

EDISON VENDOR ID REVISION



CONTRACT

(no cost contract, involving no monetary obligation between the parties, with an individual, business, non-profit, or government entity of another state or country)

Begin Date September 1, 2014	End Date August 31, 2019	Agency Tracking # 31865-00134	Edison ID NV -- 43119
Contractor Legal Entity Name Vanderbilt University Medical Center			Edison Vendor ID (optional) 0000006442
Service Caption Conduct Quality Assessment Studies			
Ownership/Control <input type="checkbox"/> African American <input type="checkbox"/> Asian <input type="checkbox"/> Hispanic <input type="checkbox"/> Native American <input type="checkbox"/> Female <input type="checkbox"/> Person w/Disability <input type="checkbox"/> Small Business <input type="checkbox"/> Government <input checked="" type="checkbox"/> NOT Minority/Disadvantaged <input type="checkbox"/> Other:			
Selection Method & Process Summary (mark the correct response to confirm the associated summary)			
<input type="checkbox"/> RFP	The procurement process was completed in accordance with the approved RFP document and associated regulations.		
<input type="checkbox"/> Competitive Negotiation	The predefined, competitive, impartial, negotiation process was completed in accordance with the associated, approved procedures and evaluation criteria.		
<input type="checkbox"/> Alternative Competitive Method	The predefined, competitive, impartial, procurement process was completed in accordance with the associated, approved procedures and evaluation criteria.		
<input checked="" type="checkbox"/> Non-Competitive Negotiation	The non-competitive contractor selection was completed as approved, and the procurement process included a negotiation of best possible terms & price.		
<input type="checkbox"/> Other	The contractor selection was directed by law, court order, settlement agreement, or resulted from the state making the same agreement with <u>all</u> interested parties or <u>all</u> parties in a predetermined "class."		
OCR USE - NC			



CONTRACT AMENDMENT COVER SHEET

Agency Tracking # 31865-00134	Edison ID 43119	Contract #	Amendment # 01		
Contractor Legal Entity Name Vanderbilt University School of Medicine			Edison Vendor ID 0000091864		
Amendment Purpose & Effect(s) Amends Scope					
Amendment Changes Contract End Date: <input type="checkbox"/> YES <input checked="" type="checkbox"/> NO		End Date: August 31, 2019			
TOTAL Contract Amount INCREASE or DECREASE per this Amendment (zero if N/A):			\$0.00 No Cost Contract		
Funding —					
FY	State	Federal	Interdepartmental	Other	TOTAL Contract Amount
TOTAL:					\$0.00
American Recovery and Reinvestment Act (ARRA) Funding: <input type="checkbox"/> YES <input checked="" type="checkbox"/> NO					
Budget Officer Confirmation: There is a balance in the appropriation from which obligations hereunder are required to be paid that is not already encumbered to pay other obligations.			<i>OCR USE</i>		
Speed Chart (optional)		Account Code (optional)			



**AMENDMENT #1 TO
CONTRACT # 43119
BETWEEN THE STATE OF TENNESSEE,
DEPARTMENT OF FINANCE AND ADMINISTRATION,
DIVISION OF HEALTH CARE FINANCE AND ADMINISTRATION
BUREAU OF TENNCARE
AND
VANDERBILT UNIVERSITY
VANDERBILT SCHOOL OF MEDICINE**

This Amendment is made and entered by and between the State of Tennessee, Department of Finance and Administration, Division of Health Care Finance and Administration, Bureau of TennCare, hereinafter referred to as the "State" or "TennCare" and Vanderbilt University, Vanderbilt School of Medicine, hereinafter referred to as the "Contractor." For good and valuable consideration, the sufficiency of which is hereby acknowledged, it is mutually understood and agreed by and between said, undersigned contracting parties that the subject contract is hereby amended as follows:

1. The following is added as Contract Section A.11.:

A.11. The Contractor shall conduct pragmatic research, including, but not limited to, facilitating assessments of prevention, diagnosis, and treatment options to help clinicians, patients and other stakeholders in making informed decisions that improve health care for both individuals and populations. The Contractor shall:

- a. maintain and use study data for preparation to research queries and de-identified or HIPAA limited data set studies following governance procedures outlined by the MidSouth CDRN;
- b. provide ad hoc and periodic (quarterly) reports and consultation with TennCare staff on use and sharing of de-identified data or HIPAA limited data sets by the project;
- c. link the study data to other healthcare data for patients within the MidSouth CDRN, including patients of Vanderbilt, VHAN, and Greenway, and
- d. Collaborate with TennCare on projects of value to TennCare for optimizing quality and population health.

When conducting pragmatic research, the Contractor shall submit only studies using identified data for review and approval prior to data release.

3. The following is added as Contract Section A.12.:

A.12. TennCare agrees that, as a part of its responsibility as the agency charged with improving the health of residents of Tennessee, it is beneficial to promote studies that are aimed at improving healthcare system-level approaches to managing care and assessing the effectiveness of interventions or practices conducted in routine clinical settings. TennCare agrees that the Contractor shall be allowed to utilize TennCare data to develop and carry out studies for these purposes.

