distance increase and MRI-derived bound water) will be predictive of osteoporotic fractures (femoral neck and distal radius) among diabetics and individuals over 60 years old as well as fractures among NF1 patients (distal tibia).	CMMI-1068988	Dynamic Mechanical Behavior of Bone Tissue as Characterized by Nanoindentation	\$188,926	Not Available	Not Available	Not Available

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**February 25, 2016
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Year	Program Name	Brief Program Description	Funding Source #1	Grant Title	Funding Amount Granted	Patient Admissions	Patient Days	Outpatient Visits
April 15, 2015	VICCRRE1462 & "A Phase I Dose Escalation Study of POL6326 with Erlubulin in Patients with Relapsed, Triple Negative and Hormone Refractory ER Positive Metastatic Breast Cancer	Metastatic breast cancer (mBC) remains an incurable disease. Hormonal therapy is the initial course of treatment for those breast cancers that are estrogen receptor positive. Unfortunately, most of these patients become resistant to hormone therapy, and like those patients that are hormone receptor negative, they must then rely upon cytotoxic chemotherapy to control their disease. Despite new targeted therapies and cytotoxic agents that have recently been added to the treatment armamentarium, most patients with metastatic breast cancer develop resistance within months and overall survival remains poor. Clearly, new strategies in the treatment of metastatic breast cancer are warranted. The purpose of this research study is to evaluate the combination of two drugs & " POL6326 and erlubulin & " in the treatment of metastatic breast cancer and to find the best dose of POL6326 when given in combination with erlubulin.	UL1 TR000445	Vanderbilt Clinical and Translational Science Award	\$14,715	Not Available	Not Available	Not Available
April 22, 2015	Bone Fracture Risk Assessment Through Bound- and Pore-Water MRI	The purpose of this study is to find ways to assess bone tissue in response to treatment for high fracture risk. While DXA is commonly used for assessing fracture risk, MRI can measure different properties of the bone by evaluating the water content. This study will compare MRI measures and DXA measures before treatment and 6 months and 1 year after treatment. The project will provide preliminary data which may enable us to write a renewal proposal to our current bone imaging grant. In the current phase, we are developing and testing the technology, in the next funding period we would like to evaluate our technology as a tool for measuring treatment response in patients with elevated fracture risk.	National Institutes of Health R01EB014308	Bone Fracture Risk Assessment Through Bound- and Pore - Water MRI	\$1,346,821	Not Available	Not Available	Not Available
April 22, 2015	Clinical Trial of Metformin in Pulmonary Arterial Hypertension	We plan to use metformin as an agent to test our hypothesis that treatment of insulin resistance in patients reduces oxidant stress, ameliorates adipokines, improves six minute walk distance and, potentially, clinical outcomes. If the trial is successful, then the door is open for initiation of phase III clinical trials with the ultimate goal of proving metformin a safe and effective drug in treating pulmonary arterial hypertension.	National Institutes of Health PO1HL108800	Hormonal, Metabolic and Signaling Interactions in PAH	\$13,576,414	Not Available	Not Available	Not Available
April 28, 2015	Nicotinic Treatment of Post-Chemotherapy Subjective Cognitive Impairment: A Pilot Study	This study will be a double-blind, randomized, placebo-controlled, parallel group pilot study to evaluate the effect of transdermal nicotine to 1) produce positive effects on subjective complaints and 2) enhance cognitive performance on laboratory measures of cognitive performance in breast cancer patients with persistent CRCI. This proposed study has broad clinical and scientific significance. Nicotinic agonists are shown to improve cognitive performance in several clinical populations with cognitive impairment, including AD, MCI, Parkinson's disease, and ADHD. While the concept of nicotinic receptor stimulation for cognitive enhancement is not in itself novel, the idea of using nicotine treatment for non-smoking individuals with persistent CRCI has never been explored. The majority of women now diagnosed with breast cancer are long-term survivors and will likely die of other, non-breast cancer related illness. With deaths from breast cancer on the decline, it is of critical importance to address quality of life issues, such as persistent CRCI, for long-term survivors. If the hypotheses were validated, these findings would support a novel, broadly available, and inexpensive intervention for persistent CRCI and would encourage early treatment intervention to improve subjective cognitive complaints and/or cognitive performance and could have significant benefits for large numbers of breast cancer survivors.	UL1 TR000445	Vanderbilt Clinical and Translational Science Award	\$25,176	Not Available	Not Available	Not Available

SUPPLEMENTAL #1

Year	Program Name	Brief Program Description	Funding Source #1	Grant Title	Funding Amount Granted	Patient Admissions	Patient Days	Outpatient Visits
May 1, 2015 February 25, 2016 2:57 pm	Prospective Observation of Cardiac Safety with Proteasome Inhibition (PROTECT)	The primary objective is to prospectively quantitate the incidence of cardiac events of patients receiving PIs for MM. This is a prospective, non-randomized, non-interventional, multi-institutional study. Approximately 130 patients will be enrolled, all of whom will be initiated on PIs for relapsed and/or refractory MM, and are being treated with either (1) bortezomib-based or (2) carfilzomib-based therapy. The choice of treatment will be based on the treating hematologist's interpretation as to optimal cancer therapy and is not dictated by this research protocol. Sixtyfive patients will be sought for each group as an initial treatment strategy and will be analyzed on an intention-to-treat basis. Patient enrollment between the two groups will be conducted in approximately equal fashion at each site, maintaining less than 30% difference between enrolled groups. All patients will be carefully characterized from a cardiac risk profile perspective at baseline and will undergo basic screening tests to assess for underlying cardiovascular disease. Typical cardiac risk factors will be appropriately addressed before and during treatment for myeloma and all patients will be followed in a prospective manner with periodic cardiac assessments	UL1 TR000445	Vanderbilt Clinical and Translational Science Award	\$26,240	Not Available	Not Available	Not Available
May 1, 2015	Genome Wide Association Study of Childhood Onset Idiopathic Nephrotic Syndrome	The study seeks to perform genome wide association study (GWAS) to define common disease loci for childhood onset idiopathic nephrotic syndrome. To accomplish this aim, a GWAS will be conducted in several hundred disease cases around the world and ethnically matched controls in order to identify genetic risk loci associated with idiopathic NS.	UL1 TR000445	Vanderbilt Clinical and Translational Science Award	\$260	Not Available	Not Available	Not Available
May 4, 2015	Prevalence of Vascular Dysfunction In Obese Children With Developmental Bone Disease	It has been established that obesity and vascular dysfunction adversely impacts bone growth and development. Specifically, these pathologies disrupts the biology of the growth plate (physis) resulting in both premature initiation and cessation of long-bone growth. As the number of obese children with vascular dysfunction is rising rapidly and the morbidity and cost of joint impairment is substantial there is a considerable need to determine the key physical and biological factors that cause these obesity related developmental diseases. Benefits to the larger community include the possible identification of predictive markers of disease severity and progression in developmental bone disease. Further, considering the cost burden of obesity and bone disease, determining the pathophysiologic cause of obesity related bone disease has the potential to reduce morbidity and health care cost of affected patients. Funds will be used to acquire data and analyze data as well as develop database of patients with these diseases.	UL1 TR000445	Vanderbilt Clinical and Translational Science Award	\$18,070	Not Available	Not Available	Not Available

SUPPLEMENTAL #1

Year	Program Name	Brief Program Description	Funding Source #1	Grant Title	Funding Amount Granted	Patient Admissions	Patient Days	Outpatient Visits
May 7, 2015 February 25, 2016 2:57 pm	Safety and Cardiovascular Efficacy of Spirolactone in Dialysis-Dependent ESRD (Spin-D) Trial	The primary objective of this study is to characterize the safety and tolerability of multiple doses of chronic SPL therapy compared with placebo in maintenance hemodialysis patients and to assess the feasibility of conducting a full-scale, mortality-powered trial of SPL. The effects of SPL compared with placebo on multiple cardiovascular efficacy parameters will also be analyzed. The primary efficacy parameter will be the change in the E _a E ₂ measurement on tissue Doppler echocardiography (TDI) as an index of diastolic function and a surrogate for myocardial fibrosis. Secondary cardiac parameters of interest that will be studied in the overall population or in sub-studies include heart rate variability, circulating markers of fibrosis, and coronary flow reserve (CFR) as an index of microvascular function. These parameters are designed to broaden insight into the potential effects of SPL on cardiac structure and function in individuals with dialysis-dependent ESRD and to assess the feasibility of conducting a full-scale, mortality-powered trial.	National Institutes of Health U01DK099923	Anti-inflammatory Interventions in Maintenance Hemodialysis Patients	\$461,819	Not Available	Not Available	Not Available
May 19, 2015	Transdermal Vagal Stimulation For the Treatment of Postural Tachycardia Syndrome	Postural Tachycardia Syndrome (POTS) is a syndrome characterized by disabling symptoms of inadequate cerebral perfusion on assuming the upright posture. It is characterized by an excessive increase in heart rate and exaggerated increase in plasma catecholamine levels on standing in the absence of a blood pressure fall. These patients have also decreased heart rate variability. The present project is a pilot study to test that transcutaneous vagal stimulation in POTS will reduce heart rate, increase heart rate variability and reduce symptoms during upright. If the study supports our hypothesis, the proposed method of vagal stimulation could be used as a possible treatment of POTS. Pharmacological approaches to treat orthostatic intolerance have limitations or are not successful in many cases. Electrical vagal stimulation would be an alternative non-pharmacological approach to prevent orthostatic intolerance. If the study supports our hypothesis, the proposed method of vagal stimulation could be used as a possible treatment of POTS.	U11 TR000445	Vanderbilt Clinical and Translational Science Award	\$95,176	Not Available	Not Available	Not Available
May 22, 2015	Glucose Metabolism in subjects with Aldosterone-producing Adenomas	Subjects with an aldosterone producing adenoma (APA) have resistant hypertension and an increased risk of developing type 2 diabetes, but the reason they develop diabetes is unknown. We have demonstrated that aldosterone impairs insulin secretion in islets, and will test the hypothesis that adrenalectomy improves insulin secretion in patients with APAs. We have demonstrated that aldosterone impairs insulin secretion in mice and in isolated islets. We will now see if this holds true in humans. VICTR support will help provide research infrastructure to conduct these studies in the CRC.	National Institutes of Health R01DK096994	Endogenous Aldosterone and glucose metabolism	\$422,541	Not Available	Not Available	Not Available

SUPPLEMENTAL #1

Year	Program Name	Brief Program Description	Funding Source #1	Grant Title	Funding Amount Granted	Patient Admissions	Patient Days	Outpatient Visits
May 22, 2015	Tozilumab in the Treatment of Refractory Polymyositis and Dermatomyositis	We propose a multi-center, double-blind, randomized placebo-controlled proof of concept pilot study to evaluate the efficacy and tolerability of Tozilumab (anti-IL-6R) in patients with refractory adult Polymyositis and Dermatomyositis. Secondly objective to assess the rapidity, the magnitude, the steroid-sparing effect, the durability and the presence of adverse effects on the subjects treated with Tozilumab. Blocking the effects of IL-6 has shown promising results in RA and other autoimmune patients in several trials. It is noted in mouse model of myositis, IL-6 as a mediator of muscle inflammation, these mouse when treated with anti-IL-6 receptor monoclonal antibodies have shown improvement in disease activity. Tozilumab is antibody against IL-6 receptor produced by recombinant DNA technology.	UL1 TR000445	Vanderbilt Clinical and Translational Science Award	\$28,800	Not Available	Not Available	Not Available
February 25, 2016 12:57 pm	Autism Speaks Autism Treatment Network: Call-Back Assessment	The goals of this study are to (1) describe the trajectory of major medical co-morbidities over 3-4 years; (2) describe the longitudinal relationship between medical co-morbidities and behavioral / functional outcomes, and (3) secondary examination will be made of the relationship of medical co-morbidity to other adaptive and behavioral outcomes. The ATN is currently targeting four groups of co-morbidities: sleep, epilepsy, GI issues (abdominal pain and constipation), and psychiatric issues (anxiety and hyperactivity). We are committed to developing standards and guidelines for the evaluation and treatment of medical conditions associated with autism that can be disseminated into community settings. The ATN serves as a model for autism care in community pediatrician practices through the development of algorithms and toolkits, as well as outreach and education.	VUMC35051(UA3MC 11054)	Autism Intervention Research Network for Physical Health (Infrastructure)	\$242,286	Not Available	Not Available	Not Available
May 26, 2015	A Randomized, Double-Blind, Placebo-Controlled, Parallel-Group, Fixed-Dose Study of NNZ-2566 in Fragile X Syndrome	There is a dearth of effective treatments available for individuals with Fragile X Syndrome. No disease-modifying medications are available for this syndrome. Rather, most of the medications that are utilized in the treatment of individuals with Fragile X Syndrome have a narrow scope of benefit that is directed towards the associated neuropsychiatric symptoms that are responsible, to varying degrees, for day-to-day impairment in functioning. In light of this, better medicines are desperately needed for these individuals. This study could directly impact the FXS community by helping researchers further understand the nature of the disorder as well as possibly provide a treatment for this disorder.	UL1 TR000445	Vanderbilt Clinical and Translational Science Award	\$5,940	Not Available	Not Available	Not Available
May 28, 2015	Assessment of Plasma Angiotensin Profile in Postural Tachycardia Syndrome (POTS)	It has been difficult to understand why ANG II levels are so high and yet aldosterone levels and blood volume are low in POTS. One possible explanation is that there is a problem with adrenal responsiveness to ANT II. If our hypothesis is true, then the pathophysiological problem in POTS is not with the AT1 receptor or the adrenal gland, but with Angiotensin metabolism.	National Institutes of Health R01HL102387	Aldosterone and Sodium Regulation in Postural Tachycardia Syndrome	\$2,131,680	Not Available	Not Available	Not Available
May 28, 2015	Aldosterone & Sodium Regulation in Postural Tachycardia Syndrome: Screening Protocol	Physicians often prescribe a high-sodium diet for the treatment of POTS. The rationale behind this approach is that sodium in the diet will help subjects to retain fluid, and thereby raise blood volume and/or blood pressure. We have preliminary evidence that a high-salt diet raises plasma volume (as determined by changes in hematocrit) and blunts the tachycardia with standing. This treatment is also felt to decrease symptoms in some patients with POTS. We will now use the DAXOR BVA-100 Blood Volume Analyzer to test whether patients with POTS have a blunted plasma volume expansion in response to a high-sodium diet and assess the influences of dietary sodium on components of the renin-angiotensin-aldosterone systems.	National Institutes of Health R01HL102387	Aldosterone and Sodium Regulation in Postural Tachycardia Syndrome	\$2,131,680	Not Available	Not Available	Not Available

SUPPLEMENTAL #1

Year	Program Name	Brief Program Description	Funding Source #1	Grant Title	Funding Amount Granted	Patient Admissions	Patient Days	Outpatient Visits
May 28, 2015	A Pilot Study of the Effect of Dietary Sodium Intake on Assessments of Vascular Endothelial Function - A substudy of Dietary Salt in POTS	Short-term high salt intake has been shown to produce reductions in NO as reported by Dishy et al. Elevated ADMA was also implicated in patients with high salt diet by a study reported by Fujiwara et al. Many of these studies have assessed patients on their native diets, and thus may be confounded by many unknown variables. Most of these studies were also carried out on middle aged or older patients with confounding risk factors such as hypertension. We propose to study young to middle aged subjects who will undergo acute, but steady state HIGH and LOW sodium diets, and assess the acute changes in measures of endothelial events. Differences in measures of endothelial function between the diet phases might suggest that dietary sodium intake is an important variable that would need to be controlled in future studies of endothelial function.	National Institutes of Health R01HL102387	Aldosterone and Sodium Regulation in Postural Tachycardia Syndrome	\$378,378	Not Available	Not Available	Not Available
May 28, 2015	Aldosterone and Sodium Regulation in Postural Tachycardia Syndrome Aim 1b: ACTH Stimulation	We found that patients with postural tachycardia syndrome had a subnormal increment in aldosterone with upright posture, which might reflect a blunted adrenal response to stimulation upon assuming upright posture. In this AIM, we propose to assess the adrenal response to aldosterone stimulation with IV adrenocorticotropin hormone.	National Institutes of Health R01HL102387	Aldosterone and Sodium Regulation in Postural Tachycardia Syndrome	\$2,131,680	Not Available	Not Available	Not Available
May 28, 2015	Aldosterone and Sodium Regulation in Postural Tachycardia Syndrome - Umbrella	We will mechanistically assess aldosterone and sodium handling in patients with Postural Tachycardia Syndrome (POTS). We have previously shown many of these patients to have a low blood volume and a low aldosterone level, despite a high level of angiotensin II. Combined these data suggest dysregulation in the aldosterone regulation and an inability to retain enough sodium to maintain adequate blood volume. We have identified a problem with blood volume regulation and are proposing a series of clinical bedside studies to understand the pathophysiology of POTS. We hope that by providing this needed mechanistic understanding that more rational treatments can be developed for patients with POTS.	National Institutes of Health R01HL102387	Aldosterone and Sodium Regulation in Postural Tachycardia Syndrome	\$2,131,680	Not Available	Not Available	Not Available