4. The following is added as Contract Section A.13.:

A.13. TennCare agrees to allow the Contractor to provide the information necessary to conduct pragmatic research such studies from Vanderbilt's node of the US Food and Drug Administration (FDA) Sentinel Initiative (site PI Marie R. Griffin MD MPH) to the Mid-South Clinical Data Research Network (CDRN) (site PI Russell Rothman). The Mid-South data sets will be derived from the data core already established at Vanderbilt



University through its Vanderbilt School of Medicine, Department of Health Policy. The data core is currently headed by Wayne A. Ray PhD and co-directed by Dr. Carlos G Grijalva MD MPH. Data core personnel with TennCare permission will make available data derived from enrollment, encounter and provider and other files of the TennCare program from the existing project database

Required Approvals. The State is not bound by this Amendment until it is signed by the contract parties and approved by appropriate officials in accordance with applicable Tennessee laws and regulations (depending upon the specifics of this contract, said officials may include, but are not limited to, the Commissioner of Finance and Administration, the Commissioner of Human Resources, and the Comptroller of the Treasury).

Amendment Effective Date. The revisions set forth herein shall be effective June 30, 2015. All other terms and conditions of this Contract not expressly amended herein shall remain in full force and effect.

IN WITNESS WHEREOF,

VANDERBILT UNIVERSITY, VANDERBILT SCHOOL OF MEDICINE:

Recommended by:

Wayne A. Ray 22 June 2015
SIGNATURE DATE

PRINTED NAME AND TITLE

C. Wright Pinson 6/22/15
SIGNATURE DATE

C. Wright Pinson, MD, MBA
Deputy Vice Chancellor for Health Affairs

DEPARTMENT OF FINANCE AND ADMINISTRATION
DIVISION OF HEALTH CARE FINANCE AND ADMINISTRATION
BUREAU OF TENNCARE:

Larry B. Martin /co 6/29/2015
Larry B. Martin, Commissioner DATE

Reviewed for Signature
Contracts Mgmt

[Signature]
Contract Analyst



CONTRACT

(no cost contract, involving no monetary obligation between the parties, with an individual, business, non-profit, or government entity of another state or country)

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OCR USE - NC			



**CONTRACT
BETWEEN THE STATE OF TENNESSEE,
DEPARTMENT OF FINANCE AND ADMINISTRATION,
DIVISION OF HEALTH CARE FINANCE AND ADMINISTRATION
BUREAU OF TENNCARE
AND
VANDERBILT UNIVERSITY
VANDERBILT SCHOOL OF MEDICINE**

This Contract, by and between the State of Tennessee, Department of Finance and Administration, Division of Health Care Finance and Administration, Bureau of TennCare, hereinafter referred to as the "State" or "TennCare" and Vanderbilt University by and through its Vanderbilt School of Medicine, Department of Preventive Medicine, hereinafter referred to as the "Contractor," is for the provision of studies which perform a quality assurance function for medical care within the State, as further defined in the "SCOPE OF SERVICES."

The Contractor is a Non-Profit Corporation.

Contractor Place of Incorporation or Organization: Nashville, Tennessee

A. SCOPE OF SERVICES:

- A.1. The Contractor shall provide all service and deliverables as required, described, and detailed by this Scope of Services and shall meet all service and delivery timelines specified in the Scope of Services section or elsewhere in this Contract.
- A.2. The Contractor shall conduct quality assurance studies, including, but not limited to, assessment of the effectiveness of policy changes or other programs designed to improve quality or economy of care, identification of populations of children and of persons of other ages at high risk of adverse health outcomes, quantifying the possible unanticipated adverse or beneficial effects of medications and other therapeutic interventions.
- A.3. The Contractor shall:
 - a. provide ad hoc and periodic reports and consultation with Bureau of TennCare staff on quality of care concerns as agreed upon between TennCare and Contractor;
 - b. maintain archived databases to the extent data is used to support findings in a study;
 - c. provide data to third parties only at the request of TennCare and with certification of full HIPAA compliance by such third parties, said certification to be obtained by TennCare, unless otherwise agreed upon by the parties; and
 - d. conduct special quality of care evaluations and studies contingent on available staff resources.
- A.4. The Contractor shall submit all studies to be conducted under this Contract to TennCare for review and approval.
- A.5. The Contractor shall periodically inform TennCare of status of ongoing studies and final reports for completed studies during the term of this contract.
- A.6. The studies and reports conducted pursuant to this Section A, Scope of Services shall be agreed upon by the parties on a case - by - case basis and subject to Contractor's available staff. The Contractor shall submit draft manuscripts to TennCare for review and approval prior to submitting any paper for publication. The parties will agree upon publication rights and copyright ownership for each study on a case-by-case basis. Both parties agree to obtain review and approval from the Institutional Review Board or governmental equivalent as required by law. The Contractor shall have the right to immediately terminate any study if it determines that the health, safety, or



welfare of any human research subject involved in any study is at risk, or the IRB or other applicable review body including governmental agency determines 1) an inappropriate conflict of interest, or 2) fails to approve, suspends or terminates any required approval of a study.

- A.7. TennCare agrees that, as a part of its responsibility as the agency charged with safeguarding the health of residents of Tennessee, it is beneficial to promote studies that evaluate quality of medical care, assess the effectiveness of policy changes or other programs designed to improve quality or economy of care, identify populations of children and of persons of other ages at high risk of adverse health outcomes, conduct interventions in these populations designed to improve adverse outcomes, and to quantify possible unanticipated adverse or beneficial effects of medications and other therapeutic interventions. TennCare agrees that the Contractor shall be allowed to utilize TennCare data to develop and carry out studies for these purposes.
- A.8. TennCare agrees that to assist the Contractor in obtaining the information necessary to conduct such studies, TennCare will make available to the Contractor current enrollment, encounter and provider files of the TennCare program. TennCare warrants that it has complied with the Health Insurance Portability and Accountability Act of 1996 (HIPAA) when providing data, or access to data, to the Contractor.
- A.9. TennCare agrees that when there is necessity for quality assurance to collect and/or inspect health related records, TennCare will assist the Contractor in obtaining permission to collect and/or inspect those health related records under the following conditions:
 - a. Contractor has obtained approval for the study requiring collection and/or inspection of the health related records per Section A.4.;
 - b. Contractor will report to TennCare all information from the records, data and/or studies, as may be required by TennCare, to fulfill its obligations for quality assurance.
- A.10. TennCare shall designate a single contact person within TennCare who will coordinate access to databases by the Contractor, requests for consultation from TennCare, review of Contractor studies, and other contract activities.