SUPPLEMENTAL #1

Year	Program Name	Brief Program Description	Funding Source #1	Grant Title	Funding Amount Granted	Patient Admissions	Patient Days	Outpatient Visits
June 1, 2015 February 25, 2016 2:57 pm	Inhaled corticosteroid use to prevent acute chest syndrome recurrence in children between 1 and 4 with sickle cell disease: a feasibility trial	This is a single-arm feasibility trial investigating the use of inhaled corticosteroids in the prevention of acute chest syndrome recurrence in children between the ages of 1 and 4 years with sickle cell disease. Acute and chronic pulmonary complications are a leading cause of morbidity and mortality in children with sickle cell disease (SCD). Acute chest syndrome (ACS), defined broadly as an increase in respiratory effort, fever, and new radiodensity on chest x-ray, is a major cause of death in children and adults with SCD. Dr. DeBaun's research team has been extramurally funded for over a decade, focusing on the pathogenesis of lung complications in SCD. Their group has developed several lines of evidence to support the proposed feasibility trial: 1) ACS is associated with a clinical diagnosis of asthma; 2) the high rate of ACS in children between 1 and 4 years of age is associated with an asthma diagnosis; and 3) children with ACS events before 4 years of age have a 50% rate of being hospitalized for either ACS or pain within 1 year of admission (DeBaun unpublished observation). For children with SCD that develop ACS, we propose that the use of budesonide inhalation suspension (BIS) will attenuate pulmonary inflammation after an ACS episode, and decrease future vaso-occlusive pain and ACS episodes. Currently, no standard care treatment guidelines exist to prevent the recurrence of ACS in children between 1 and 4 years of age, the group with the highest incidence of ACS and repeat ACS. Through a single-arm feasibility trial and in preparation for a limited-institution randomized trial, we plan to assess the acceptability, feasibility, and adherence of inhaled corticosteroids. We will conduct a single-arm prospective feasibility trial with a maximum of 10 children less than 4 years of age with at least 1 episode of ACS.	UL1 TR000445	Vanderbilt Clinical and Translational Science Award	\$3,730	Not Available	Not Available	Not Available
June 4, 2015	A Pilot and Feasibility Study to Determine if a Common Atrial Fibrillation Risk Locus Modulates Differential Response to Antiarrhythmic Drugs	In a recent retrospective study, we found that common variants at the chromosome 4q25 atrial fibrillation susceptibility locus were associated with a differential response to class I and III anti-arrhythmic drugs. We intend to apply for NIH funding to test this hypothesis prospectively. Here, we propose to conduct a pilot/feasibility crossover study assessing the efficacy of flecainide and sotalol at suppressing atrial fibrillation, as measured by a new, FDA approved insertable cardiac monitor, in patients with paroxysmal atrial fibrillation.	UL1 TR000445	Vanderbilt Clinical and Translational Science Award	\$39,368	Not Available	Not Available	Not Available
June 4, 2015	Long-Term Investigative Follow-Up in TrialNet	What is the clinical outcome for research subjects who participated in a diabetes prevention or intervention trial through the Type 1 Diabetes TrialNet consortium? How did exposure to study medications influence their subsequent diabetes management or their health and safety when compared to subjects who did not receive study medications? This is a human clinical research follow-up study. The study will determine long-term effects of study drug exposure, whether or not the subject developed diabetes. Type 1 diabetes affects over 3 million individuals and 30,000 new cases are diagnosed each year. TrialNet aims to prevent the development of type 1 diabetes and will have profound effects on communities and health services once an effective prevention is identified. Funds are requested to support CRC nursing and facilities in order to carry out the followup of subjects who were exposed to study interventions or who developed diabetes while being monitored for type 1 diabetes risk.	National Institutes of Health U01DK085465	Vanderbilt University: Clinical Center Application, Type 1 Diabetes TrialNet	\$2,283,788	Not Available	Not Available	Not Available

SUPPLEMENTAL #1

Year	Program Name	Brief Program Description	Funding Source #1	Grant Title	Funding Amount Granted	Patient Admissions	Patient Days	Outpatient Visits
June 11, 2015	Anti-CD3 MAB (Teplizumab) for Prevention of Diabetes in Relatives At Risk for T1DM	Type 1 Diabetes is a chronic and potentially disabling disease that represents a major public health and clinical concern. The number of patients being diagnosed with type 1 diabetes is increasing each year and is approaching an epidemic level in some countries that track this information. The primary objective of this clinical trial is to determine whether intervention with teplizumab will prevent or delay the development of T1DM in high risk autoantibody positive non-diabetic relatives of patients with T1DM. This project is a human clinical trial. If T-cell modulation by the anti-CD3 antibody, teplizumab, can delay the development of diabetes in this very high-risk population with antibody positive dysglycemia (>95% likelihood of developing diabetes in the next five years), the most likely followup study would be to extend this work to subjects who are autoantibody positive but still retain enough islet function to have normal glucose tolerance. The ultimate goal is to be able to intervene in the autoimmune process at the earliest possible point at which intervention is both safe and effective, and result in the preservation of the greatest number of insulin-producing cells. The requested funds assist us in establishing whether this therapy, shown to be modestly effective in maintaining beta cell mass after diabetes has already been diagnosed, can be useful in the ultimate goal of diabetes prevention.	National Institutes of Health U01DK085465	Vanderbilt University: Clinical Center Application, Type 1 Diabetes TrainNet	\$2,283,788	Not Available	Not Available	Not Available
June 17, 2015	TrainNet Natural History Study of the Development of Type 1 Diabetes	The overall objective of this study is to perform baseline and repeat assessments over time of the metabolic and immunologic status of individuals at risk for Type 1 Diabetes (T1D) in order: a) To characterize their risk for developing T1D, b) To describe the pathogenetic evolution of T1D, and c) To increase the understanding of the pathogenetic factors involved in the development of T1D.	National Institutes of Health U01DK085465	Vanderbilt University: Clinical Center Application, Type 1 Diabetes TrainNet	\$2,283,788	Not Available	Not Available	Not Available
June 17, 2015	Oral Insulin for the Prevention of Diabetes in Relatives at Risk for Type 1 Diabetes Mellitus	Type 1 Diabetes is a chronic and potentially disabling disease that represents a major public health and clinical concern. The number of patients being diagnosed with type 1 diabetes is increasing each year and is approaching an epidemic level in some countries that track this information. The primary objective of this clinical trial is to determine whether intervention with oral insulin will prevent or delay the development of T1DM in high risk MIAA antibody positive non-diabetic relatives of patients with T1DM.	National Institutes of Health U01DK085465	Vanderbilt University: Clinical Center Application, Type 1 Diabetes TrainNet	\$2,283,788	Not Available	Not Available	Not Available

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Year	Program Name	Brief Program Description	Funding Source #1	Grant Title	Funding Amount Granted	Patient Admissions	Patient Days	Outpatient Visits
June 23, 2015	Meal Schedule effects on Circadian Energy Balance in Adults	A growing body of evidence supports the hypothesis that disruptions in the circadian clock, either through primary dysregulation of genes of the circadian clock system or through alterations in the external environmental cycles (e.g., shift-work or jet-lag), lead to defects in glucose tolerance, dyslipidemia and abnormal secretion of appetite/metabolic hormones such as leptin and disruption of metabolic gene expression. A reasonable inference based on these results would be that how nutrients are metabolized and the consequences of that metabolism would show significant variation with the specific time of food consumption relative to the internally driven cycles of genes involved in metabolism. Our goal is to extend these findings with a focus on the role of the circadian system and the effect of body composition. We propose a feasibility study in which we will continuously monitor metabolism and circadian phase over a 64-h period in individuals with high or low BMI to examine the relationships among metabolism, the timing of food consumption, and circadian phase. This is translational because it could lead to therapies for obesity and diabetes based on meal scheduling.	UL1 TR000445	Vanderbilt Clinical and Translational Science Award	\$82,115	Not Available	Not Available	Not Available
June 23, 2015	Effects of theophylline on cAMP signaling in children with pseudohypoparathyroidism type 1a	The phenotype of PHP1a is due to reduction of Gs-alpha coupled receptor signaling. Our goal is to directly treat the underlying cause of PHP1a by improving Gs-alpha signaling. This pilot study will test the effects of PDE inhibitors on parathyroid hormone resistance, sleep apnea and resting energy expenditure. This is a phase IIa study to test the safety and efficacy of PDE inhibitors in children with PHP1a. If this pilot study is promising, we will move forward with a longer term, randomized control subjects using an oral PDE inhibitor.	UL1 TR000445	Vanderbilt Clinical and Translational Science Award	\$61,706	Not Available	Not Available	Not Available
June 29, 2015	Metabolic and Cardiovascular Impact of CD36 deficiency in humans	CD36 is a class B scavenger receptor which is ubiquitously expressed on a variety of cell types important for lipid metabolism. CD36 plays a major role in lipid absorption, processing and metabolism, all of which may have both short and long term metabolic and cardiovascular effects. Despite our understanding of the role of CD36 on lipid metabolism, it is still unclear whether individuals who carry genetic variants that affect CD36 expression have persistently elevated blood lipids following a high fat meal, typical of western diets. The overall purpose of this proposal is to determine the contribution of genetic variants of CD36 to postprandial lipid profile and vascular endothelial function. Abnormalities in complex interactions between diet, life style, and genetic factors influence risk for metabolic and cardiovascular diseases. In industrialized countries individuals spend most of the day in a postprandial state, thus identification and characterization of variations in genes involved in lipid absorption and processing is important. The overall purpose of this proposal is to determine the contribution of a genetic variant of CD36 (rs3211938) to postprandial lipid profile and vascular endothelial function in a population with the highest prevalence of cardiovascular disease (African Americans).	UL1 TR000445	Vanderbilt Clinical and Translational Science Award	\$50,667	Not Available	Not Available	Not Available

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Year	Program Name	Brief Program Description	Funding Source #1	Grant Title	Funding Amount Granted	Patient Admissions	Patient Days	Outpatient Visits
June 30, 2015	INSPIRE	Studies of the natural history of children following RSV bronchiolitis have long suggested that these children are at high risk of developing childhood asthma, however, not all do, and it is still not possible to predict which patients will ultimately develop childhood asthma, or who might most benefit from vigorous attempts at preventing early viral infection. While severe bronchiolitis has been clearly linked to the development of asthma, an important unanswered question is whether mild RSV infection may actually protect against the inception of childhood asthma. Thus, there are compelling reasons to focus on the development of new approaches to understanding why certain infants are predisposed to developing viral LRTI, and subsequently childhood asthma. This study will help understand which children are at increased risk of asthma following RSV infection, by collecting viral samples, urine and blood on infants in the first year of life. We will use molecular virology to determine which viral strains are more severe and mucogenic to assist with targets for vaccine prevention. Our use of biomarkers in the urine and nasal washes will help us understand the immune response to RSV. Our eventual focus on genetics will help us understand the extent to which RSV is causal in asthma development.	National Institutes of Health U19AI095227	Host and Viral Determinants of Infant and Childhood Allergy and Asthma	\$1,900,883	Not Available	Not Available	Not Available
June 30, 2015	Non-invasive Assessment of Skeletal Muscle Metabolism in Pulmonary Hypertension	There is increasing evidence that PH is associated with primary abnormalities of skeletal muscle function that contribute to reduced exercise capacity in this population. The evidence to date derives from experimental models and muscle biopsies from human subjects. We propose to use non-invasive imaging techniques to evaluate skeletal muscle metabolism in PH patients and place those findings in clinical context with exercise capacity and blood metabolic markers. This proposal builds on findings from both animal models and humans but non-invasive methods have not been used to study skeletal muscle metabolism in PH patients. Characterization of skeletal muscle metabolism with non-invasive imaging will allow us to develop therapeutic targets for clinical trials of metabolic therapy and exercise in this population.	U11 TR000445	Vanderbilt Clinical and Translational Science Award	\$9,276	Not Available	Not Available	Not Available
July 2, 2015	Host-Helicobacter pylori co-evolution and protection from atopic disease	The goals of the larger project, for which the current proposal is a pilot/feasibility study, seeks to understand the interaction of human and H. pylori ancestry, and particularly the potential protection from atopic disease (asthma, allergies, and eczema) and gastric atrophy, from infection with an H. pylori strain of the same ancestry as the human host. To do this, we propose to collect H. pylori DNA, using the minimally invasive string test, from a sample of individuals without cancer, to determine the ancestry of their H. pylori, and to then compare the interaction of host ancestry with bacterial ancestry with the prevalence of atopic disease and gastric atrophy. The proposed project will thus provide important insights regarding risk assessment in this high-risk and under-served population, as well as to potentially explain the racial differences in occurrence of these chronic diseases. The proposed project will thus provide important insights regarding risk assessment in this high-risk and under-served population, as well as to potentially explain the racial differences in occurrence of atopic diseases.	U11 TR000445	Vanderbilt Clinical and Translational Science Award	\$22,741	Not Available	Not Available	Not Available

SUPPLEMENTAL #1

Year	Program Name	Brief Program Description	Funding Source #1	Grant Title	Funding Amount Granted	Patient Admissions	Patient Days	Outpatient Visits
July 10, 2015	Determination of novel diagnostic approaches for fibromyalgia syndrome	We are analyzing gene expression signatures in whole blood with the goal of developing novel diagnostic strategies. This project will enable us to design new diagnostic tools for the diagnosis of autoimmune and non-autoimmune disease.	UL1 TR0000445	Vanderbilt Clinical and Translational Science Award	\$9,601	Not Available	Not Available	Not Available
February 15, 2015 2:57 pm	NOBLE Study of T-817	The primary objective is to evaluate the efficacy of T-817MA as measured by neuropsychological measures (ADAS-cog and ADCS-CGIC). Additional aims include evaluating the safety and tolerability of T-817MA measured by clinical safety laboratories, physical examinations, ECGs and solicitation of adverse events; as well as evaluating the efficacy of T-817MA as measured by ADCS-ADL, FAQ, Neuropsychiatric Inventory (NPI) and Mini-mental State Examination (MMSE). This clinical trial specifically seeks to benefit patients with mild to moderate Alzheimer's disease, improving their clinical care in a field with limited pharmacotherapy.	UL1 TR0000445	Vanderbilt Clinical and Translational Science Award	\$19,440	Not Available	Not Available	Not Available
July 17, 2015	Small RNAs in Rheumatoid Arthritis (StARRA)	High density lipoprotein (HDL), or the "good cholesterol" may not be good in patients with RA, and may be partly to explain for the increased cardiovascular risk in RA. HDL transports small strings of nucleic acids called "microRNAs" or "small RNAs" to cells, leading to altered gene expression. Moreover some of these small RNAs come from bacteria and fungi that live in the body. HDL-microRNA cargo can be altered by different disease states and may be responsible for some disease sequelae, such as increased cardiovascular disease, but underlying mechanisms are unclear. Currently, nothing is known about HDL-microRNA cargo of RA. The goal of this study is to determine if in the HDL-microRNA cargo, both human and non-human, is altered in patients with RA and is associated with inflammation and vascular dysfunction in RA. If certain HDL miRNAs appear to play a role in the vascular dysfunction in RA, these can be modified to potentially reduce cardiovascular risk in patients with RA.	National Institutes of Health 1K23AR0068443-01	Functional Impact of HDL transport of miRNA in rheumatoid arthritis	\$624,645	Not Available	Not Available	Not Available

SUPPLEMENTAL #1

Year	Program Name	Brief Program Description	Funding Source #1	Grant Title	Funding Amount	Patient Admissions	Patient Days	Outpatient Visits
2015 July 21, February 25, 2016 2:57 pm	Reduced Opioid Analgesic Requirements Via Improved Endogenous Opioid Function	Daily use of high-dose opioid analgesics for chronic pain management has increased dramatically, and is associated with increasing numbers of patients experiencing opioid-related negative health effects, abuse, overdose, and even death. Ways of providing effective chronic pain relief with less reliance on high-dose opioid analgesics are sorely needed. Based on recent work indicating that responses to opioid analgesics are influenced by functioning in natural (endogenous) opioid systems, this project will determine whether enhancing endogenous opioids (via aerobic exercise training) permits achieving desired levels of analgesia with lower dosages of opioid analgesics, and fewer side effects and abuse-related drug effects. If hypotheses are confirmed, results of this study could substantially alter chronic pain management by facilitating use of mechanism-based strategic combinations of nonpharmacological and pharmacological pain therapies to achieve acceptable pain relief with fewer side effects and reduced abuse risk. This approach could have significant population level benefits, given the frequency with which chronic high-dose opioids are currently used and their increasingly recognized negative sequelae. Findings would also add important knowledge to the sparse human literature regarding links between chronic pain, EO function, and responses to opioid analgesics, knowledge with important implications for achieving the goal of personalized pain medicine. Appropriate research space and research nursing support necessary to carry out the project are not funded by the primary NIH grant. This VICTR request would provide the necessary space and nursing support to make the project successful.	National Institutes of Health R01DA037891	Reduced Opioid Analgesic Requirements Via Improved Endogenous Opioid Function	\$670,940	Not Available	Not Available	Not Available
2015 July 23,	VX14-661-109: A Phase 3, Randomized, Double-Blind, Ivacaftor-Controlled, Parallel-Group Study to Evaluate the Efficacy and Safety of VX-661 in Combination With Ivacaftor in Subjects Aged 12 Years and Older With Cystic Fibrosis, Heterozygous for the F508del-CFTR Mutation and a Second CFTR Allele With a Gating Defect That Is Clinically Demonstrated to be Ivacaftor Responsive	The study population will be subjects with CF who are 12 years of age or older and who are heterozygous for the F508del-CFTR mutation and a second CFTR allele with a gating defect that is clinically demonstrated to be responsive to ivacaftor. This population was selected based on a deoProof-of-Concept study (Study VX11-661-101 [Study 101]). Results from the Study 101, Group 7, in subjects heterozygous for F508del-CFTR and G551D-CFTR, suggest that clinically meaningful improvement in percent predicted FEV1 can be achieved with the combination of VX-661 and ivacaftor compared with just ivacaftor alone. An 8-week period was selected as the duration for the Active Comparator Treatment Period. A significant response in percent predicted FEV1 is anticipated to be observed after 2 to 4 weeks of treatment with VX-661 in combination with ivacaftor. The 8-week primary endpoint was selected in order to obtain a more robust assessment of the durability of response that is less affected by short-term variability in FEV1. The Week 8 Visit is the conclusion of the Active Comparator Treatment Period in this study.	UL1 TR0000445	Vanderbilt Clinical and Translational Science Award	\$14,952	Not Available	Not Available	Not Available