B. CONTRACT PERIOD:

This Contract shall be effective for the period beginning September 1, 2014, and ending on August 31, 2019.

C. PAYMENT TERMS AND CONDITIONS:

There shall be no cost to the State for the performance of services under this contract.

D. STANDARD TERMS AND CONDITIONS:

- D.1. Required Approvals. The State is not bound by this Contract until it is signed by the contract parties and approved by appropriate officials in accordance with applicable Tennessee laws and regulations (depending upon the specifics of this contract, said officials may include, but are not limited to, the Commissioner of Finance and Administration, the Commissioner of Human Resources, and the Comptroller of the Treasury).
- D.2. Modification and Amendment. This Contract may be modified only by a written amendment signed by all parties hereto and approved by both the officials who approved the base contract and, depending upon the specifics of the contract as amended, any additional officials required by Tennessee laws and regulations (said officials may include, but are not limited to, the Commissioner of Finance and Administration, the Commissioner of Human Resources, and the Comptroller of the Treasury).



- D.3. Termination for Convenience. The Contract may be terminated by either party by giving written notice to the other, at least thirty (30) days before the effective date of termination. Said termination shall not be deemed a breach of contract. Upon such termination, neither the State nor the Contractor shall have a right to any actual general, special, incidental, consequential, or any other damages whatsoever of any description or amount.
- D.4. Termination for Cause. If the Contractor fails to properly perform its obligations under this Contract in a timely or proper manner, or if the Contractor violates any terms of this Contract, the State shall have the right to immediately terminate the Contract. Notwithstanding the above, the Contractor shall not be relieved of liability to the State for damages sustained by virtue of any breach of this Contract by the Contractor.
- D.5. Subcontracting. The Contractor shall not assign this Contract or enter into a subcontract for any of the services performed under this Contract without obtaining the prior written approval of the State. If such subcontracts are approved by the State, each shall contain, at a minimum, sections of this Contract below pertaining to "Conflicts of Interest," "Nondiscrimination," and "Records" (as identified by the section headings). Notwithstanding any use of approved subcontractors, the Contractor shall be the prime contractor and shall be responsible for all work performed.
- D.6. Conflicts of Interest. The Contractor warrants that no amount shall be paid directly or indirectly to an employee or official of the State of Tennessee as wages, compensation, or gifts in exchange for acting as an officer, agent, employee, subcontractor, or consultant to the Contractor in connection with any work contemplated or performed relative to this Contract.
- D.7. Nondiscrimination. The Contractor hereby agrees, warrants, and assures that no person shall be excluded from participation in, be denied benefits of, or be otherwise subjected to discrimination in the performance of this Contract or in the employment practices of the Contractor on the grounds of handicap or disability, age, race, color, religion, sex, national origin, or any other classification protected by Federal, Tennessee State constitutional, or statutory law. The Contractor shall, upon request, show proof of such nondiscrimination and shall post in conspicuous places, available to all employees and applicants, notices of nondiscrimination.
- D.8. Prohibition of Illegal Immigrants. The requirements of Tennessee Public Chapter No. 878 and Tennessee Executive Order 41, addressing the use of illegal immigrants in the performance of any Contract to supply goods or services to the state of Tennessee, shall be a material provision of this Contract, a breach of which shall be grounds for monetary and other penalties, up to and including termination of this Contract.
- a. The Contractor hereby attests, certifies, warrants, and assures that the Contractor shall not knowingly utilize the services of an illegal immigrant in the performance of this Contract and shall not knowingly utilize the services of any subcontractor who will utilize the services of an illegal immigrant in the performance of this Contract. The Contractor shall reaffirm this attestation, in writing, by submitting to the State a completed and signed copy of the document at Attachment A, hereto, semi-annually during the period of this Contract. Such attestations shall be maintained by the Contractor and made available to state officials upon request.
- b. Prior to the use of any subcontractor in the performance of this Contract, and semi-annually thereafter, during the period of this Contract, the Contractor shall obtain and retain a current, written attestation that the subcontractor shall not knowingly utilize the services of an illegal immigrant to perform work relative to this Contract and shall not knowingly utilize the services of any subcontractor who will utilize the services of an illegal immigrant to perform work relative to this Contract. Attestations obtained from such subcontractors shall be maintained by the Contractor and made available to state officials upon request.