SUPPLEMENTAL #1

Year	Program Name	Brief Program Description	Funding Source #1	Grant Title	Funding Amount Granted	Patient Admissions	Patient Days	Outpatient Visits
July 29, 2015	Glycemia Reduction Approaches in Diabetes: A Comparative Effectiveness Study (GRADE)	The trial is designed to be pragmatic (i.e. with immediate potential for transition) since we will be using approved medications and their combinations according to labeling. The results of this trial will identify the most effective means of treating type 2 diabetes. We anticipate that the results from this comparative effectiveness study will translate to changes in guidelines or setting of national standards for treatment. Data emanating from this study will likely be used for future updates of such standards or guidelines. The funds requested for this study will be for the venipuncture required for the annual oral glucose tolerance test for each of the study participants.	National Institutes of Health / Contract with George Washington University	Approaches in Diabetes: A comparative Effectiveness Study	\$256,652	Not Available	Not Available	Not Available
February 25, 2016 2:57 pm	Prospect : A two-part, multi-center, prospective longitudinal, exploratory study of biomarkers, clinical, and physiological profiles in CF	Cystic fibrosis (CF) is a genetic disorder caused by mutations in the gene encoding the cystic fibrosis transmembrane conductance regulator (CFTR) protein. Progressive obstructive lung disease is the main determinant of morbidity and mortality in CF; therefore it is critical to identify biomarker profiles that reflect and predict this phenotypic variability, and understand their relationship to residual CFTR activity. Emerging CFTR modulator therapies that directly target defective CFTR are being evaluated in pivotal clinical trials and may become available in the next few years. It is not known how partial restoration of CFTR function might impact CF disease progression and disease-related biomarkers. Thus there is urgent need to i) identify and validate biomarkers that might reflect partial restoration of CFTR function and can be used to monitor disease progression, and ii) evaluate the mechanistic effects of CFTR modulators on biomarkers and exploratory outcome measures in individuals with CF.	UL1 TR000445	Vanderbilt Clinical and Translational Science Award	\$11,903	Not Available	Not Available	Not Available
August 14, 2015	PHI 1436-A Phase 1, Open-Label, Non-Randomized, Dose-Escalating Safety, Tolerability and Pharmacokinetic Study of TAS-119 in Combination with Paclitaxel in Patients with Advanced Solid Tumors	To investigate the safety and determine the maximum tolerated dose (MTD) of TAS-119 in combination with paclitaxel (Combination Therapy MTD); and the Recommended Phase 2 Dose (RP2D) for TAS-119 in combination with paclitaxel in patients with advanced and unresectable solid tumors. The purpose of this trial is to investigate the tolerability and safety and to find the appropriate dose of TAS-119 when given in addition to paclitaxel. The recommended dose of TAS-119 identified from this trial will be the dose level used in future clinical research trials of TAS-119 when it is administered in addition to paclitaxel.	UL1 TR000445	Vanderbilt Clinical and Translational Science Award	\$28,800	Not Available	Not Available	Not Available
August 24, 2015	Role of the Foregut in nutrient metabolism in lean and obese humans	The intestines can sense the nutrient content of a meal and communicate this information to the body via hormonal and neuronal signals to control food intake and nutrient metabolism. In this proposal, we will determine if enteric nutrient sensing and neural signaling in the foregut regulates nutrient metabolism in humans and is impaired in obesity. The information derived from our human studies could point to gut chemosensing as a therapeutic target for obesity and related metabolic diseases. Much of the information related to nutrient sensing pathways has been obtained from animal studies, and it remains unknown whether foregut nutrient sensing mechanisms regulate nutrient metabolism in humans. This project will directly translate knowledge derived from animal studies into humans. VICTR support will augment my grant funding to provide the infrastructure resources necessary to accomplish these translational human studies.	National Institutes of Health R01DK100431	Role of the foregut in nutrient metabolism in lean and obese humans	\$341,475	Not Available	Not Available	Not Available

SUPPLEMENTAL #1

Year	Program Name	Brief Program Description	Funding Source #1	Grant Title	Funding Amount Granted	Patient Admissions	Patient Days	Outpatient Visits
August 24, 2015	Measuring aerobic intensity of yoga activity (MAYVA)	Yoga is a popular form of exercise with 1 out of 10 adults in the U.S. reporting practice for health. There are various styles of yoga with different levels of physical intensity. This variability makes research and consensus on the cardiometabolic benefits of yoga difficult. One out of ten adults in the U.S. uses yoga for physical exercise. However, it is not clear if specific movements provide more benefit. This project will measure the energy expenditure of different yoga movements to inform yoga use for health. Since yoga is so popular this research will provide valuable information to individuals making choices about different types of exercise.	UL1 TR0000445	Vanderbilt Clinical and Translational Science Award	\$1,080	Not Available	Not Available	Not Available
February 25, 2016 2:57 pm	GS-US-361-1157 - A Phase 2/3, Randomized, Double-Blind, Placebo-Controlled Study to Evaluate the Effect of GS-6615 on Exercise Capacity in Subjects with Symptomatic Hypertrophic Cardiomyopathy	This is a randomized, double-blind, placebo-controlled, global, multicenter study to evaluate the effect of GS-6615 on exercise capacity in subjects with symptomatic HCM. Eligible subjects will be enrolled and randomized 1:1 to receive either GS-6615 or matching placebo for a treatment duration of 24 weeks. Potential new drug for HCM patient population Randomization will be stratified by sex and by age (3% X 50 years and < 50 years).	UL1 TR0000445	Vanderbilt Clinical and Translational Science Award	\$108,340	Not Available	Not Available	Not Available
August 31, 2015	Randomized, double-blind, placebo controlled, phase 3 trial of ZGN-440 in obese subjects with Prader-Willi syndrome to evaluate total body fat mass, food-related behavior and safety over 6 months	PWS is a genetic condition that causes excessive hyperphagia, weight gain, and associated developmental delays. To minimize food access and life threatening obesity. Those with PWS cannot live independently due to the need for constant 24 hour a day supervision and vigilant food restriction over a lifetime. They can overeat and rupture their stomach if unsupervised. This drug, if effective, could be the difference between independent life for those with PWS and life in a locked down group home specialized for those with PWS.	UL1 TR0000445	Vanderbilt Clinical and Translational Science Award	\$157,740	Not Available	Not Available	Not Available

Year	Program Name	Brief Program Description	Funding Source #1	Grant Title	Funding Amount Granted	Patient Admissions	Patient Days	Outpatient Visits
September 2015	[UDN882825 RB] "Clinical and Genetic Evaluation of Patients with Undiagnosed Disorders Through the Undiagnosed Diseases Network"	Undiagnosed diseases are constellations of significant signs, symptoms and/or test results seen by a number of provider specialists over an extended period of time without resolution as to the underlying cause(s), and for which traditional diagnostic procedures and tests have been exhausted. Physicians and scientists studying the causes of rare and undiagnosed disease have found that both are resistant to classical discovery methods at the bedside or in the lab because of the heterogeneous and unwieldy variety of diseases that may be included. Our purpose is to bring expertise and compassionate care to afflicted individuals to give them hope and improve their lives. We will begin the UDN study for RB with a blood draw for her and her family members that will yield DNA to be sent for sequencing. Based on the sequencing results we will further adapt her future UDN patient evaluation and work-up. (This application is for purposes of doing the blood draw and consent for RB and her mom. Other family will be consented over the phone and blood obtained by mail.) All VICTR resources that we utilize will be focused on the diagnosis of rare and the discovery of new human diseases. An important goal of this program is to establish efficient methods to identify undiagnosed disease in other patients who may not be part of the UDN. Our hope is that the methods defined by the UDN research result in improved understanding of disease pathogenesis, better linking of genetic and clinical findings leading to diagnoses that guide prognosis and therapy. VICTR funds will be used to do state of the art phenotyping with rare and undiagnosed diseases with the goal of fostering research on improving diagnostic methods, determining the etiology, and pathophysiology and improving the treatment of these disorders.	National Institutes of Health U01HG007674	Undiagnosed Diseases Network	\$6,599,557	Not Available	Not Available	Not Available
September 9, 2015	Contribution of Substance-P to Blood Pressure Regulation in the Setting of Dipeptidyl Peptidase IV (DPP-4) and Angiotensin Converting Enzyme (ACE) Inhibition	ACE inhibitors are the first line therapy for hypertension in diabetic patients. DPP IV inhibitors are novel antidiabetic medications. The incidence of hypertension in diabetics is 1.5 to 3 times greater than in age and sex matched controls. Since DPP IV is involved in the degradation of a wide variety of vasoactive peptides, it becomes important to understand the interactive effects of DPP IV inhibitors, as sitagliptin, and ACE inhibitors on hemodynamic parameters. This project will allow us to examine the interaction of the DPP IV inhibitor, sitagliptin and chronic ACE inhibition in subjects with Type 2 Diabetes Mellitus and Hypertension, who are at greater risk of developing cardiovascular events.	National Institutes of Health R01HL125426	Cardiovascular Consequences of Peptidase Inhibition	\$444,120	Not Available	Not Available	Not Available
September 9, 2015	A study analyzing blood monocytes stimulated with TLR ligands	The Sherwood lab discovered that administration of toll-like receptor (TLR) ligands, ligands that mimic pathogens, improves the host response to infection in multiple mouse models. TLR ligands have the potential to revolutionize prophylactic anti-infection therapy, currently dominated by antibiotics, in critically-ill patients that have a known high risk of infection. However, in order to translate TLR ligands to clinical practice, the effects of TLR ligands on primary human cells must be studied. This project will advance TLR ligands towards a clinical application for which they will prevent infections in the intensive care unit. Further, broadening our understanding of macrophage metabolism has application to a variety of disease processes including atherosclerosis and chronic infections.	National Institutes of Health F30	The Role of Macrophage Metabolism in Trained Immunity	\$28,226	Not Available	Not Available	Not Available

SUPPLEMENTAL #1

Year	Program Name	Brief Program Description	Funding Source #1	Grant Title	Funding Amount Granted	Patient Admissions	Patient Days	Outpatient Visits
September 2015 February 25, 2015 2:57 pm	[UDN525928 TWJ] "Clinical and Genetic Evaluation of Patients with Undiagnosed Disorders Through the Undiagnosed Diseases Network"	<p>Undiagnosed diseases are constellations of significant signs, symptoms and/or test results seen by a number of provider specialists over an extended period of time without resolution as to the underlying cause(s), and for which traditional diagnostic procedures and tests have been exhausted. Physicians and scientists studying the causes of rare and undiagnosed disease have found that both are resistant to classical discovery methods at the bedside or in the lab because of the heterogeneous and unwieldy variety of diseases that may be included. Our purpose is to bring expertise and compassionate care to afflicted individuals to give them hope and improve their lives.</p> <p>We will begin the UDN study for TWJ with a blood draw for him and his family members that will yield DNA to be sent for sequencing. Based on the sequencing results we will further adapt his future UDN patient evaluation and work-up. (This application is for purposes of doing the blood draw and consent for TWJ and his family (parents and siblings.) Undiagnosed diseases are constellations of significant signs, symptoms and/or test results seen by a number of provider specialists over an extended period of time without resolution as to the underlying cause(s), and for which traditional diagnostic procedures and tests have been exhausted. Physicians and scientists studying the causes of rare and undiagnosed disease have found that both are resistant to classical discovery methods at the bedside or in the lab because of the heterogeneous and unwieldy variety of diseases that may be included. Our purpose is to bring expertise and compassionate care to afflicted individuals to give them hope and improve their lives.</p>	National Institutes of Health U01HG007674	Undiagnosed Diseases Network	\$6,599,557	Not Available	Not Available	Not Available
September 10, 2015	A5342 - A Phase I Study to Evaluate the Safety, Tolerability, and Effect of a Human Monoclonal Antibody, VRC-HIVMAB060-00-AB (VRC01), on Markers of HIV Persistence in ART-treated, HIV-infected Adults	<p>Potent broadly-neutralizing antibodies to the HIV-1 envelope protein (env) have been isolated from HIV-1-infected individuals and are being developed for preventative and therapeutic use. If broadly neutralizing mAbs induce antibody-dependent cell-mediated cytotoxicity (ADCC), this may reduce viral persistence in HIV-1-infected individuals on ART by promoting the elimination of cells expressing HIV-1. HIV-1 is able to persist despite anti-retroviral therapy (ART) due to the establishment of latent infection in long-lived cells, including resting memory CD4+ T-cells [1-3]. This latent cellular reservoir does not decay appreciably over time even with ART. ART blocks infection of new cells, but has no impact on latently infected cells or cells that chronically produce HIV-1. Therefore, to eradicate these sources of HIV-1 persistence and achieve cure, alternative therapies are being explored. One strategy being investigated for HIV-1 cure is known as the "kick and kill" approach. This strategy includes reactivation of latent virus (kick) followed by enhanced elimination of virus-expressing cells (kill) [4].</p> <p>VICTR funding allows our site to take part in these Phase I safety trials. Because this study requires infusion of an experimental drug, PK specimen processing, and observation of the participant post-infusion, the CRC setting with the trained nursing staff and necessary equipment provides us with a safer environment for accomplishing these procedures.</p>	National Institutes of Health UM1A1069439	Vanderbilt HIV Clinical Trials Unit	\$11,928,141	Not Available	Not Available	Not Available

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Year	Program Name	Brief Program Description	Funding Source #1	Grant Title	Funding Amount Granted	Patient Admissions	Patient Days	Outpatient Visits
September 16, 2015	VICCBREP14115-An Open-Label, Phase I Study of GDC-0927 in Postmenopausal Women with Locally Advanced or Metastatic Estrogen Receptor Positive Breast Cancer (GO29656)	To determine the maximum tolerated dose (MTD) and/or recommended Phase II dose (RP2D) and assess the safety of SRN-927 in postmenopausal women with locally advanced or metastatic ER+ (HER2-) breast cancer. The study is looking to determine the MTD and to assess the safety of SRN-927 in postmenopausal women with locally advanced or metastatic ER+ (HER2-) breast cancer.	UL1 TR000445	Vanderbilt Clinical and Translational Science Award	\$14,680	Not Available	Not Available	Not Available
September 21, 2015	Efficacy and Safety of Sparsentan (RE-021), a Dual Endothelin Receptor and Angiotensin Receptor Blocker, in Patients with Focal Segmental Glomerulosclerosis (FSGS): A Randomized, Double-Blind,	FSGS is a leading and growing cause of nephrotic syndrome and accounts for 3-4% of the prevalence of end stage renal disease. This is a phase 2 trial. If the drug is approved after phase 3 trials, this drug may offer an added option for an unmet need of FSGS treatment.	UL1 TR000445	Vanderbilt Clinical and Translational Science Award	\$19,918	Not Available	Not Available	Not Available
September 16, 2015	UDN147107 BKJ "Clinical and Genetic Evaluation of Patients with Undiagnosed Disorders Through the Undiagnosed Diseases Network"	Undiagnosed diseases are constellations of significant signs, symptoms and/or test results seen by a number of provider specialists over an extended period of time without resolution as to the underlying cause(s), and for which traditional diagnostic procedures and tests have been exhausted. Physicians and scientists studying the causes of rare and undiagnosed disease have found that both are resistant to classical discovery methods at the bedside or in the lab because of the heterogeneous and unwieldy variety of diseases that may be included. Our purpose is to bring expertise and compassionate care to afflicted individuals to give them hope and improve their lives. We will begin the UDN study for BK with a blood draw for him and his family members that will yield DNA to be sent for sequencing. Based on the sequencing results we will further adapt her future UDN patient evaluation and work-up. (This application is for purposes of doing the blood draw and consent for BK and his parents.) All VICTR resources that we utilize will be focused on the diagnosis of rare and the discovery of new human diseases. An important goal of this program is to establish efficient methods to identify undiagnosed disease in other patients who may not be part of the UDN. Our hope is that the methods defined by the UDN research result in improved understanding of disease pathogenesis, better linking of genetic and clinical findings leading to diagnoses that guide prognosis and therapy. VICTR funds will be used to do state of the art phenotyping with rare and undiagnosed diseases with the goal of fostering research on improving diagnostic methods, determining the etiology, and pathophysiology and improving the treatment of these disorders.	National Institutes of Health U01HG007674	Undiagnosed Diseases Network	\$6,599,557	Not Available	Not Available	Not Available
February 25, 2016	A Phase 2, Randomized, Double-Blind, Placebo-Controlled Pilot Study to Assess the Effects of RM-493, a Melanocortin 4 Receptor (MC4R) Agonist, in Obese Subjects with Prader-Willi Syndrome (PWS) on Safety, Weight Reduction, and Food Related Behaviors	PWS is caused by a genetic mechanism that affects the hypothalamus and causes excessive hunger that leads to life threatening morbid obesity. There is no treatment for this genetic condition at this time. This study proposes that RM-493 may curb appetite and reduce obesity in PWS providing an effective treatment for this condition. If the investigation drug proves effective and safe, it will obtain FDA approval and improve treatment for those with PWS.	UL1 TR000445	Vanderbilt Clinical and Translational Science Award	\$43,164	Not Available	Not Available	Not Available

SUPPLEMENTAL #1

Year	Program Name	Brief Program Description	Funding Source #1	Grant Title	Funding Amount Granted	Patient Admissions	Patient Days	Outpatient Visits
September 2015 February 25, 2016 2:54pm	Active-Control, Dose-Escalation Study Rett Syndrome, MECP2 Duplication Disorder, and Rett-Related Disorders Natural History Study	<p>The purpose of this study is to advance our understanding of the natural history of Rett syndrome (RTT), MECP2-duplication disorder (MECP2 Dup), RTT-related disorders including CDKL5, FOXP1, and individuals with MECP2 mutations who do not have RTT including the range of clinical involvement and to correlate genotype-phenotype over a broad spectrum of phenotypes. While much has been learned about RTT, we still have to improve our understanding of the role of factors such as X chromosome inactivation, genetic background, and others including the environment, on the great variability observed even between individuals with the same MECP2 mutation. These data will be essential to the development and conduct of clinical trials that are anticipated from ongoing studies in animal models for RTT. This study will not include clinical trials, but should set the stage for such trials and other translational research projects (e.g., development of biomarkers). This study will set the stage for expanding translational studies and emerging clinical trials. It can therefore benefit the people with these disorders by allowing researchers to develop the necessary background information needed to conduct a clinical trial should a potential treatment become available.</p>	National Institutes of Health US4HDD061222	Rare Disease CRC for New Therapies and New Diagnostics - AS	\$116,398	Not Available	Not Available	Not Available

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SUPPLEMENTAL #1

Year	Program Name	Brief Program Description	Funding Source #1	Grant Title	Funding Amount Granted	Patient Admissions	Patient Days	Outpatient Visits
September 2015	[UDN813101 LB] "Clinical and Genetic Evaluation of Patients with Undiagnosed Disorders Through the Undiagnosed Diseases Network"	<p>Undiagnosed diseases are constellations of significant signs, symptoms and/or test results seen by a number of provider specialists over an extended period of time without resolution as to the underlying cause(s), and for which traditional diagnostic procedures and tests have been exhausted. Physicians and scientists studying the causes of rare and undiagnosed disease have found that both are resistant to classical discovery methods at the bedside or in the lab because of the heterogeneous and unwieldy variety of diseases that may be included. Our purpose is to bring expertise and compassionate care to afflicted individuals to give them hope and improve their lives.</p> <p>We will begin the UDN study for LB with a blood draw for her and her family members that will yield DNA to be sent for sequencing. Based on the sequencing results we will further adapt her future UDN patient evaluation and work-up. (This application is for purposes of doing the blood draw for the proband's father. Other family will be consented over the phone and blood obtained by mail.) All VICTR resources that we utilize will be focused on the diagnosis of rare and the discovery of new human diseases. An important goal of this program is to establish efficient methods to identify undiagnosed disease in other patients who may not be part of the UDN. Our hope is that the methods defined by the UDN research result in improved understanding of disease pathogenesis, better linking of genetic and clinical findings leading to diagnoses that guide prognosis and therapy. VICTR funds will be used to do state of the art phenotyping with rare and undiagnosed diseases with the goal of fostering research on improving diagnostic methods, determining the etiology, and pathophysiology and improving the treatment of these disorders.</p> <p>Recent advances in medical treatment including surgical correction of congenital heart disease and treatment of endocrine disease have led to a significant increase in the life expectancy of people with Down syndrome, from a median age of 25 years in 1983 to 60 years today (Bitles et al. 2007). The increased life expectancy, combined with evolving societal attitude towards individuals with intellectual disabilities result in more individuals with Down syndrome being active members of, and integrated in to, the community. There is currently no therapeutic option available for the treatment of intellectual disability associated with Down syndrome. Targeted early intervention, that improves learning, memory and functioning, would provide an option for children with Down syndrome to live a more independent life. This study could directly impact the Down Syndrome community by helping researchers further understand the nature of the disorder as well as possibly provide a treatment for this disorder.</p>	National Institutes of Health U01HG007674	Undiagnosed Diseases Network	\$6,599,557	Not Available	Not Available	Not Available
September 22, 2015	A randomized, double-blind, placebo-controlled, parallel group 26-week dose-investigating study to explore the pharmacokinetics, pharmacodynamic effects, efficacy/safety and tolerability of RO5186582 in children with Down syndrome aged 6-11 years.	<p>Recent advances in medical treatment including surgical correction of congenital heart disease and treatment of endocrine disease have led to a significant increase in the life expectancy of people with Down syndrome, from a median age of 25 years in 1983 to 60 years today (Bitles et al. 2007). The increased life expectancy, combined with evolving societal attitude towards individuals with intellectual disabilities result in more individuals with Down syndrome being active members of, and integrated in to, the community. There is currently no therapeutic option available for the treatment of intellectual disability associated with Down syndrome. Targeted early intervention, that improves learning, memory and functioning, would provide an option for children with Down syndrome to live a more independent life. This study could directly impact the Down Syndrome community by helping researchers further understand the nature of the disorder as well as possibly provide a treatment for this disorder.</p>	UL1 TR000445	Vanderbilt Clinical and Translational Science Award	\$10,764	Not Available	Not Available	Not Available

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2:57 pm

SUPPLEMENTAL #1

Year	Program Name	Brief Program Description	Funding Source #1	Grant Title	Funding Amount Granted	Patient Admissions	Patient Days	Outpatient Visits
September 2015	Childrengē™s Autism Metabolome Project (CAMP): Development and Clinical Evaluation of the SeminaMetabolic Biomarker-Based Test to Diagnose Autism Spectrum Disorder in Early Childhood	There is a need for a reliable biomarker-based test for diagnosing autism. Earlier diagnosis of children with ASD will improve outcomes, including higher cognitive and social function and improved communication, subsequently decreasing the financial and emotional burden on families and society (Dawson et al., 2010; Ganz, 2007). Children who receive early intensive therapy show significant improvement such that many do not require special education. In addition, a metabolomic diagnostic approach will allow better understanding of differences in the metabolism of patients with ASD from typically developing (TD) children and from children with other developmental delays (DD). This test, based on the individual's biochemical profile, offers the promise to select treatments matched to the metabolic subtype of the patient including modified diet, dietary supplements, and existing and new therapeutics developed from newly identified drug targets. Furthermore, increased understanding regarding likely responders to a particular therapy will increase efficacy rates in clinical trials enabling new therapies and companion diagnostic tests. This study could directly impact the ASD community by helping researchers further understand the nature of the disorder as well as possibly provide earlier, more reliable diagnoses.	UL1 TR000445	Vanderbilt Clinical and Translational Science Award	\$27,300	Not Available	Not Available	Not Available
February 25, 2016 2:57 pm								
October 5, 2015	The Prevalence of Symptomatic Obstructive Sleep Apnea in Lung Transplant Patients	Lung transplantation is now a common route of treatment for appropriate candidates with chronic respiratory failure, but there is still an absence of robust data regarding OSA in patients referred for lung transplantation and patients after they have received a lung transplant. Other unknown information includes the influence of OSA and its treatment on transplant outcomes, or the effect of lung transplantation on OSA. This study would aim to determine the prevalence of OSA in both the pre and post lung transplant populations and to determine the directionality of change in AHI events from pre to post-transplant. The study will also be able to examine the ability of validated OSA screening tools to identify patients with OSA in this population, and identify risk factors associated with OSA in the pre and post populations. For pre-transplant patients the study can elucidate whether treatment of OSA through non-invasive ventilation could be considered a good bridge to transplant. For post-transplant patients the study can elucidate whether OSA treatment improves mortality outcomes and chronic rejection. The funds for the CRC sleep studies for patients whose insurance will not pay will help us gather a robust amount of data in this population, accurately estimate prevalence, and better understand the validity of our screening tools.	UL1 TR000445	Vanderbilt Clinical and Translational Science Award	\$46,897	Not Available	Not Available	Not Available

SUPPLEMENTAL #1

Year	Program Name	Brief Program Description	Funding Source #1	Grant Title	Funding Amount Granted	Patient Admissions	Patient Days	Outpatient Visits
October 5, 2015 February 25, 2016 2:57 pm	[UDN808220 RO] "Clinical and Genetic Evaluation of Patients with Undiagnosed Disorders Through the Undiagnosed Diseases Network"	Undiagnosed diseases are constellations of significant signs, symptoms and/or test results seen by a number of provider specialists over an extended period of time without resolution as to the underlying cause(s), and for which traditional diagnostic procedures and tests have been exhausted. Physicians and scientists studying the causes of rare and undiagnosed disease have found that both are resistant to classical discovery methods at the bedside or in the lab because of the heterogeneous and unwieldy variety of diseases that may be included. Our purpose is to bring expertise and compassionate care to afflicted individuals to give them hope and improve their lives. We will begin the UDN study for RO with a blood draw for her and her family members that will yield DNA to be sent for sequencing. Based on the sequencing results we will further adapt her future UDN patient evaluation and work-up. (This application is for purposes of doing the blood draw and consent for RO and her husband, children, and her mother.) All VICTR resources that we utilize will be focused on the diagnosis of rare and the discovery of new human diseases. An important goal of this program is to establish efficient methods to identify undiagnosed disease in other patients who may not be part of the UDN. Our hope is that the methods defined by the UDN research result in improved understanding of disease pathogenesis, better linking of genetic and clinical findings leading to diagnoses that guide prognosis and therapy. VICTR funds will be used to do state of the art phenotyping with rare and undiagnosed diseases with the goal of fostering research on improving diagnostic methods, determining the etiology, and pathophysiology and improving the treatment of these disorders.	National Institutes of Health U01HG007674	Undiagnosed Diseases Network	\$6,599,557	Not Available	Not Available	Not Available
October 16, 2015	A Phase 2, multi-center, randomized, double-blind, placebo controlled study in subjects with late prodromal and early manifest Huntington disease (HD) to assess the safety, tolerability, pharmacokinetics, and efficacy of VX15/2503 (SIGNAL)	Huntington disease (HD) is a genetic, terminal neurodegenerative disease for which there is no cure. The study drug is being investigated to see if it may prevent or slow the progression of HD through a mechanism that alters the neuroinflammatory response in the disease.	U11 TR000445	Vanderbilt Clinical and Translational Science Award	\$44,472	Not Available	Not Available	Not Available

SUPPLEMENTAL #1

Year	Program Name	Brief Program Description	Funding Source #1	Grant Title	Funding Amount Granted	Patient Admissions	Patient Days	Outpatient Visits
October 28, 2015	Electrical Stimulation Of Laryngeal Muscles To Restore Glottal Opening In Patients With Bilateral Vocal Fold Paralysis	The goal of this study is to develop a safe surgical approach to implantation of a laryngeal stimulation system for restoring bilateral glottal opening in patients with bilateral vocal fold paralysis. The efficacy of the device in restoring ventilation through the mouth without impairing voice will be assessed by comparing outcome measures to preoperative values. Ventilation and voice outcome measures will also be compared to those obtained following conventional treatment of vocal fold resection, cordotomy. The PI/Vanderbilt participated in the first human trial of unilateral laryngeal pacing in 1996 under IDE G940065, with the Medtronic device. While the human trial of unilateral pacing was successful, the amount of ventilation provided was not adequate for heavy activity or exertion. The PI began work on bilateral pacing in canines with a different neurostimulator device. Now that this device has been tested for safety and efficacy in dogs, we have submitted an IDE to the FDA, and received approval to conduct this study in humans.	UL1 TR000445	Vanderbilt Clinical and Translational Science Award	\$10,320	Not Available	Not Available	Not Available
October 28, 2015	[UDN829699 MH] "Clinical and Genetic Evaluation of Patients with Undiagnosed Disorders Through the Undiagnosed Diseases Network"	At the present time we do not have funding for this study. We intend to apply for a grant and/or other outside funding sources, but need to request V/CTR funding for the portion that will take place in the CRC. We will need to gather pilot data from the study to strengthen a federal grant application. This study has potential to identify a genetic modifier for CMT2A. The modifier may become a molecular target for therapeutic development. Also, if we find there are variances in the junction protein genes with different types of CMT, there is potential for different molecular targets for therapy for specific types of CMT.	National Institutes of Health U01HG007674	Undiagnosed Diseases Network	\$6,599,557	Not Available	Not Available	Not Available

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Year	Program Name	Brief Program Description	Funding Source #1	Grant Title	Funding Amount Granted	Patient Admissions	Patient Days	Outpatient Visits
October 29, 2015	[UDN688025 JD] "Clinical and Genetic Evaluation of Patients with Undiagnosed Disorders Through the Undiagnosed Diseases Network"	<p>Undiagnosed diseases are constellations of significant signs, symptoms and/or test results seen by a number of provider specialists over an extended period of time without resolution as to the underlying cause(s), and for which traditional diagnostic procedures and tests have been exhausted. Physicians and scientists studying the causes of rare and undiagnosed disease have found that both are resistant to classical discovery methods at the bedside or in the lab because of the heterogeneous and unwieldy variety of diseases that may be included. Our purpose is to bring expertise and compassionate care to afflicted individuals to give them hope and improve their lives.</p> <p>We will begin the UDN study for JD with a blood draw for her and her family members that will yield DNA to be sent for sequencing. Based on the sequencing results we will further adapt her future UDN patient evaluation and work-up. (This application is for purposes of doing the blood draw and consent for JD and her family members.) All VICTR resources that we utilize will be focused on the diagnosis of rare and the discovery of new human diseases. An important goal of this program is to establish efficient methods to identify undiagnosed disease in other patients who may not be part of the UDN. Our hope is that the methods defined by the UDN research result in improved understanding of disease pathogenesis, better linking of genetic and clinical findings leading to diagnoses that guide prognosis and therapy. VICTR funds will be used to do state of the art phenotyping with rare and undiagnosed diseases with the goal of fostering research on improving diagnostic methods, determining the etiology, and pathophysiology and improving the treatment of these disorders.</p> <p>ACE inhibitors are first line therapy for hypertension in diabetic patients. DPP4 inhibitors are novel oral antidiabetic medications. The prevalence of hypertension is 1.5-3 times greater in diabetics compared to sex-aged matched controls. Since DPP4 is involved in the degradation of multiple vasoactive peptides, it is important to understand how inhibition of this enzyme affects vessel properties and sympathetic activation. This project will help us understand how DPP4 inhibition in diabetics affects hemodynamic parameters and sympathetic activation in the setting of increasing concentrations of neuropeptide Y.</p>	National Institutes of Health U01HG007674	Undiagnosed Diseases Network	\$6,599,557	Not Available	Not Available	Not Available
October 29, 2015	Contribution of Neuropeptide Y (NPY) to Vasoconstriction and Sympathetic Activation in the Setting of Dipeptidyl Peptidase IV (DPP4) Inhibition	<p>ACE inhibitors are first line therapy for hypertension in diabetic patients. DPP4 inhibitors are novel oral antidiabetic medications. The prevalence of hypertension is 1.5-3 times greater in diabetics compared to sex-aged matched controls. Since DPP4 is involved in the degradation of multiple vasoactive peptides, it is important to understand how inhibition of this enzyme affects vessel properties and sympathetic activation. This project will help us understand how DPP4 inhibition in diabetics affects hemodynamic parameters and sympathetic activation in the setting of increasing concentrations of neuropeptide Y.</p>	National Institutes of Health R01HL125426	Cardiovascular Consequences of Peptidase Inhibition (Brown)	\$444,120	Not Available	Not Available	Not Available