- c. The Contractor shall maintain records for all personnel used in the performance of this Contract. Said records shall be subject to review and random inspection at any reasonable time upon reasonable notice by the State.
 - d. The Contractor understands and agrees that failure to comply with this section will be subject to the sanctions of Tennessee Public Chapter No. 878 and Tennessee Executive Order 41 for acts or omissions occurring after its effective date. This law requires the Commissioner of Finance and Administration to prohibit a contractor from contracting with, or submitting an offer, proposal, or bid to contract with the State of Tennessee to supply goods or services for a period of one year after a contractor is discovered to have knowingly used the services of illegal immigrants during the performance of this Contract.
 - e. For purposes of this Contract, "illegal immigrant" shall be defined as any person who is not either a United States citizen, a Lawful Permanent Resident, or a person whose physical presence in the United States is authorized or allowed by the federal Department of Homeland Security and who, under federal immigration laws and/or regulations, is authorized to be employed in the U.S. or is otherwise authorized to provide services under the Contract.
- D.9. Records. The Contractor shall maintain documentation of services rendered under this Contract. The books, records and documents of the Contractor, insofar as they relate to work performed under this Contract, shall be maintained for a period of three (3) full years from the final date of this Contract and shall be subject to audit, at any reasonable time and upon reasonable notice, by the State, the Comptroller of the Treasury, or their duly appointed representatives.
- D.10. Monitoring. The Contractor's activities conducted and records maintained pursuant to this Contract shall be subject to monitoring and evaluation by the State, the Comptroller of the Treasury, or their duly appointed representatives.
- D.11. Strict Performance. Failure by any party to this Contract to insist in any one or more cases upon the strict performance of any of the terms, covenants, conditions, or provisions of this Contract shall not be construed as a waiver or relinquishment of any such term, covenant, condition, or provision. No term or condition of this Contract shall be held to be waived, modified, or deleted except by a written amendment signed by the parties hereto.
- D.12. Independent Contractor. The parties hereto, in the performance of this Contract, shall not act as employees, partners, joint venturers, or associates of one another. It is expressly acknowledged by the parties hereto that such parties are independent contracting entities and that nothing in this Contract shall be construed to create an employer/employee relationship or to allow either to exercise control or direction over the manner or method by which the other transacts its business affairs or provides its usual services. The employees or agents of one party shall not be deemed or construed to be the employees or agents of the other party for any purpose whatsoever.
- The Contractor, being an independent contractor and not an employee of the State, agrees to carry adequate public liability and other appropriate forms of insurance, including adequate public liability and other appropriate forms of insurance on the Contractor's employees, and to pay all applicable taxes incident to this Contract.
- D.13. State Liability. The State shall have no liability except as specifically provided in this Contract.
- D.14. Force Majeure. The obligations of the parties to this Contract are subject to prevention by causes beyond the parties' control that could not be avoided by the exercise of due care including, but not limited to, natural disasters, riots, wars, epidemics, or any other similar cause.



- D.15. State and Federal Compliance. The Contractor shall comply with all applicable State and Federal laws and regulations in the performance of this Contract.
- D.16. Governing Law. This Contract shall be governed by and construed in accordance with the laws of the State of Tennessee. The Contractor agrees that it will be subject to the exclusive jurisdiction of the courts of the State of Tennessee in actions that may arise under this Contract. The Contractor acknowledges and agrees that any rights or claims against the State of Tennessee or its employees hereunder, and any remedies arising therefrom, shall be subject to and limited to those rights and remedies, if any, available under *Tennessee Code Annotated*, Sections 9-8-101 through 9-8-407.
- D.17. Completeness. This Contract is complete and contains the entire understanding between the parties relating to the subject matter contained herein, including all the terms and conditions of the parties' agreement. This Contract supersedes any and all prior understandings, representations, negotiations, and agreements between the parties relating hereto, whether written or oral.
- D.18. Severability. If any terms and conditions of this Contract are held to be invalid or unenforceable as a matter of law, the other terms and conditions hereof shall not be affected thereby and shall remain in full force and effect. To this end, the terms and conditions of this Contract are declared severable.
- D.19. Headings. Section headings of this Contract are for reference purposes only and shall not be construed as part of this Contract.
- D. 20. HIPAA Compliance. The State and Contractor shall comply with obligations under the Health Insurance Portability and Accountability Act of 1996 (HIPAA), Health Information Technology for Economic and Clinical Health (HITECH) Act and any other relevant laws and regulations regarding privacy (collectively the "Privacy Rules").
- a. Contractor warrants to the State that it is familiar with the requirements of the Privacy Rules, and will comply with all applicable requirements in the course of this Contract.
 - b. Contractor warrants that it will cooperate with the State, including cooperation and coordination with State privacy officials and other compliance officers required by the Privacy Rules, in the course of performance of the Contract so that both parties will be in compliance with the Privacy Rules.
 - c. The State and the Contractor will sign documents, including but not limited to business associate agreements, as required by the Privacy Rules and that are reasonably necessary to keep the State and Contractor in compliance with the Privacy Rules. This provision shall not apply if Information received or delivered by the parties under this Contract is NOT "protected health information" as defined by the Privacy Rules, or if the Privacy Rules permit the parties to receive or deliver such information without entering into a business associate agreement or signing another such document.
 - d. The Contractor will indemnify the State and hold it harmless for any violation by the Contractor or its subcontractors of the Privacy Rules. This includes the costs of responding to a breach of protected health information, the costs of responding to a government enforcement action related to the breach, and any fines, penalties, or damages paid by the State because of the violation.



E. SPECIAL TERMS AND CONDITIONS:

- E.1. Conflicting Terms and Conditions. Should any of these special terms and conditions conflict with any other terms and conditions of this Contract, these special terms and conditions shall control.
- E.2. Communications and Contacts. All instructions, notices, consents, demands, or other communications required or contemplated by this Contract shall be in writing and shall be made by certified, first class mail, return receipt requested and postage prepaid, by overnight courier service with an asset tracking system, or by EMAIL or facsimile transmission with recipient confirmation. Any such communications, regardless of method of transmission, shall be addressed to the respective party at the appropriate mailing address, facsimile number, or EMAIL address as set forth below or to that of such other party or address, as may be hereafter specified by written notice.

The State:

Deputy Commissioner
Department of Finance and Administration
Division of Health Care Finance and Administration
Bureau of TennCare
310 Great Circle Road
Nashville TN 37243
Telephone # (615) 507-6443
FAX # (615) 253-5607

The Contractor:

Vanderbilt University, Office of Grants and Contract Management
3319 West End Avenue, Suite 100
Nashville, TN 37203-6869
Telephone #: 615-322-7401
FAX #: 615-322-7405

All instructions, notices, consents, demands, or other communications shall be considered effectively given upon receipt or recipient confirmation as may be required.

- E.3. Tennessee Department of Revenue Registration. The Contractor shall be registered with the Department of Revenue for the collection of Tennessee sales and use tax. This registration requirement is a material requirement of this Contract.
- E.4. Debarment and Suspension. The Contractor certifies, to the best of its knowledge and belief, that it, its current and future principals, its current and future subcontractors and their principals:
- a. are not presently debarred, suspended, proposed for debarment, declared ineligible, or voluntarily excluded from covered transactions by any federal or state department or agency;
 - b. have not within a three (3) year period preceding this Contract been convicted of, or had a civil judgment rendered against them from commission of fraud, or a criminal offence in connection with obtaining, attempting to obtain, or performing a public (federal, state, or local) transaction or grant under a public transaction; violation of federal or state antitrust statutes or commission of embezzlement, theft, forgery, bribery, falsification, or destruction of records, making false statements, or receiving stolen property;
 - c. are not presently indicted or otherwise criminally or civilly charged by a government entity (federal, state, or local) with commission of any of the offenses detailed in section b. of this certification; and



- d. have not within a three (3) year period preceding this Contract had one or more public transactions (federal, state, or local) terminated for cause or default.

The Contractor shall provide immediate written notice to the State if at any time it learns that there was an earlier failure to disclose information or that due to changed circumstances, its principals or the principals of its subcontractors are excluded or disqualified.

- E.5. Confidentiality of Records. Strict standards of confidentiality of records and information shall be maintained in accordance with applicable state and federal law. All material and information, regardless of form, medium or method of communication, provided to the Contractor by the State or acquired by the Contractor on behalf of the State shall be regarded as confidential information in accordance with the provisions of applicable state and federal law, state and federal rules and regulations, departmental policy, and ethical standards. Such confidential information shall not be disclosed, and all necessary steps shall be taken by the Contractor to safeguard the confidentiality of such material or information in conformance with applicable state and federal law, state and federal rules and regulations, departmental policy, and ethical standards.

The Contractor's obligations under this section do not apply to information in the public domain; entering the public domain but not from a breach by the Contractor of this Contract; previously possessed by the Contractor without written obligations to the State to protect it; acquired by the Contractor without written restrictions against disclosure from a third party which, to the Contractor's knowledge, is free to disclose the information; independently developed by the Contractor without the use of the State's information; or, disclosed by the State to others without restrictions against disclosure. Nothing in this paragraph shall permit Contractor to disclose any information that is confidential under federal or state law or regulations, regardless of whether it has been disclosed or made available to the Contractor due to intentional or negligent actions or inactions of agents of the State or third parties.

It is expressly understood and agreed the obligations set forth in this section shall survive the termination of this Contract.

- E.6. HIPAA and HITECH Compliance. As a party to this Contract, the Contractor hereby acknowledges its designation as a covered entity and/or business associate under the HIPAA regulations and the Omnibus Rule effective September 23, 2013 and agrees to comply with all applicable HIPAA and HITECH (hereinafter "HIPAA/HITECH") regulations. In accordance with HIPAA/HITECH regulations, the Contractor shall, at a minimum:
 - a. Comply with requirements of the Health Insurance Portability and Accountability Act of 1996 and the Health Information Technology for Economic and Clinical Health Act of 2009 (HITECH), including, but not limited to, the transactions and code sets, privacy, security, and identifier regulations, by their designated compliance dates. Compliance includes meeting all required transaction formats and code sets with the specified data sharing agreements required under the regulations;
 - b. Transmit/receive from/to its providers, subcontractors, clearinghouses and TennCare all transactions and code sets required by the HIPAA/HITECH regulations in the appropriate standard formats, utilizing appropriate and adequate safeguards, as specified under the law and as directed by TennCare so long as TennCare direction does not conflict with the law;
 - c. Agree that if it is not in compliance with all applicable standards defined within the transactions and code sets, privacy, security and all subsequent HIPAA/HITECH standards, that it will be in breach of this Contract and will then take all reasonable steps to cure the breach or end the violation as applicable. Since inability to meet the transactions and code sets requirements, as well as the privacy and security requirements can bring basic business practices between TennCare and the Contractor



and between the Contractor and its providers and/or subcontractors to a halt, if for any reason the Contractor cannot meet the requirements of this Section, TennCare may terminate this Contract in accordance with the Business Associate Agreement ancillary to this Contract;