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Year	Program Name	Brief Program Description	Funding Source #1	Grant Title	Funding Amount Granted	Patient Admissions	Patient Days	Outpatient Visits
October 2015	A Phase 3, Open-label, Rollover Study to Evaluate the Safety and Efficacy of Long-term Treatment With VX-661 in Combination With Ivacaftor in Subjects Aged 12 Years and Older With Cystic Fibrosis, Homozygous or Heterozygous for the F508del-CFTR Mutation	Cystic fibrosis (CF) affects an estimated 70,000 children and adults worldwide and is the most common fatal genetic disease in persons of European descent. Based on the size of the population, CF qualifies as an orphan disease. Despite progress in the treatment of CF with antibiotics and mucolytics, the predicted median age of survival for a person with CF is in the mid-40s. Although the disease affects multiple organs, most morbidity and mortality is caused by progressive loss of lung function. The search continues for drug compounds which will be effective in increasing CFTR function and work as CFTR correctors for as many genetic mutations as possible. This will be an open label study of patients who have receptive genetic mutations and who received either Ivacaftor alone or Ivacaftor and VX661 in the previous VX14-661-109 study. All patients will be eligible to receive the combination of both drugs for this study. VX-661 is a compound developed by Vertex Pharmaceuticals Incorporated (Vertex) that has been shown to have CFTR corrector properties. Ivacaftor (also known as VX-770) is the first CFTR modulator to show an improvement in CFTR function and clinical benefit in patients with CF. Results from several Phase 3 studies showed that Ivacaftor is effective in the treatment of patients with CF who have mutations that result in gating defects as evidenced by sustained improvements in CFTR channel function (measured by reduction in sweat chloride concentration) and corresponding substantial, durable improvements in lung function, respiratory symptoms, and weight gain. Ivacaftor was also well tolerated, as evidenced by the rates and reasons for premature discontinuation and results of safety assessments.	UL1 TR000445	Vanderbilt Clinical and Translational Science Award	\$8,388	Not Available	Not Available	Not Available
October 2015	The Effect of Dipeptidyl Peptidase 4 Inhibition on Growth Hormone Secretion in Women with Polycystic Ovarian Syndrome	Adults with abdominal obesity are at high risk for cardiovascular disease and also exhibit diminished growth hormone (GH) secretion; the latter further contributes to the development of visceral adiposity, impaired fibrinolysis and inflammation. Growth hormone releasing hormone (GHRH), the primary stimulus for endogenous GH secretion, is a substrate of dipeptidyl peptidase 4 (DPP4); inhibition of DPP4 with the currently available anti-diabetic therapy, sitagliptin, may therefore increase GH secretion by decreasing the degradation of GHRH. The proposed research will test the hypothesis that chronic DPP4 inhibition with sitagliptin will enhance GH secretion and endothelium-dependent vasodilation while improving glucose tolerance in patients with impaired GH secretion who are at risk for the development of diabetes mellitus and cardiovascular disease, specifically obese women with polycystic ovary syndrome. Patients with obesity and insulin resistance, including young females with PCOS, have impaired pulsatile GH secretion. Sitagliptin and other DPP4 inhibitor therapies are a currently approved and well-tolerated oral medication for patients with type 2 diabetes mellitus. DPP4 inhibition has the potential to restore physiologic GH secretion in at-risk populations through a variety of mechanisms that affect GHRH-stimulated GH secretion. The translational application of currently available DPP4 inhibitor therapies to patients with impaired GH secretion at high cardio-metabolic risk represents a cost-effective, high impact strategy which may rapidly be put into effect to address our nation's obesity epidemic.	National Institutes of Health K23HL11962	Effect of dipeptidyl Inhibition on growth hormone secretion	\$609,660	Not Available	Not Available	Not Available

SUPPLEMENTAL #1

Year	Program Name	Brief Program Description	Funding Source #1	Grant Title	Funding Amount Granted	Patient Admissions	Patient Days	Outpatient Visits
October 2015	New Tools for Assessing Fracture Risk	The current gold-standard for assessing fracture risk is areal bone mineral density (aBMD) by dual energy X-ray absorptiometry (DXA). It is not particularly effective at identifying individuals at imminent risk suffering a fracture. In effect, there is a disproportionate increase in fracture risk relative to the age-related decrease in bone density. This is partly due to certain limitations in the clinical measurement of aBMD. Namely, DXA is a projection method that does not discern the relative contribution of macro-structure, micro-architecture, collagen integrity, or porosity to fracture resistance. If successful, the project will provide evidence for the efficacy of two new, clinically viable techniques in assessing aspects of bone that could help clinicians decide whether a patient needs to be treated for fracture prevention.	National Institutes of Health R01EB014308	Bone Fracture Risk Assessment Through Bound - and Pore - Water MRI	\$1,346,821	Not Available	Not Available	Not Available
February 25, 2016 2:57 pm	Lysosomes in Atherosclerosis	The studies in the current proposal are designed to understand the causes and nature of the lysosomal cholesterol accumulation that is found in late stage atherosclerosis. The sequestration of cholesterol and cholesterol esters in lysosomes away from normal cellular cholesterol efflux leads to cells that are substantially more proatherogenic than foam cells without lysosomal sequestration. Establishing the mechanism of lysosomal accumulation is therefore crucial to our understanding of atherosclerosis. One recent key to understanding how cholesterol inhibits lysosomes is the observation that triglyceride accumulation in lysosomes reverses the cholesterol effect. It is this key finding we hope to gain further preliminary data in anticipation of an ROI application.	U11 TR0000445	Vanderbilt Clinical and Translational Science Award	\$30,000	Not Available	Not Available	Not Available
November 5, 2015	A Randomized, Double-Blind, Placebo-Controlled, Single Ascending Dose Study to Assess the Safety, Tolerability, and Pharmacokinetics of C2N-8E12 in Subjects with Progressive Supranuclear Palsy	PSP is an incurable neurodegenerative disease with few treatments available to patients. This drug has the potential to slow or prevent the disease progress by removing tau from the brain.	U11 TR0000445	Vanderbilt Clinical and Translational Science Award	\$17,285	Not Available	Not Available	Not Available
November 13, 2015	Neuromodulation of Decision Making in Young and Middle-Aged Adults: Part 1	Financial decision-making changes with aging, but the cognitive and neural correlates of these changes are not well-understood. This proposal aims to construct a model of the specific psychological and neural mechanisms that support financial decisions in young adulthood and late middle age. In Part 1 of this study, middle-age and young adults will complete basic cognitive, motivational, and decision making tasks. Participants will be studied with fMRI to determine the relation between neural circuit activation and individual and age-related differences in decision making. This study involves humans. Aspects of the dopamine system change with aging, which impacts both normal functioning and age-related disease processes (such as Parkinson's symptoms, and responses to dopaminergic medications). The study of amphetamine-induced dopamine release is directly relevant to psychostimulant abuse/dependence, and treatments involving psychostimulants, such as those used in attention deficit hyperactivity disorder and narcolepsy.	National Institutes of Health R01AG043458	Dopaminergic Neuromodulation of Decision Making in Young and Middle-Aged Adults	\$526,807	Not Available	Not Available	Not Available

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Year	Program Name	Brief Program Description	Funding Source #1	Grant Title	Funding Amount Granted	Patient Admissions	Patient Days	Outpatient Visits
November 20, 2015	An Open-Label, Multi-Center, 48-Week Study with a Concurrent Untreated Control Arm to Evaluate the Efficacy and Safety of Eteplisen in Duchenne Muscular Dystrophy	There are currently no disease-modifying treatments for DMD (Duchenne Muscular Dystrophy). Existing interventions are largely supportive in nature and include bracing, muscle-stretching exercises to avoid onset of contractures, tendon-release surgery, and eventual wheelchair use and assisted ventilation. Current pharmacologic treatments, such as corticosteroids, focus on alleviation of symptoms, but do not address the underlying cause of the disease. Their benefits are only temporary, and their use is often limited by numerous side effects. DMD is a progressive and inevitably fatal disease for which there are currently no approved disease specific therapies. Given the inevitably fatal outcome of DMD and the unmet medical need represented by this disease, the promising preclinical and clinical data, and the safety factors built into this protocol to ensure patient safety, the overall balance of potential benefits to risks for this trial is considered positive. This project may show an indication that enables the production of an internally deleted, yet functional, dystrophin protein, similar to that observed in Becker muscular dystrophy (BMD), a much less severe form of dystrophinopathy. In contrast to DMD, most BMD patients remain ambulatory and have a near-normal life expectancy.	UL1 TR0000445	Vanderbilt Clinical and Translational Science Award	\$74,178	Not Available	Not Available	Not Available
November 19, 2015	A Phase 3, Multi-National, Double-Blind, Randomized, Placebo-Controlled, Stratified, Parallel Group Study to Evaluate the Safety, Tolerability and Effect of Tirasemtiv in Patients with Amyotrophic Lateral Sclerosis (ALS)	Amyotrophic lateral sclerosis, or ALS, is a disease of the nerve cells in the brain and spinal cord that control voluntary muscle movement. In ALS, progressive death of motor neurons leads to denervation of skeletal muscles. Surviving motor units attempt to compensate for dying ones by innervating more muscle fibers (a process called sprouting) but are only partially successful (Kiernan, Vucic et al. 2011). Over time, progressive denervation and its consequent skeletal muscle atrophy lead to weakness, fatigue, and eventually complete paralysis and death, primarily from respiratory complications. To date, there are no available treatments that can improve skeletal muscle function, and in particular respiratory function. Because tirasemtiv has been demonstrated both to amplify skeletal muscle force production in response to diminished neuronal input and to delay the onset and reduce the magnitude of skeletal muscle fatigue during repeated or sustained efforts, it may be useful in the treatment of patients with ALS.	UL1 TR0000445	Vanderbilt Clinical and Translational Science Award	\$52,880	Not Available	Not Available	Not Available
November 20, 2015	Myocardial Perfusion, Oxidative Metabolism, and Fibrosis in Heart Failure with Preserved Ejection Fraction (HFpEF-PROF)	Approximately half of all patients with heart failure have HFpEF; however, there are no evidence based therapies proven to improve outcomes in HFpEF, suggesting that the underlying mechanisms for this condition are not well understood. Pre-clinical studies support LV fibrosis, altered subendocardial perfusion and reduced LV oxidative metabolism as possible causative factors. However, these mechanisms and the associations between them have not been specifically evaluated in humans. To study this problem, we have been approved for an investigator-sponsored research grant by Astellas Pharma, and this VICTR Resource Request will provide the critical supplemental funding, such as blood tests for collagen breakdown products, circulating markers of fibrosis and cardiac repair, plus research subject stipends that will enable the execution of the study.	UL1 TR0000445	Vanderbilt Clinical and Translational Science Award	\$50,771	Not Available	Not Available	Not Available

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Year	Program Name	Brief Program Description	Funding Source #1	Grant Title	Funding Amount Granted	Patient Admissions	Patient Days	Outpatient Visits
November 2015	Local Heat Stress in Autonomic Failure Patients with Supine Hypertension	<p>It is well known that heat exposure (e.g. hot weather or a hot bath or shower) produces an acute and temporary worsening of orthostatic hypotension in autonomic failure patients.</p> <p>-The neural and hemodynamic effects of heat stress have not been systematically studied in the absence of autonomic reflexes in human subjects. -We will evaluate the effect of local passive heat stress on blood pressure, The underlying hemodynamic mechanisms and its potential use in the treatment of supine hypertension in autonomic failure patients. This study will provide unique insight into The non-autonomic hemodynamic mechanisms of BP regulation during heat stress in humans.</p> <p>- We will also evaluate whether application of controlled local passive heat can be an effective non-pharmacological approach for The treatment of supine hypertension in autonomic failure patients.</p>	National Institutes of Health R01HL122847	Splanchnic Circulation and Blood Pressure Regulation	\$392,500	Not Available	Not Available	Not Available
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November 24, 2015	A Double Blind Randomized Placebo Controlled Study of CM-AT for the Treatment of Autism in Children With All Levels of Fecal Chymotrypsin	<p>The intended indication of CM-AT is for the treatment of irritability and social withdrawal, in children ages 3-8 who have autism. Curemark's findings indicate that a large subset of children with autism have an endogenous lack of chymotrypsin, as expressed by low fecal chymotrypsin levels. Chymotrypsin is a serine protease that cleaves only the essential amino acids tryptophan, phenylalanine, leucine, and methionine, and the β-conditionally essential α-amino acid tyrosine. It is hypothesized that if there is an underlying defect in the digestion of dietary proteins, it would contribute to a deficiency in essential and semi-essential amino acids. This would leave the child unable to synthesize new proteins. Proteins such as neurotransmitters and other essential proteins needed for key bodily functions may not be able to be produced by the body due to a lack of essential amino acids. A partial or complete lack of protein digestion could further lead to allergy and/or other digestive dysfunctions. Tryptophan and phenylalanine are involved in and necessary for the synthesis of serotonin and dopamine respectively. Methionine serves as the initiation codon for all RNA translation and leucine is necessary to stimulate muscle synthesis. A death of these amino acids can result potentially in a decrease in their intended activity. Research conducted by Curemark has indicated that digestive enzyme therapy with CM-AT may lead to increased neurological function and a concomitant reduction in autistic and gastrointestinal symptoms. The enzyme therapy may also reduce the potential for undigested proteins to become allergens or promote the growth of pathogenic agents, thereby reducing immunopathologic effects.</p>	U11 TR000445	Vanderbilt Clinical and Translational Science Award	\$4,212	Not Available	Not Available	Not Available
December 1, 2015	CDC Public Health Surveillance for Bleeding Disorders	The purpose of this project is to collect surveillance data from the U.S. network of Hemophilia Treatment Centers (HTCs) to describe the epidemiologic characteristics of people with bleeding disorders and the complications of these disorders.	National Institutes of Health / UNC-Chapel Hill U27 CCU413185	Prevention of the Complications of Hemophilia through HTCS	\$116,184	Not Available	Not Available	Not Available

SUPPLEMENTAL #1

Year	Program Name	Brief Program Description	Funding Source #1	Grant Title	Funding Amount Granted	Patient Admissions	Patient Days	Outpatient Visits
December 8, 2015	A Longitudinal Study of Personal Health Information Needs and Practices for Maternal Fetal Care	Pregnancy is a common health condition that generates a diverse set of personal health information needs for the mother and caregivers. During pregnancy, the mother and her support network have increased interaction with the healthcare system and may experience significant physiological, social, and financial changes that may influence their information needs as well as how they seek and manage health information. Little research has focused on these phenomena. Two specific aims of the study are, one, to describe the characteristics, capacities, and beliefs of pregnant patients and their caregivers and, two, to characterize their health information needs and information management practices. These aims will produce a comprehensive description of these healthcare consumers to whom medical information could be delivered through HIT as well as a catalog of best practices and design guidelines to enable HIT to address consumer health information needs. The requested resource (study visit/interview space) will aid us in accomplishing these aims.	R01HS021496	Personal Health Information Needs and Practices for Maternal Fetal Care	\$1,553,906	Not Available	Not Available	Not Available
December 10, 2015	A Phase 2, Open-Label, Multicenter, Multi-cohort, Single-Arm Study to Investigate the Safety and Efficacy of Sofosbuvir Ribavirin in Adolescents and Children with Genotype 2 or 3 Chronic HCV Infection	Currently PEG and weight-based RBV are considered the standard of care for the treatment of HCV infection in children. However, this PEG and RBV regimen is long in duration, relatively toxic, and not well tolerated. Thus, there continues to be a need for new treatments for HCV that combine potent and sustained efficacy with improved tolerability and safety. Therapy that provides shorter duration and improved efficacy with an all-oral regimen would be a significant advancement over current options in pediatric patients.	UL1 TR000445	Vanderbilt Clinical and Translational Science Award	\$49,730	Not Available	Not Available	Not Available
December 10, 2015	Blood Pressure Lowering Effects of Angiotensin-(1-7) in Primary Autonomic Failure	Hypertension is a major public health problem worldwide that is linked to an increased risk for cardiovascular disease and death. The mechanisms underlying this disease, however, remain incomplete. The goal of this study is to better understand the role of the beneficial hormone angiotensin-(1-7) in blood pressure regulation in human hypertension. These findings will hopefully improve our understanding of the causes of hypertension to improve treatment strategies and long-term outcomes in this disease. This project will provide new insight into the potential for targeting angiotensin-(1-7) in the treatment of human hypertension. In addition, these studies will provide new mechanistic insight into the supine hypertension of autonomic failure as well as improve our understanding of hypertension in general. This funding would provide needed resources to generate preliminary data to move these studies forward.	National Institutes of Health K99HL122507	Autonomic: Angiotensin-(1-7) Interactions in Hypertension	\$124,929	Not Available	Not Available	Not Available
December 11, 2015	A Phase 2, Open-Label, Multicenter, Multi-cohort Study to Investigate the Safety and Efficacy of Ledipasvir/Sofosbuvir Fixed Dose Combination +/- Ribavirin in Adolescents and Children with Chronic HCV Infection	Currently PEG and weight-based RBV are considered the SOC for the treatment of HCV-infection in children. Therefore, there is a need for new treatments for HCV in the pediatric population that combine potent and sustained efficacy with improved tolerability and safety. The primary aim for new treatments of pediatric patients with HCV is to eliminate the need to use PEG. In this way, pediatric patients would be able to avoid the necessity of weekly injections which can be traumatic and burdensome, and significantly reduce the serious adverse events seen with PEG administration. The secondary aim is to eliminate RBV and the adverse events seen with its administration within GT-1 and GT-4 HCV infected subjects. his trial is aimed at finding more tolerable treatments	UL1 TR000445	Vanderbilt Clinical and Translational Science Award	\$20,090	Not Available	Not Available	Not Available