- d. Ensure that Protected Health Information (PHI) exchanged between the Contractor and TennCare is used only for the purposes of treatment, payment, or health care operations and health oversight and its related functions. All PHI not transmitted for these purposes or for purposes allowed under the federal HIPAA/HITECH regulations shall be de-identified to secure and protect the individual enrollee's PHI;
- e. Report to TennCare's Privacy Office immediately upon becoming aware of any use or disclosure of PHI in violation of this Contract by the Contractor, its officers, directors, employees, subcontractors or agents or by a third party to which the Contractor disclosed PHI;
- f. Specify in its agreements with any agent or subcontractor that will have access to PHI that such agent or subcontractor agrees to be bound by the same restrictions, terms and conditions that apply to the Contractor pursuant to this Section;
- g. Make available to TennCare enrollees the right to amend their PHI in accordance with the federal HIPAA regulations;
- h. Make an enrollee's PHI accessible to TennCare immediately upon request by TennCare;
- i. Make its internal policies and procedures, records and other documentation related to the use and disclosure of PHI available to the U.S. Secretary of Health and Human Services for the purposes of determining compliance with the HIPAA/HITECH regulations upon request;
- j. Certify through execution of this Contract that Contractor already follows established policies and procedures to periodically audit adherence to all HIPAA/HITECH regulations, and for which Contractor acknowledges and promises to perform, including but not limited to, the following obligations and actions:
- k. Agree to ensure that any agent, including a subcontractor, to whom it provides PHI that was created, received, maintained, or transmitted on behalf of TennCare agrees to use reasonable and appropriate safeguards to protect the PHI.
- l. If feasible, return or destroy all PHI, in whatever form or medium (including any electronic medium) and all copies of any data or compilations derived from and allowing identification of any individual who is a subject of that PHI upon termination, cancellation, expiration or other conclusion of the Agreement, and in accordance with this Section of this Contract. The Contractor shall complete such return or destruction as promptly as possible, but not later than thirty (30) days after the effective date of the termination, cancellation, expiration or other conclusion of the Agreement. The Contractor shall identify any PHI that cannot feasibly be returned or destroyed. Within such thirty (30) days after the effective date of the termination, cancellation, expiration or other conclusion of the Agreement, the Contractor shall: (1) certify on oath in writing that such return or destruction has been completed; (2) identify any PHI which cannot feasibly be returned or destroyed; and (3) certify that it will only use or disclose such PHI for those purposes that make its return or destruction infeasible;
- m. Implement all appropriate administrative, physical and technical safeguards to prevent the use or disclosure of PHI other than pursuant to the terms and conditions of this Contract and, including, but not limited to, privacy, security and confidentiality requirements in 45 CFR Parts 160 and 164;
- n. Set up appropriate mechanisms to limit use or disclosure of PHI to the minimum necessary to accomplish the intended purpose of the use or disclosure;



- o. Create and implement policies and procedures to address present and future HIPAA/HITECH regulatory requirements as needed, including, but not limited to: use and disclosure of data; de-identification of data; minimum necessary access; accounting of disclosures; enrollee's right to amend, access, request restrictions; notice of privacy practices and right to file a complaint;
- p. Provide an appropriate level of training to its staff and employees regarding HIPAA/HITECH-related policies, procedures, enrollee rights and penalties prior to the HIPAA/HITECH implementation deadlines and at appropriate intervals thereafter;
- q. Track training of Contractor staff and employees and maintain signed acknowledgements by staff and employees of the Contractor's HIPAA/HITECH policies;
- r. Be allowed to use and receive information from TennCare where necessary for the management and administration of this Contract and to carry out business operations where permitted under the regulations;
- s. Be permitted to use and disclose PHI for the Contractor's own legal responsibilities;
- t. Adopt the appropriate procedures and access safeguards to restrict and regulate access to and use by Contractor employees and other persons performing work for the Contractor to have only minimum necessary access to PHI and personally identifiable data within their organization;
- u. Continue to protect and secure PHI AND personally identifiable information relating to enrollees who are deceased;
- v. Be responsible for informing its enrollees of their privacy rights in the manner specified under the regulations;
- w. Make available PHI in accordance with 45 CFR 164.524;
- x. Make available PHI for amendment and incorporate any amendments to PHI in accordance with 45 CFR 164.526; and

The Contractor shall track all security incidents as defined by HIPAA/HITECH, and, as required by the HIPAA/HITECH Reports. The Contractor shall periodically report in summary fashion such security incidents.

Contractor warrants that it is familiar with the requirements of HIPAA and HITECH and their accompanying regulations, and shall comply with all applicable HIPAA and HITECH requirements in the course of this Agreement including but not limited to the following:

- 1. Compliance with the Privacy Rule, Security Rule, Notification Rule;
- 2. The creation of and adherence to sufficient Privacy and Security Safeguards and Policies;
- 3. Timely Reporting of Violations in the Access, Use and Disclosure of PHI; and
- 4. Timely Reporting of Privacy and/or Security Incidents.

Contractor warrants that it shall cooperate with the State, including cooperation and coordination with the State's privacy officials and other compliance officers required by HIPAA and its accompanying regulations, in the course of performance of the Agreement so that both parties will be in compliance with HIPAA.

The State and Contractor shall sign documents, including but not limited to business associate agreements, as required by HIPAA and that are reasonably necessary to keep the State and Contractor in compliance with HIPAA. This provision shall not apply if information received by the State under this Contract is NOT "protected health information" as defined by HIPAA, or if HIPAA permits the State to receive such information without entering into a business associate agreement or signing another such document.