SUPPLEMENTAL #1

Year	Program Name	Brief Program Description	Funding Source #1	Grant Title	Funding Amount Granted	Patient Admissions	Patient Days	Outpatient Visits
December 2015	Preserving Beta-Cell Function with Tocilizumab in New-onset Type 1 Diabetes	Type 1 diabetes is a particular burden in children. Any therapy that preserves the ability to secrete even modest amounts of endogenous insulin secretion significantly improves the quality of life and reduces long-term complications. This is a human clinical trial- phase 2, which will extend to humans with T1D a large body of preclinical data and clinical data on the effectiveness of tocilizumab in other autoimmune conditions.	U11 TR000445	Vanderbilt Clinical and Translational Science Award	\$59,514	Not Available	Not Available	Not Available
February 25, 2016 2:57 PM	Evaluation of Ferumoxytol as an Anatomic and Functional Magnetic Resonance Imaging Contrast Agent	Patients needing cross-sectional imaging, who have concurrent acute or chronic kidney disease (CKD), cannot get optimal contrast enhanced evaluation using current gadolinium (Gd) based MR contrast media due to risk of nephrogenic systemic fibrosis or with iodinated CT contrast media due to risk of further renal function decline. Unlike the aforementioned agents, iron-based contrast agents do not pose similar risks to patients with CKD. Ferumoxytol (Feraheme A® AMAG Pharmaceuticals) is a FDA approved intravenous iron replacement therapy for patients with CKD and has recently been studied as an intravenous MRI contrast agent causing strong enhancement on T1-weighted images and also strong susceptibility effect. Ferumoxytol can potentially enable adequate anatomical imaging of various pathologies in patients with suboptimal renal function. Ferumoxytol is also taken up by inflammatory cells and tumor-associated macrophages and will also be useful for functional imaging of the reticuloendothelial system. These funds will support pilot studies in 8 patients allowing initial anatomical imaging as well as longitudinal functional imaging necessary to demonstrate feasibility and effect size of this method.	U11 TR000445	Vanderbilt Clinical and Translational Science Award	\$8,596	Not Available	Not Available	Not Available
December 22, 2015	The Role of Adipose-resident T cell Receptor Diversity in HIV-associated Metabolic Disease	Epidemiologic studies of diabetes in HIV-infected individuals on ART have reported incidence rates of up to 14 per 1000 patient-years, considerably higher than the general population. Furthermore, treated HIV infection appears to act synergistically with other risk factors, and diabetes prevalence is especially high among HIV-infected individuals with higher BMI and advanced age. This study will assess whether insulin resistance in HIV-infected individuals is related to the density and activation status of adipose tissue-resident T cells. While our study is specific to the HIV population, our findings may also help to understand the role of T cells in insulin resistance in non-HIV infected persons as well. This study will lead to a better understanding of the immunologic mechanisms driving increased risk of metabolic disease in HIV infected individuals, and may lead to improved treatment/prevention strategies for these individuals and non-HIV infected persons. This study requires a dedicated clinical research environment to perform percutaneous adipose tissue biopsies and a DEXA scan, and the advanced flow cytometry and T cell receptor sequencing capabilities of the Flow Cytometry and VANTAGE core labs. VICTR funding is requested to utilize the Clinical Research Center and these core facilities.	1P30AI110527-01A1	TENNESSEE CENTER FOR AIDS RESEARCH (TN-CFAR)	\$1,500,021	Not Available	Not Available	Not Available

SUPPLEMENTAL #1

Year	Program Name	Brief Program Description	Funding Source #1	Grant Title	Funding Amount Granted	Patient Admissions	Patent Days	Outpatient Visits
December 2015	Study of Residual Insulin (C-Peptide) Secretion (The EDIC C-Peptide Study)	In the Diabetes Control and Complications Trial (DCCCT) the benefits associated with higher concentrations of stimulated C-peptide ranged from the possibility of achieving optimal glycemic control with a lower incidence of hypoglycemia to the reduction of the incidences of microvascular complications, both retinopathy and nephropathy. The Mixed Meal Tolerance Test (MIMTT) has been shown superior for determining the incidence and strength of beta-cell function. Ultimately, we want to better understand the prevalence and amount of residual beta cell function in patients with long standing T1DM, understand the effects of intensive vs conventional glycemic control on the preservation of beta cell function, identify pt characteristics associated with preserved beta cell function, whether preserved beta cell function correlates with lower HbA1C and lower insulin dose requirements and also with less hypoglycemia and less micro and macrovascular complications - all to possibly impact conventional treatment of DM.	National Institutes of Health / Case Western Reserve DK104438	Epidemiology of diabetes intervention and complications	\$149,579	Not Available	Not Available	Not Available
January 7, 2016	Endoscopic Treatment for Weight Reduction in Patients with Obesity Using the TransPyloric Shuttle System: A Multicenter, Prospective, Randomized, Double-Blind, Sham-Controlled, Parallel-Design Study	Obesity (being severely overweight) may be the result of a fatty diet, irregular meals, lack of daily physical activity, certain medications, and genetic (what you inherit from your parents) or hormonal problems. It affects over a third of both men and women in the United States. Obesity increases the risk of getting high blood pressure, diabetes (type 2), heart disease, stroke, gallbladder disease, and cancer of the breast, prostate and colon. Losing weight has a positive effect on several of these conditions. A weight loss of 5-10% can often improve health and reduce risk of these diseases. Obesity is a major public health issue in the United States with 78 million adults now obese. In 2009-2010, the prevalence of obesity in the US was 35.5% among men and 35.8% among women. The annual healthcare costs associated with obesity have been estimated at up to 8% of overall healthcare budgets. The funds associated with this project will directly address the issue of obesity by working towards making non-surgical methods of weight reduction more accessible to patients overcome with obesity.	UL1 TR000445	Vanderbilt Clinical and Translational Science Award	\$11,640	Not Available	Not Available	Not Available
January 11, 2016	Acute Respiratory Illness Surveillance	We plan to determine the burden of pediatric ARI seen in the Emergency Department (ED) and/or the inpatient setting. A subcohort of the participants will return in 3-6 weeks and supply comparison samples (blood, respiratory swabs, and other samples like urine or saliva). With this funding, we will be able to conduct our follow up visits in the pediatric CRC to collect comparison samples once the patient has recovered and then perform research laboratory analysis on the samples (which that part is covered by the main grant).	National Institutes of Health U01C1000304	Emerging Infections Program	\$5,632,800	Not Available	Not Available	Not Available

SUPPLEMENTAL #1

Year	Program Name	Brief Program Description	Funding Source #1	Grant Title	Funding Amount Granted	Patient Admissions	Patient Days	Outpatient Visits
January 15, 2016 February 25, 2016 2:57 pm	Investigating the Alternate Pathway of Complement in Adults with Sickle Cell Disease and Acute Chest Syndrome	Acute chest syndrome (ACS) is a leading cause of mortality in adults with sickle cell disease (SCD). A subset of patients with ACS develop rapidly progressive respiratory failure (often with multi-organ dysfunction), and are at highest risk of mortality. Multiple lines of evidence suggest that sickle erythrocytes and hemolysis-derived free heme can activate alternate pathway of complement. We will test our novel hypothesis in a case-control study by (1) measuring APC activation by a functional assay (the modified Ham test) in 3 groups (n=14 in each group): adults with SCD and (a) ACS with rapidly progressive (< 24 hours) respiratory failure, (b) ACS without respiratory failure, and (c) adults with SCD that are not acutely ill (without ACS or vasoocclusive pain). (2) We will perform deep sequencing of genes implicated in the pathogenesis of atypical HUS, particularly complement regulatory genes including CFH, CFI, CD46 (MCP), CFB, C3, CFHR1, CFHR3, CFHR4, CFHR5, THBD, C4BP, PLG and DGKE.	UL1 TR000445	Vanderbilt Clinical and Translational Science Award	\$1,896	Not Available	Not Available	Not Available
January 21, 2016	[UDN090100, CH "Clinical and Genetic Evaluation of Patients with Undiagnosed Disorders Through the Undiagnosed Diseases Network"	Undiagnosed diseases are constellations of significant signs, symptoms and/or test results seen by a number of provider specialists over an extended period of time without resolution as to the underlying cause(s), and for which traditional diagnostic procedures and tests have been exhausted. Physicians and scientists studying the causes of rare and undiagnosed disease have found that both are resistant to classical discovery methods at the bedside or in the lab because of the heterogeneous and unwieldy variety of diseases that may be included. Our purpose is to bring expertise and compassionate care to afflicted individuals to give them hope and improve their lives. We will begin the UDN study for CH with a blood draw for her and her family members that will yield DNA to be sent for sequencing. Based on the sequencing results we will further adapt her future UDN patient evaluation and work-up. (This application is for purposes of doing the blood draw and consent for CH and her family (parents and siblings.) Undiagnosed diseases are constellations of significant signs, symptoms and/or test results seen by a number of provider specialists over an extended period of time without resolution as to the underlying cause(s), and for which traditional diagnostic procedures and tests have been exhausted. Physicians and scientists studying the causes of rare and undiagnosed disease have found that both are resistant to classical discovery methods at the bedside or in the lab because of the heterogeneous and unwieldy variety of diseases that may be included. Our purpose is to bring expertise and compassionate care to afflicted individuals to give them hope and improve their lives.	SU01HG007674-02	Undiagnosed Diseases Network	\$6,599,557	Not Available	Not Available	Not Available
January 25, 2016	Weight reduction surgery followed by kidney transplantation for patients with class III obesity and renal failure	1. Determine whether patients with class II or III obesity and renal insufficiency can safely undergo RYGB with slowing or reversal of renal disease progression. 2. Determine whether RYGB can be safely performed in renal failure patients and allow these patients to undergo renal transplant. 3. Compare RYGB to medical management followed by transplant on long term health outcomes and quality of life.	UL1 TR000445	Vanderbilt Clinical and Translational Science Award	\$30,971	Not Available	Not Available	Not Available

SUPPLEMENTAL #1

Year	Program Name	Brief Program Description	Funding Source #1	Grant Title	Funding Amount Granted	Patient Admissions	Patient Days	Outpatient Visits
January 25, 2016 February 25, 2016 2:57 pm	History of Major Depressive Disorder and Estradiol Effects on Psychosocial Stress Response and Emotional Episodic Memory	There is an increased incidence of Major Depressive Disorder (MDD) in women compared to men, and the concurrence of increased MDD risk and the reproductive life phase in women suggests that ovarian hormones have a likely role. An altered response to psychosocial stress has been one of the most consistent findings in MDD. However, the interaction of MDD vulnerability and ovarian hormone effects on the acute psychosocial stress response have not been investigated. Understanding the interactions of stress and sensitivity to ovarian hormones in MDD risk will provide important information about the vulnerability to MDD in women, and inform the development of new prevention and treatment strategies for a large portion of MDD patients.	National Institutes of Health 7R01AG021476	Estrogen Effects on Cholinergic Function in Older Women	\$1,836,834	Not Available	Not Available	Not Available
January 25, 2016	[UDN152296, MN] "Clinical and Genetic Evaluation of Patients with Undiagnosed Disorders Through the Undiagnosed Diseases Network"	Undiagnosed diseases are constellations of significant signs, symptoms and/or test results seen by a number of provider specialists over an extended period of time without resolution as to the underlying cause(s), and for which traditional diagnostic procedures and tests have been exhausted. Physicians and scientists studying the causes of rare and undiagnosed disease have found that both are resistant to classical discovery methods at the bedside or in the lab because of the heterogeneous and unwieldy variety of diseases that may be included. Our purpose is to bring expertise and compassionate care to afflicted individuals to give them hope and improve their lives.	SU01HG007674-02	Undiagnosed Diseases Network	\$6,599,557	Not Available	Not Available	Not Available

SUPPLEMENTAL #1

Year	Program Name	Brief Program Description	Funding Source #1	Grant Title	Funding Amount Granted	Patient Admissions	Patient Days	Outpatient Visits
January 27, 2016	(VTEU 2014.02) Assays for RSV Vaccine Development (DMID 14-0074)	The current methods to detect Respiratory Syncytial Virus (RSV) infection or recent exposure to the virus are based on detecting RSV antigens, RNA-based assays or serology. These methods work best for acute or very recent primary infections. However, immune responses in young children can be transient and of reduced magnitude and underestimate pre-existing RSV immunity. A better understanding of the immune responses to RSV and a sensitive way to measure these responses are critical for determining previous exposure to RSV infection and determining who would be eligible for future RSV vaccine trials. If successful, these assay(s) could be further validated and made available to the broader community. This study may allow doctors to better detect/treat RSV in pediatric populations more effectively.	Department of Health & Human Services/Division of Microbiology & Infectious Disease HHSN272201300023	Vaccine and Treatment Evaluation Units (VTEUs): Evaluation of Control Measures Against Diseases Other Than AIDS	\$23,700,303	Not Available	Not Available	Not Available
January 29, 2016	Development of 3T MRI/MRS Applications for Diabetes Research	The primary focus of this project is to develop, optimize, and validate novel quantitative MRI of the pancreas of newly diagnosed patients (< 100 days) with type 1 diabetes. A second aim is to perform MMTIs to determine if and how much insulin is still being produced. Healthy controls will also be employed. This research is expected to provide new insight into the pathogenesis of recent onset type 1 diabetes and may improve our ability to detect and monitor early T1D.	Juvenile Diabetes Research Foundation	Quantitative MRI of the Pancreas in Type 1 Diabetes	\$750,000	Not Available	Not Available	Not Available
February 8, 2016	Defining the Serum Antibody Response to Staphylococcus aureus Infections	Each year infections caused by methicillin-resistant Staphylococcus aureus (MRSA) are responsible for nearly 20,000 deaths in the United States alone. At the root of the problem is that S. aureus is a ubiquitous microorganism, colonizing the anterior nares of nearly one-third of the entire human population at any given time. However, S. aureus does not remain merely a commensal; rather, it is the leading cause of skin, soft-tissue, and bone infections and has a spectrum of illness ranging from boils and cellulitis to infective endocarditis, necrotizing pneumonia, sepsis, and death. Knowledge gained from this study will further expand the knowledge of Staphylococcus aureus (MRSA) and how to better treat the symptom in the human population.	National Institutes of Health HHSN27220140019C	Vaccine and Treatment Evaluation Units (VTEUs): Evaluation of Control Measures Against Diseases Other Than AIDS	\$23,700,303	Not Available	Not Available	Not Available
February 10, 2016	A Balanced, Randomized, Placebo-Controlled, Double-Blind Study of the Efficacy and Safety of AUTD0063 Versus Placebo in Age-Related Hearing Loss [CLARTY-1 Study]	Hearing loss is the second most common chronic disease in old age. In the USA, 27% of individuals in their 60s, and 55% of 70- to 79-year-olds have bilateral hearing loss (Lin et al, 2011). Although there is no clear etiology for ARHL, it is characterized by a bilateral, symmetrical hearing impairment that begins with higher frequencies and subsequently affects the main frequencies of everyday speech (Gates et al, 2005). Although ARHL may often be associated with other causes, general aging of the auditory system seems to be the predominant factor (Williger et al, 2014). The purpose of the current Phase IIa clinical study is to evaluate the efficacy of AUTD0063 in improving the symptoms of ARHL. Our measures of hearing will also advance our understanding of how age-related hearing loss associated with the neural pathways in the central auditory system and how these are modulated by AUTD0063. We are seeking to use and pay for services from the CRC which will allow us to participate in this industry funded clinical trial. It is our hope that participation in this trial will allow for other treatment options for individuals with age-related hearing loss.	UL1 TR000445	Vanderbilt Clinical and Translational Science Award	\$21,240	Not Available	Not Available	Not Available