- E.7. TennCare and the Contractor are "information holders" as defined in TCA 47-18-2107. In the event of a breach of the security of Contractor's information system, as defined by TCA 47-18-2107, the Contractor shall indemnify and hold TennCare harmless for expenses and/or damages related to the breach. Such obligations shall include, but not be limited to, mailing notifications to affected enrollees. Substitute notice to written notice, as defined by TCA 47-18-2107(e)(2)and(3), shall only be permitted with TennCare's express written approval. The Contractor shall notify TennCare's Privacy Office immediately upon becoming aware of any security incident that would constitute a "breach of the security of the system" as defined in TCA 47-18-2107.
- E.8. Notification of Breach and Notification of Provisional Breach. The Contractor shall notify TennCare's Privacy Office immediately upon becoming aware of any incident, either confirmed or provisional, that represents or may represent unauthorized access, use or disclosure of encrypted or unencrypted computerized data that materially compromises the security, confidentiality, or integrity of enrollee PHI maintained or held by the Contractor, including any unauthorized acquisition of enrollee PHI by an employee or otherwise authorized user of the Contractor's system. This includes, but is not limited to, loss or suspected loss of remote computing or telework devices such as laptops, PDAs, Blackberrys or other Smartphones, USB drives, thumb drives, flash drives, CDs, and/or disks.
- E.9. Sensitive Data Related to Alcohol and Drug Abuse Enrollee Records for Substance Abuse Treatment. This information has been disclosed to you from records protected by Federal confidentiality rules (42 CFR Part 2). The Federal rules prohibit you from making any further disclosure of this information unless further disclosure is expressly permitted by the written consent of the person to whom it pertains or as otherwise permitted by 42 CFR Part 2. A general authorization for the release of medical or other information is NOT sufficient for this purpose. The Federal rules restrict any use of the information to criminally investigate or prosecute any alcohol or drug abuse patient. 42 C.F.R. § 2.32 (SAMHSA).
- E.10. Federal Tax Information (FTI). Any FTI made available shall be used only for the purpose of carrying out the provisions of this Agreement. Information contained in such material shall be treated as confidential and shall not be divulged or made known in any manner to any person except as may be necessary in the performance of this Agreement. Inspection by or disclosure to anyone other than an officer of employer of the Grantee is strictly prohibited.
- Failure to comply with federal regulations regarding HIPAA/HITECH, SSA, Medicaid, CHIP, SAMHSA, and FTI data may result in criminal and civil fines and penalties.
- E.11. Social Security Administration (SSA) Required Provisions for Data Security. The Contractor shall comply with limitations on use, treatment, and safeguarding of data under the Privacy Act of 1974 (5 U.S.C. 552a), as amended by the Computer Matching and Privacy Protection Act of 1988, related Office of Management and Budget guidelines, the Federal Information Security Management Act of 2002 (44 U.S.C. § 3541, *et seq.*), and related National Institute of Standards and Technology guidelines. In addition, the Contractor shall have in place administrative, physical, and technical safeguards for data.
- a. The Contractor shall not duplicate in a separate file or disseminate, without prior written permission from TennCare, the data governed by the Contract for any purpose other than that set forth in this Contract for the administration of the TennCare program. Should the Contractor propose a redisclosure of said data, the Contractor must specify in writing to TennCare the data the Contractor proposes to redisclose, to whom, and the reasons that justify the redisclosure. TennCare will not give permission for such redisclosure unless the redisclosure is required by law or essential to the administration of the TennCare program.
 - b. The Contractor agrees to abide by all relevant federal laws, restrictions on access, use, and disclosure, and security requirements in this Contract.



- c. Upon request, the Contractor shall provide TennCare a current list of the employees of the Contractor with access to SSA data.
- d. The Contractor shall restrict access to the data obtained from TennCare to only those authorized employees who need such data to perform their official duties in connection with purposes identified in this Contract. The Contractor shall not further duplicate, disseminate, or disclose such data without obtaining TennCare's prior written approval.
- e. The Contractor shall ensure that its employees:
 - (1) properly safeguard PHI/PII furnished by TennCare under this Contract from loss, theft or inadvertent disclosure;
 - (2) understand that they are responsible for safeguarding this information at all times, regardless of whether or not the Contractor employee is at his or her regular duty station;
 - (3) ensure that laptops and other electronic devices/ media containing PHI/PII are encrypted and/or password protected;
 - (4) send emails containing PHI/PII only if encrypted or if to and from addresses that are secure; and,
 - (5) limit disclosure of the information and details relating to a PHI/PII loss only to those with a need to know.

Contractor employees who access, use, or disclose TennCare or TennCare SSA-supplied data in a manner or purpose not authorized by this Contract may be subject to civil and criminal sanctions pursuant to applicable federal statutes.

- f. **Loss or Suspected Loss of Data** – If an employee of the Contractor becomes aware of suspected or actual loss of PHI/PII provided by TennCare to Contractor under this agreement, Contractor must immediately contact TennCare immediately upon becoming aware to report the actual or suspected loss. The Contractor will use the Loss Worksheet located at http://www.tn.gov/tenncare/forms/phi_piiworksheet.pdf to quickly gather and organize information about the incident. The Contractor must provide TennCare with timely updates as any additional information about the loss of PHI/PII becomes available.

If the Contractor experiences a loss or breach of said data, TennCare will determine whether or not notice to individuals whose data has been lost or breached shall be provided and the Contractor shall bear any costs associated with the notice or any mitigation.

- g. TennCare may immediately and unilaterally suspend the data flow under this Contract, or terminate this Contract, if TennCare, in its sole discretion, determines that the Contractor has: (1) made an unauthorized use or disclosure of TennCare SSA-supplied data; or (2) violated or failed to follow the terms and conditions of this Contract.
- h. In order to meet certain requirements set forth in the State's Computer Matching and Privacy Protection Act Agreement (CMPPA) with the SSA, the Parties acknowledge that this Section shall be included in all agreements executed by or on behalf of the State. The Parties further agree that FISMA and NIST do not apply in the context of data use



and disclosure under this Agreement as the Parties shall neither use nor operate a federal information system on behalf of a federal executive agency. Further, NIST is applicable to federal information systems; therefore, although encouraged to do so, the State, its contractors, agents and providers are not required to abide by the NIST guidelines.