SUPPLEMENTAL #1

Year	Program Name	Brief Program Description	Funding Source #1	Grant Title	Funding Amount Granted	Patient Admissions	Patient Days	Outpatient Visits
February 2016	A Multicenter, Randomized, Placebo-Controlled, Double-Blind, Parallel Group, Phase 2 Clinical Trial to Evaluate the Safety and Efficacy of GR-MD-02 for the Treatment of Liver Fibrosis and Resultant Portal Hypertension in Patients with NASH Cirrhosis: The NASH-CX Trial	Nonalcoholic steatohepatitis is a chronic inflammatory disease of the liver characterized by progressive fibrosis that eventually leads to cirrhosis in a subset of subjects. Cirrhosis results in portal hypertension, the complications of which (variceal hemorrhage, ascites with bacterial peritonitis, hepatic encephalopathy) can result in death or the need for liver transplantation. There are currently no medical therapies approved for NASH or for portal hypertension by reducing liver fibrosis, and this therapeutic area represents an area of significant unmet medical need. Galectin-3, a protein that binds to galactose-containing oligosaccharides, has been shown to be critical in the pathophysiology of NASH and liver fibrosis. GR-MD-02 (galactosylated-riamogalacturonate), a complex carbohydrate drug that binds to galectin-3, has shown robust efficacy in preclinical models of NASH and liver fibrosis and was safe and well tolerated in Phase 1 studies. Therefore, the overall objective of this clinical study is to establish the safety and efficacy of GR-MD-02 as compared to placebo in the reduction of portal pressure as a result of a reduction in fibrosis in subjects with compensated cirrhosis due to NASH.	U11 TR0000445	Vanderbilt Clinical and Translational Science Award	\$16,770	Not Available	Not Available	Not Available
February 10, 2016	Metabolic Effects of Angiotensin-(1-7)	The overall purpose of this study is to learn more about the metabolic effects of angiotensin-(1-7) in the insulin resistant state associated with obesity. Pharmacologic approaches to increase angiotensin-(1-7) levels or its actions are currently in development for the treatment of cardiometabolic disease, based on findings from animal studies. It is unclear, however, if this peptide contributes to regulation of insulin action in humans. These studies will provide new insight into the potential for targeting angiotensin-(1-7) to improve insulin sensitivity as well enhance our general understanding of mechanisms involved in insulin resistance. These funds will allow us to generate critical preliminary data to submit an extramural R01 grant application.	U11 TR0000445	Vanderbilt Clinical and Translational Science Award	\$29,352	Not Available	Not Available	Not Available
February 10, 2016	A phase 2b study to evaluate the safety and efficacy of VRC01 broadly neutralizing monoclonal antibody in reducing acquisition of HIV-1 infection	This study will test the potential protective efficacy of a monoclonal antibody. We will be recruiting men who have sex with men (MSM) and transgender (TG) HIV infection. This study will test the level of efficacy of the VRC01 mAb in preventing HIV infection.	National Institutes of Health U01A1068614	HVTN Protocol Funds (PF)	\$4,328,813	Not Available	Not Available	Not Available
February 19, 2016	Perioperative Endothelial Function and Oxidative Stress	Patients undergoing cardiac surgery are exposed to hyperoxic conditions as the current clinical standard, however these conditions may precipitate harmful oxidative stress. This project will test the relationships between endothelial dysfunction, oxidative stress, and morbidity/end-organ dysfunction. This is a human subjects study that is highly translational. Findings could help the design of interventions for patients undergoing cardiac surgery to reduce clinical morbidity.	National Institutes of Health R01GM112871	Hyper-oxygenation, oxidative stress, and kidney injury following cardiac surgery	\$348,262	Not Available	Not Available	Not Available

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**February 25, 2016
2:57 pm**

SUPPLEMENTAL #1

247

Year	Program Name	Brief Program Description	Funding Source #1	Grant Title	Funding Amount Granted	Patient Admissions	Patient Days	Outpatient Visits
February 22, 2016	Pulmonary Vascular Complications of Liver Disease 2 (PVCLD2)	A complication is portopulmonary hypertension (PPHTN) which is pulmonary arterial hypertension (PAH) in the setting of portal hypertension. PPHTN is found in about six percent of patients evaluated for liver transplantation (totaling almost 170,000 Americans with PPHTN) and is one of the most common causes of PAH. This is a prospective cohort study of subjects with PPHTN to determine the mechanisms and outcomes of Pulmonary Vascular complications of liver disease. The main purpose of this study is to determine if certain genes, hormones, or other factors predict the risk of developing lung vessel disease in patients with liver disease and whether they determine outcome. Answering these questions may provide us with new treatment options for this specific group of patients.	National Institutes of Health / University of Pennsylvania	Pulmonary Vascular Complications of Liver Disease	\$20,000	Not Available	Not Available	Not Available
February 22, 2016	A Phase 1b, single center, open-label, dose-escalation, and multiple dose study to evaluate the safety of recombinant human soluble angiotensin converting enzyme 2 (rhACE2) in subjects with pulmonary arterial hypertension	Management strategies for PAH include prevention of microthrombosis using anticoagulants such as warfarin and promoting vasodilation and regression of muscular hypertrophy and intimal fibrosis using endothelin receptor antagonists and phosphodiesterase (PDE) 5 inhibitors (Humbert 2004, N Engl J Med). In severe disease or in cases of treatment failure with oral therapy, prostanooids (inhaled, subcutaneous, or intravenous) are used. In selected patients not responsive to medical therapy, lung transplant is an option. Despite improvement in medical therapy, only 2/3 of patients are alive 3 years after treatment with most effective therapy available for PAH, continuous intravenous epoprostenol (Sitbon 2002, J Am Coll Cardiol). The current therapeutic options remain unsatisfactory, and there remains an urgent need for novel therapies. This study would be the first step towards development of a new drug for treating PAH that aims for the causes of disease rather than simply treating the symptoms of disease. If the low toxicity proves to hold true in this patient population, that would be a huge improvement over many of the currently available therapies. Positive outcome could lead to Phase 2 clinical trial of a potentially better therapy for pulmonary arterial hypertension.	National Institutes of Health P01HL108800	Hormonal, Metabolic and Signaling Interactions in PAH	\$13,576,414	Not Available	Not Available	Not Available

February 25, 2016**2:57 pm**

Please complete the following chart regarding overall historical utilization trends for the CRC unit:

RESPONSE: Please find the completed chart below. A recent audit revealed that the census for 2015 was 5,673 unique patient encounters. Please note that the occupancy percentage was calculated based on 80% occupancy, even though the existing CRC licensed beds are utilized for both inpatients and outpatients. The new CRC will have 5 inpatient rooms and 6 outpatient rooms to reflect current and projected patient growth.

Variable	2013	2014	2015
Inpatient Admissions	463	390	299
Inpatient Days	1,119	772	597
Occupancy %	3.8	2.6	2.0
ALOS	2.4	2.0	2.0
Outpatient Visits	5,710	6,415	5,374
Inpatient Admissions + Outpatient Visits	6,173	6,805	5,673

If the applicant is not able to project patient census, please explain how it is possible to complete a Projected Data Chart.

RESPONSE: Patient census is difficult to project, and as such, projected volume was kept stagnant from 2015.

7. Section C. (Economic Feasibility) Item 1.

The letter from the contractor is noted. Please ask the contractor to submit a revised letter that addresses all of the following:

- 1) a general description of the project, including size of facility
- 2) his/her estimate of the cost to construct the project to provide a physical environment, according to applicable federal, state and local construction codes, standards, specifications, and requirements and
- 3) attesting that the physical environment will conform to applicable federal standards, manufacturer's specifications, ADA, and licensing agencies' requirements including the newest AIA Guidelines for Design and Construction of Hospital and Health Care Facilities

RESPONSE: Please find the letter from RC Matthews in response to the first and second questions. In addition, please find a letter from Blair + Mui Dowd Architects, PC attesting to third question.

February 25, 2016**2:57 pm**

February 23, 2016

To whom it may concern

RE: **VUMC Clinical Research Center**
CON Application
Verification of Construction Cost Estimate

R.C. Mathews Contractor is a licensed General Contractor in Nashville, Tennessee. We have reviewed the Schematic Design Plans and construction program for the above referenced project and developed a cost estimate based on these plans. This estimate includes the costs necessary to construct the project in such a way that the physical environment will conform to all applicable federal, state and local building codes, standards, specifications and program requirements.

The project includes renovation of the existing 1st floor (ground level) of the existing "Round Wing" building and demolition of the exterior façade to allow for building expansion. We find the renovated area of the existing building to be 11,183sf and the new (expansion) area to be 2,489sf. The project cost estimate includes all necessary interior demolition, site work to accommodate the expansion, exterior demolition, new construction and renovation of the existing space to accommodate the new programmed use. The estimate also includes numerous mechanical and electrical system upgrades including replacement of 2 Air Handling units and new critical power feed to replace the existing generator. The existing fire protection and alarm systems will be upgraded and expanded to accommodate the new use and the newly constructed area.

Based on our experience and historic cost data from similar work at VUMC the construction cost estimate would be \$8,400,000 for this size and type of project in this area.

Sincerely,

A handwritten signature in black ink, appearing to read "Doug Warren", is written over a horizontal line.

Doug Warren
Project Manager
R.C. Mathews Contractor

Cc: Walker Mathews, file

February 25, 2016**2:57 pm**

BLAIR + MUI DOWD ARCHITECTS, PC
DONALD BLAIR ARCHITECTS
100 LAFAYETTE ST STE. 604
NEW YORK, NY 10013
TEL 212.941.8825
WWW.BMDARCH.NET

February 23, 2016

To Whom It May Concern:

Re: **VUMC Clinical Research Center
CON Application
Architect's Summary**

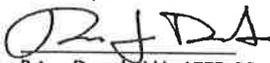
The above mentioned project is a relocation of the Clinical Research Center from Medical Center North 3rd floor to MCN 2nd floor Round Ring. The southern exterior walls of the Round Wing will be demolished and the footprint expanded resulting in 13,672 total gsf for the new CRC. A new façade will be added along with a new entry, and ambulance drop-off with canopy. The façade will consist of a glass storefront with vertical glass fins for privacy and sun-shading. Site work will be performed to accommodate the new entry, drop-off, and upgrade existing landscaping. The site topography will be adjusted, and will include retaining walls to allow a second entry into the CRC.

The program consists of both inpatient and exam rooms along with laboratory, and other ancillary support, including administrative functions. A Communicable Disease Response Unit (CDRU) will be included as part of the project, but will be used as general inpatient rooms for the CRC when not in use as a CDRU.

This project will include several mechanical infrastructure upgrades, including the replacement of (2) AHUs. A temporary air handling unit will be required during construction, as the existing unit serves spaces outside of the renovation that will remain in operation. Additionally, an existing generator, which is beyond its original life-expectancy, will be abandoned and removed, as a new critical electrical feeder will be provided from an alternate source.

Due to the inpatient functions that will occur in the CRC, the project includes converting the existing space from Business to Institutional occupancy (IBC). The physical environment will conform to applicable federal standards, manufacturer's specifications, ADA, and licensing agencies' requirements including the newest AIA Guidelines for Design and Construction of Hospital and Health Care Facilities.

Sincerely,



Brian Dowd, AIA, LEED BD+C
Principal

8. Section C. (Economic Feasibility) Item 3.

Your response to this item is noted. Please provide more detailed reasoning that explains why renovation costs/square foot are approximately 75% higher than the third quartile of previously approved projects and why new construction costs are approximately 245% higher than the third quartile of previously approved projects.

RESPONSE: The construction costs for the renovation appears higher than comparative projects due to the large amount of infrastructure required. In addition to replacing two existing air handling units, with a cost of approximately \$2,000,000, a new emergency power feed will be added to replace an existing emergency generator. The new construction component of the project represents an extension of the existing façade, and includes new footings, site work, structure, and canopy that are not clearly captured when comparing projects on a square-foot basis.

9. Section C. (Economic Feasibility) Item 4 (Historical Data Chart)

Please provide a Historical Data Chart for the CRC.

RESPONSE: Please see the Historical Data Chart for the CRC below.

February 25, 2016

2:57 pm

HISTORICAL DATA CHART

	2013	2014	2015
A. Utilization Data	6,173	6,804	5,673
B. <u>Revenues from Services to Patients</u>			
1. Inpatient Services			
2. Outpatient Services			
3. Emergency Services			
4. Other Operating Revenue	\$2,041,043	\$2,241,440	\$1,836,597
Gross Operating Revenue	\$2,041,043	\$2,241,440	\$1,836,597
C. <u>Deductions from Revenue</u>			
1. Contractual Adjustments			
2. Provision for Charity Care			
3. Provisions for Bad Debt			
Total Deductions	\$ -	\$ -	\$ -
Net Operating Revenue	\$2,041,043	\$2,241,440	\$1,836,597
D. <u>Operating Expenses</u>			
1. Salaries and Wages	\$1,807,002	\$2,114,793	\$1,743,683
2. Physician's Salaries and Wages			
3. Supplies and Drug Costs	\$ 234,041	\$ 126,647	\$ 92,914
4. Taxes			
5. Depreciation			
6. Rent			
7. Interest, other than Capital			
8. Management Fees:			
a. Fees to Affiliates			
b. Fees to Non-Affiliates			
9. Other Expenses			
Total Operating Expenses	\$2,041,043	\$2,241,440	\$1,836,597
E. <u>Other Revenue - Net</u>			
Net Operating Income (loss)	\$ -	\$ -	\$ -
F. Capital Expenditures			
1. Retirement of Principal			
2. Interest Expense			
Total Capital Expenditures	\$ -	\$ -	\$ -
Net Operating Income (Loss)			
Less Capital Expenditures	\$ -	\$ -	\$ -

10. Section C. (Economic Feasibility) Item 4 (Projected Data Chart)

What does the 5,672 represent in Line A. Utilization, e.g., inpatient admissions, patient days, outpatient visits, etc.?

RESPONSE: A recent audit revealed that the census for 2015 was 5,673 unique patient encounters. Each encounter would have been either an inpatient admission or an outpatient visit.

Since it was stated earlier that it is difficult to project patient census, please explain how the Projected Data Chart was developed.

RESPONSE: Patient census is difficult to project, and as such, volume was kept stagnant from 2015, which is the most recent year with complete data. When comparing the Historical Data Chart to the Projected Data Chart, the dollars were adjusted to account for program realignment. In order to reduce redundancy in services offered by the CRC staff and other Vanderbilt research areas, the metabolic technician and research nutrition staff now aligns with the Vanderbilt Center for Human Nutrition Research. The supplies have been increased to account for procuring these services as a supply rather than personnel effort.

There appear to be some calculation errors in the Projected Data Chart. Please make the necessary corrections and submit a revised Chart.

RESPONSE: Please see the revised Projected Data Chart below.

11. Section C. (Economic Feasibility) Item 5

If neither the patient or third-party payors will be billed for services, please explain how a \$325 average gross charge was determined.

RESPONSE: Correct neither patient nor third-party payors will be billed for services. However, the project's average gross charge was calculated by dividing the gross operating revenue by the number of patients treated at the CRC.

12. Section C. (Economic Feasibility) Items 6 and 7

Is it correct to assume that the resources (staff and supplies) committed by the applicant to the CRC will be based solely on grant funding, so that the CRC is expected to always breakeven.

RESPONSE: The CRC resources could be supported by a variety of funding sources, including federal and non-federal grants, industry pharmaceutical clinical trial funds, or other research funds. The cost of operating the CRC has been covered by a combination of these sources (largely grant funds) for the past 9 years and will continue through the current grant period that ends May 31, 2017. We anticipate submission of a renewal application that would extend the support period for at least another 5 years beyond 2017.

13. Section C. (Contribution to the Orderly Development) Item 3.

Since it is difficult to project patient census in the CRC, are the proposed staffing levels subject to change? Would a range of projected FTEs by discipline be a better way to complete the staffing chart?

RESPONSE: As you have correctly identified, patient census and clinical trial discipline are difficult to predict and the CRC leadership is continuously reviewing staffing models to maintain an optimized unit. To minimize disruption in the conduct of a clinical trial, we have found it is critically important to retain a permanent pool of full time, specialty trained research nurses. As the CRC facility and staff are available to all disciplines at Vanderbilt, the CRC research nurses are experts in the conduct of a clinical trial and are trained at the start of the study by the primary clinical investigator to fill in details specific to discipline, patient population, and trial specifics. This long-standing practice, along with outstanding CRC unit nurse retention, has built a vast range of disciplines the CRC nurses are able to expertly practice in. This model minimizes disruption in the staffing levels and maintains expertise available at all times.

Why will the metabolic technician position no longer be needed?

RESPONSE: To eliminate redundancy in services offered by the CRC staff and other Vanderbilt research areas, the technician now aligns with the Vanderbilt Center for Human Nutrition Research, which is the institutional expertise in conducting diet, body, and human metabolism research. The CRC works closely with the Center's staff, which requires the CRC facility and nursing support to conduct the metabolic research.

14. Section C. (Contribution to the Orderly Development) Item 4

Generally speaking do the staff that are utilized for this unit tend to be part-time and/or PRN because the filling of positions is contingent on funding availability for and the length of clinical trials?

RESPONSE: The CRC research nurses are not assigned to a specific protocol but rather use their extensive training to provide all types of research clinical care. We maintain a small pool of highly trained and experienced research nursing staff and schedule research patients accordingly. We have explored the possibility of PRN staffing in the past; however, due to the complexity of research protocols and scope of care for research patients, the PRN model does not serve the CRC unit for the following reasons. First, research nursing requires additional training and credentialing standards that standard of care nursing staff do not maintain, including certification and ongoing continuing education in research patient Good Clinical Practices, and the Institutional Review Board. Second, the CRC research nurses collect and process research specimens in the CRC lab according to the clinical protocol guidelines. Finally, data standardization and collection for a clinical trial is critically important and, in our experience, is challenging to maintain within a PRN staffing pool. The CRC leadership is continuously reviewing staffing models to ensure FTEs match the need of the unit.