i. This Section further carries out Section 1106(a) of the Act (42 U.S.C. 1306), the regulations promulgated pursuant to that section (20 C.F.R. Part 401), the Privacy of 1974 (5 U.S.C. 552a), as amended by the Computer Matching and Privacy Protection Act of 1988, related Office of Management and Budget ("OMB") guidelines, the Federal Information Security Management Act of 2002 ("FISMA") (44 U.S.C. 3541 et seq.), and related National Institute of Standards and Technology ("NIST") guidelines, which provide the requirements that the SSA stipulates that the Contractor must follow with regard to use, treatment, and safeguarding data in the event data is exchanged with a federal information system.

j. Definitions

- (1) "SSA-supplied data" – information, such as an individual's social security number, supplied by the Social Security Administration to TennCare to determine entitlement or eligibility for federally-funded programs (CMPPA between SSA and F&A; IEA between SSA and TennCare).
- (2) "Protected Health Information/Personally Identifiable Information" (PHI/PII) (45 C.F.R. 160.103; OMB Circular M-06-19) – Protected health information means individually identifiable health information that is: (i) Transmitted by electronic media; (ii) Maintained in electronic media; or (iii) Transmitted or maintained in any other form or medium.
- (3) "Individually Identifiable Health Information" – information that is a subset of health information, including demographic information collected from an individual, and: (1) Is created or received by a health care provider, health plan, employer, or health care clearinghouse; and (2) relates to the past, present, or future physical or mental health or condition of an individual; the provision of health care to an individual; or the past, present, or future payment for the provision of health care to an individual; and (i) identifies the individual; or (ii) with respect to which there is a reasonable basis to believe the information can be used to identify the individual.
- (4) "Personally Identifiable Information" – any information about an individual maintained by an agency, including, but not limited to, education, financial transactions, medical history, and criminal or employment history and information which can be used to distinguish or trace an individual's identity, such as their name, Social Security Number, date and place of birth, mother's maiden name, biometric records, including any other personal information which can be linked to an individual.

E.12. Printing Authorization. The Contractor agrees that no publication coming within the jurisdiction of *Tennessee Code Annotated*, Section 12-7-101, et. seq., shall be printed pursuant to this contract unless a printing authorization number has been obtained and affixed as required by *Tennessee Code Annotated*, Section 12-7-103 (d).

E.13. Prohibited Advertising. The Contractor shall not refer to this Contract or the Contractor's relationship with the State hereunder in commercial advertising in such a manner as to state or imply that the Contractor or the Contractor's services are endorsed. It is expressly understood and agreed that the obligations set forth in this section shall survive the termination of this Contract in perpetuity.



E.14. **Lobbying.** The Contractor certifies, to the best of its knowledge and belief, that:

- a. No federally appropriated funds have been paid or will be paid, by or on behalf of the undersigned, to any person for influencing or attempting to influence an officer or employee of an agency, a Member of Congress, an officer or employee of Congress, or an employee of a Member of Congress in connection with the awarding of any Federal contract, the making of any Federal grant, the making of any federal loan, the entering into of any cooperative agreement, and the extension, continuation, renewal, amendment, or modification of any federal contract, grant, loan, or cooperative agreement.
- b. If any funds other than federally appropriated funds have been paid or will be paid to any person for influencing or attempting to influence an officer or employee of any agency, a Member of Congress, an officer or employee of Congress, or an employee of a Member of Congress in connection with this contract, grant, loan, or cooperative agreement, the Contractor shall complete and submit Standard Form-LLL, "Disclosure Form to Report Lobbying," in accordance with its instructions.
- c. The Contractor shall require that the language of this certification be included in the award documents for all sub-awards at all tiers (including subcontracts, sub-grants, and contracts under grants, loans, and cooperative agreements) and that all subrecipients shall certify and disclose accordingly.

This certification is a material representation of fact upon which reliance was placed when this transaction was made or entered into and is a prerequisite for making or entering into this transaction imposed by section 1352, title 31, U.S. Code.

IN WITNESS WHEREOF,

VANDERBILT UNIVERSITY, VANDERBILT SCHOOL OF MEDICINE:

Recommended by:

Wayne A. Ray 17 July 2014
 SIGNATURE DATE

Wayne A. Ray Professor, Health Policy
 PRINTED NAME AND TITLE

8/4/14
 SIGNATURE DATE

Libby D. Salberg
 Director
 Contracts Mgmt.



**DEPARTMENT OF FINANCE AND ADMINISTRATION
DIVISION OF HEALTH CARE FINANCE AND ADMINISTRATION
BUREAU OF TENNCARE:**

Larry B. Martin / CD

8/6/2014

Larry B. Martin, Commissioner

DATE



ATTESTATION RE PERSONNEL USED IN CONTRACT PERFORMANCE

SUBJECT CONTRACT NUMBER:	43119
CONTRACTOR LEGAL ENTITY NAME:	VANDERBILT UNIVERSITY
FEDERAL EMPLOYER IDENTIFICATION NUMBER: (or Social Security Number)	

The Contractor, identified above, does hereby attest, certify, warrant, and assure that the Contractor shall not knowingly utilize the services of an illegal immigrant in the performance of this Contract and shall not knowingly utilize the services of any subcontractor who will utilize the services of an illegal immigrant in the performance of this Contract.

CONTRACTOR SIGNATURE

NOTICE: This attestation MUST be signed by an individual empowered to contractually bind the Contractor. If said individual is not the chief executive or president, this document shall attach evidence showing the individual's authority to contractually bind the Contractor.

Libby D. Salberg

Director
Contracts Mgmt
PRINTED NAME AND TITLE OF SIGNATORY

DATE OF ATTESTATION