1002016

AFFIDAVIT

STATE OF TENNESSEE

COUNTY OF Davidson

NAME OF FACILITY: Vanderbilt University Hospitals

I, Ginna Felts, after first being duly sworn, state under oath that I am the applicant named in this Certificate of Need application or the lawful agent thereof, that I have reviewed all of the supplemental information submitted herewith, and that it is true, accurate, and complete.

Ginna Felts

VICE PRESIDENT, BUSINESS DEVELOPMENT

Sworn to and subscribed before me, a Notary Public, this the 25th day of February, 2016, witness my hand at office in the County of Davidson, State of Tennessee.

Jennifer Hygrell
NOTARY PUBLIC

My commission expires July 8, 2019.

HF-0043

Revised 7/02



Supplemental #2
-COPY-

**Vanderbilt University
Hospitals**

CN1602-010

February 29, 2016**11:27 am****1. Section B, Project Description, Item II.A.**

It has been indicated that there are currently 14 inpatient rooms in the CRC and that the proposed unit will have 5 inpatient rooms. What will become of the nine inpatient beds that were previously in the CRC?

RESPONSE: After the relocation of the CRC, the nine (9) licensed beds will remain in the space and will be temporarily utilized by other VUH nursing units while ongoing cosmetic upgrades are completed. A final use of that space and the beds has not been determined.

2. Section C, Need, Item 6

For the funding source identified as UL1 TR000445, what is the entity providing the funds?

RESPONSE: The entity providing the funds is the National Institutes of Health (NIH).

The utilization table is noted. There appears to be calculation errors in the Occupancy % and ALOS rows. For example for Year 2013, ALOS calculates to 3.0 days and occupancy based on 14 beds calculates to approximately 22%

Please make the necessary changes and submit a revised utilization trend chart.

RESPONSE: Please see the updated chart below.

Variable	2013	2014	2015
Inpatient Admissions	463	390	299
Inpatient Days	1,119	772	597
Occupancy %	22%	15%	12%
ALOS	3.0	2.0	2.0
Outpatient Visits	5,710	6,415	5,374
Inpatient Admissions + Outpatient Visits	6,173	6,805	5,673

3. Section C. (Economic Feasibility) Item 4 (Historical Data Chart)

Please explain why there are no depreciation or other expenses for the CRC's Historical Data Chart.

RESPONSE: The Clinical Research Center is a non-revenue generating unit focused on advancing clinical and translational research. Therefore, the purpose is not to generate revenue from patient care to cover the costs of operations. VUMC has never accounted for depreciation in this unit and having never done so, it is not possible to

calculate historically. The VUMC depreciation costs were submitted with the application and show the feasibility of the entity as a whole.

4. Section C. (Economic Feasibility) Item 4 (Projected Data Chart)

Please explain why there are no depreciation or other expenses for the CRC's Projected Data Chart.

RESPONSE: Similar to response in #3, the Clinical Research Center is a non-revenue generating unit focused on advancing clinical and translational research. Therefore, the purpose is not to generate revenue from patient care to cover the costs of operations. VUMC has never accounted for depreciation in this unit and having never done so, it is not possible to calculate on a projected basis.

There appears to still be calculation errors in the Projected Data Chart.

Please make the necessary corrections and submit a revised Projected Data Chart.

RESPONSE: Please see the updated Projected Data Chart.

AFFIDAVIT

STATE OF TENNESSEE

COUNTY OF Davidson

NAME OF FACILITY: Vanderbilt University Hospitals

I, Ginna Felts, after first being duly sworn, state under oath that I am the applicant named in this Certificate of Need application or the lawful agent thereof, that I have reviewed all of the supplemental information submitted herewith, and that it is true, accurate, and complete.

Ginna Felts

VICE PRESIDENT, BUSINESS DEVELOPMENT

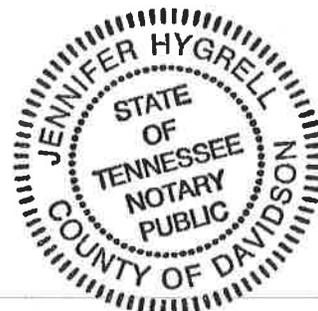
Sworn to and subscribed before me, a Notary Public, this the 29th day of February, 2016, witness my hand at office in the County of Davidson, State of Tennessee.

Jennifer Hygrell
NOTARY PUBLIC

My commission expires July 8, 2019.

HF-0043

Revised 7/02





State of Tennessee
Health Services and Development Agency

Andrew Jackson Building, 9th Floor
 502 Deaderick Street
 Nashville, TN 37243

www.tn.gov/hsda Phone: 615-741-2364 Fax: 615-741-9884

LETTER OF INTENT

The Publication of Intent is to be published in the Tennessean which is a newspaper
 of general circulation in Davidson, Tennessee, on or before February 10, 2016,
 for one day.
(Name of Newspaper)
(County) (Month / day) (Year)

This is to provide official notice to the Health Services and Development Agency and all interested parties, in accordance with T.C.A. § 68-11-1601 *et seq.*, and the Rules of the Health Services and Development Agency, that:

Vanderbilt University Hospitals an existing acute care hospital
(Name of Applicant) (Facility Type-Existing)

owned by: Vanderbilt University with an ownership type of not-for-profit

and to be managed by: Vanderbilt University Hospitals intends to file an application for a Certificate of Need for [PROJECT DESCRIPTION BEGINS HERE]: the renovation and the relocation of the inpatient unit operated as the Clinical Research Center on the campus of Vanderbilt University Hospitals at 1211 Medical Center Drive, Nashville, Tennessee. The project will require approximately 13,672 square feet of renovation. The project does not involve the initiation of new health care services for which a certificate of need is required or the acquisition of major medical equipment. The project will not change the number of licensed beds at Vanderbilt University Hospitals. The estimated project cost is \$10,579,159.

The anticipated date of filing the application is: February 12, 2016

The contact person for this project is Ginna Felts Vice President, Business Development
(Contact Name) (Title)

who may be reached at: Vanderbilt University Medical Center 3319 West End Avenue, Suite 920
(Company Name) (Address)

Nashville TN 37203 615/936-6005
(City) (State) (Zip Code) (Area Code / Phone Number)

2.10.16 ginna.rader@vanderbilt.edu
(Signature) (Date) (E-mail Address)

**CERTIFICATE OF NEED
REVIEWED BY THE DEPARTMENT OF HEALTH
DIVISION OF POLICY, PLANNING AND ASSESSMENT
615-741-1954**

DATE: April 30, 2016

APPLICANT: Vanderbilt University Medical Center
1211 Medical Center Drive
Nashville, Tennessee 37203

CONTACT PERSON: Ginna Felts, Business Development
3319 West End Avenue, Suite 920
Nashville, Tennessee 37203

COST: \$10,579,159

In accordance with Section 68-11-1608(a) of the Tennessee Health Services and Planning Act of 2002, the Tennessee Department of Health, Division of Policy, Planning, and Assessment, reviewed this certificate of need application for financial impact, TennCare participation, compliance with *Tennessee's State Health Plan*, and verified certain data. Additional clarification or comment relative to the application is provided, as applicable, under the heading "Note to Agency Members."

SUMMARY:

The applicant, Vanderbilt University Hospitals, an existing 1,025 (1,159 beds when all current projects are completed) bed acute care not for profit hospital, seeks Certificate of Need (CON) approval for the renovation and relocation of the inpatient unit operated as the Clinical Research Center on the campus of Vanderbilt University Hospitals located at 1211 Medical Center Drive, Nashville, Tennessee 37203.

The project will require approximately 13,672 square feet of renovation and new construction (11,183 and 2,489, respectively) at a cost of \$8,400,000, or \$523 per square foot for new construction and \$1,025 per square foot for renovation. Both these square foot estimates are above the HSDA cost per square foot 3rd Quartile.

Vanderbilt University (VU), by and through its Vanderbilt University Medical Center, owns Vanderbilt University Hospital (VUH), the Monroe Carrell, Jr. Children's Hospital at Vanderbilt (MCJCHV), and Vanderbilt Psychiatric Hospital (VPH). These facilities operate under one hospital license as Vanderbilt University Hospitals, and they, as well as their associated clinics are collectively known as Vanderbilt University Medical Center (VUMC). The applicant reports that it is anticipated during the first half of 2016, VU will sell substantially all the clinical assets used in the operation of Vanderbilt University Medical Center (VUMC) to a newly formed not-for-profit, tax-exempt Tennessee corporation, which similarly will be named "Vanderbilt University Medical Center,".

The total estimated project cost is \$10,579,159 and will be funded through cash reserves as documented by the Chief Financial Officer.

GENERAL CRITERIA FOR CERTIFICATE OF NEED

The applicant responded to all of the general criteria for Certificate of Need as set forth in the document *Tennessee's State Health Plan*.

NEED:

The applicant's service area consists of all 95 Tennessee counties. The 2016 population of Tennessee is 6,812,005, increasing to 7,108,031 in 2020, an increase of 4.3%.

The CRC is the core physical research hub within the Vanderbilt Institute for Clinical and Translational Research that has been providing a full-service, hospital based, clinical research center since 1967. Additionally, patients come from across the United States to receive the trials available at the Clinical Research Center (CRC). The applicant reports that over the last five years, CRC has been used by 400 investigators to conduct 500 unique research projects. In the last year, the CRC supported 210 active protocols serving all stages and types of research, with approximately 294 inpatients and 5,328 outpatient visits.

The following table provides a three year utilization history of the CRC.

Variable	2013	2014	2015
Inpatient Admissions	463	390	299
Inpatient Days	1,119	772	597
Occupancy	22%	15%	12%
ALOS	3.0	2.0	2.0
Outpatient Visits	5,710	6,415	5,374
Inpatient Admissions + Outpatient Visits	6,173	6,805	5,673

The CRC focus is to allow the rapid translation of new medical research to clinical care in a patient care setting. Investigators are from the Vanderbilt Schools of Medicine and Nursing, Vanderbilt Peabody School of Education and Human Development, Vanderbilt School of Engineering, the Lipscomb University School of Pharmacy, and the Meharry Medical and Dental Colleges. The CRC conducts a variety of clinical trials, including the study and treatment of rare diseases, clinical and genetic evaluation of patients with undiagnosed diseases, elderly populations and health concerns for their demographic, including Alzheimer’s disease, oncology clinical trials, pediatric research trials, community health surveys, and other research in hard to reach populations.

The CRC is currently located on the third floor of Medical Center North. The current location has supported research efforts and accomplishments, but the proposed new space will add convenience for patients and researchers and promote a state-of-the-art design that aligns with the cutting edge of patient oriented research. The 3rd floor was renovated in 1971 and at the time was a state-of-the-art facility designed for the specific needs of the CRC. As the CRC has evolved, the CRC has managed changes within the original space. Relocating to a different location will allow a single move rather than a phased renovation within the 3rd floor space. Additionally, by moving to the second floor, the applicant will gain a grade level drop off and entry for ambulatory patients, a connection to the hospital via a patient transport tunnel, and closer proximity to parking and shuttle services. The proposed new CRC will be located directly below six floors of inpatient beds and is located in the center of the clinical enterprise.

The proposed new space will be located on the second floor of the Round Wing, and will house five relocated inpatient licensed beds and six exam and outpatient rooms. Two of the five inpatient rooms will be designed to meet requirements established by the Vanderbilt Communicable Disease Response Team (CSRT) for the Communicable Disease Response Unit (CDRU). The CDRU is designed for the care of a patient with a rare or unknown communicable disease, such as EBOLA Virus Disease (EVD). This unit consists of three areas: patient room, anteroom, and nurse’s station. It provides a safe environment to care for patients while protecting staff, other patients, and the community.

The CDRT consists of nurses, physicians, paramedics, and educators from adult and pediatric enterprise. Each team member possesses the knowledge and skills to care for patients who require intensive medical care. Each volunteer receives intensive training in the care of communicable, serious infectious diseases; receiving initial and ongoing training the key principals to maintain staff competencies. The training consists of specific disease pathology, personal protective equipment, and infection control measures.

TENNCARE/MEDICARE ACCESS:

The Clinical Research Center is funded by both federal and non-federal sources. Patients and third party payers are not billed for services provided to them. No Medicaid or Medicare participation is involved in this project.

ECONOMIC FACTORS/FINANCIAL FEASIBILITY:

The Department of Health, Division of Policy, Planning, and Assessment have reviewed the Project Costs Chart, the Historical Data Chart, and the Projected Data Chart to determine if they are mathematically accurate and if the projections are based on the applicant’s anticipated level of utilization. The location of these charts may be found in the following specific locations in the Certificate of Need Application or the Supplemental material:

Project Costs Chart: The Project Costs Chart is located on page 14 of the application. The total estimate cost of the project is \$10,579,159.

Historical Data Chart: The Historical Data Chart is located page 17 of the application. The applicant reported 80%, 81%, and 82% occupancy in 2013, 2014, and 2015, with net operating revenues of (\$23,201,130), \$102,579,776, and \$215,576,897 each year, respectively.

Projected Data Chart: The Projected Data Chart is located in Supplemental 2. The applicant projects 5,672 discharges in 2017 and 2018 with net operating revenues of \$0 each year, respectively.

The relocation of the CRC to a location that is proximate to the clinical core, and is more convenient and identifiable for outpatient visitors has long been a goal of VUMC. Several location options were studied, all of which involved building new space because no area was identified as having adequate size near the clinical core. The most developed study involved a new addition above The Vanderbilt Clinic (TVC). This option was prosed as part of an NIH grant applicant in 2004, but was more expensive than the current proposed renovation. The option of renovating the current CRC in-place was ruled out due to the lack of a temporary location for the CRC and the negative impact on the CRC operations. The proposed CRC relocation includes 11,183 square feet of existing renovation and 2,489 square feet of new construction. The location identified is the only available space adjacent to the clinical core with the ability to accommodate the CRC program.

CONTRIBUTION TO THE ORDERLY DEVELOPMENT OF HEALTHCARE:

The proposed project will improve access and convenience to patients and researchers at CRC. The CRC will be able become more significant with a prominent and well-designed space and configuration. The CRC is a widely utilized facility with 56 specialties using the facility in 2015. This facility is a one of a kind facility and is not duplicative of any other facility in the region.

The current and proposed staffing is provided in the following table.

Staff Positions	Current Staffing	Future Staffing
Outpatient RN	14	12
Inpatient RN	4	4
Ultrasound Technician	1	1
Metabolic Technician	1	-
Administrative Unit Support	1	1
Visit Schedule	1	1
Medical Receptionist	1	1
Housekeeping	2	1

VUMC has accredited training programs in medicine, radiation oncology, medical physicists and dosimetrists, nursing, pharmacy, respiratory therapy, dietetics, medical technology, radiation therapy technology, cardiovascular perfusion technology, and nuclear medicine technology. VUMC is a major clinical training facility for Vanderbilt University Medical and Nursing School. VUMC support a total house staff training program of 711 residents and 267 fellows.

The applicant is licensed by the Tennessee Department of Health, Board for Licensing Healthcare Facilities and accredited by The Joint Commission.

SPECIFIC CRITERIA FOR CERTIFICATE OF NEED

The applicant responded to all relevant specific criteria for Certificate of Need as set forth in the document *Tennessee's State Health Plan*.

CONSTRUCTION, RENOVATION, EXPANSION, AND REPLACEMENT OF HEALTH CARE INSTITUTIONS

1. Any project that includes the addition of beds, services, or medical equipment will be reviewed under the standards for those specific activities.

Not applicable.

2. For relocation or replacement of an existing licensed health care institution:
 - a. The applicant should provide plans which include costs for both renovation and relocation, demonstrating the strengths and weaknesses of each alternative.
 - b. The applicant should demonstrate that there is an acceptable existing or projected future demand for the proposed project.

3. For renovation or expansions of an existing licensed health care institution:
 - a. The applicant should demonstrate that there is an acceptable existing demand for the proposed project.

VUMC is a comprehensive healthcare facility dedicated to patient care, research, and biomedical education. The medical center's reputation for excellence in each of these areas has made VUMC a major referral center for the Mid-South. There are no other comparable programs in Tennessee. The proposed project will continue to allow this type of research to be performed, thus allowing more treatment options to be discovered and better patient outcomes.

- b. The applicant should demonstrate that the existing physical plant's condition warrants major renovation or expansion.

The 3rd floor was renovated in 1971 and at the time was a state-of-the-art facility designed for the specific needs of the CRC. As the CRC has evolved, the CRC has managed changes within the original space. Relocating to a different location will allow a single move rather than a phased renovation within the 3rd floor space. Additionally, by moving to the second floor, the applicant will gain a grade level drop off and entry for ambulatory patients, a connection to the hospital via a patient transport tunnel, and closer proximity to parking and shuttle services. The proposed new CRC will be located directly below six floors of inpatient beds and is located in the center of the clinical enterprise.

