Office of Informatics and Analytics

Tennessee Department of Health Institutional Review Board Application Submission Guidelines

Thank you for your interest in Tennessee Department of Health Institutional Review Board. Within this document you will find information to help you submit a successful application and navigate you through the iMedRIS system.

Contents

IRB General Information

The Tennessee Department of Health (TDH) Institutional Review Board (IRB) is a committee that reviews research protocols to assure ethical treatment of human participants involved. The IRB facilitates social, behavioral, and educational through research related to health. The TDH IRB maintains Federal wide Assurance (FWA) status with Office for Human Research Protections (OHRP) and functions under the auspices of the Code of Federal Regulations Title 45: Public Welfare, part 46 (45 CFR 46), also known as the Common Rule. The IRB administrative staff is housed within the Data Governance unit of the Office of Informatics and Analytics.

Tennessee Department of Health IRB reviews human subject research projects that may use state and public health data collected and/or maintained by TDH. During the review, members of the IRB assess research proposals to assure overall respect for persons, beneficence, and justice and to minimize privacy and confidentiality risks for individuals involved in research. IRB reviews are guided by the Common Rule and the HIPAA Privacy Rule. Regulations are observed and guided by use of an TDH institutionally approved data use agreement.

Who Should Submit an IRB Application?
IRB Approval is required for all research involving human subjects when:

- The research is conducted by or sponsored by TDH;
- The research subjects are TDH employees;
- The research requires access to data held by TDH;
- Research projects involving human subjects must obtain approval prior to the initiation of the proposed research;
- Planned or Unplanned changes or amendments to previously approved research protocol must obtain approval prior to initiation.

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IRB Membership:
IRB membership requirements are specified in the Common Rule. Requirements include:

- Individuals who demonstrate they are professionally conversant with research and scientific methods and have the capacity to competently review research projects that are typically submitted to the committee.
- At least 5 members that maintain racial, ethnic, and gender diversity.
- One member without TDH institutional affiliation.
- Members represent scientific, non-scientific, and community.
- Members represent a diversity of disciplines.

Current Meetings

Meetings are held the last Wednesday of every month at 2 P.M.

Contact Information

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TDH IRB Related Links

- iMedRIS https://tdh.imedris.net
- CITI Training https://about.citiprogram.org

TDH IRB Related Resources and Files

- Research Determination Worksheet
- Frequently Asked Questions
- Tips for successful IRB submission
- Decision charts about research
- https://www.hhs.gov/ohrp/regulations-and-policy/decision-charts/index.html#c1
- https://www.hhs.gov/ohrp
- https://www.hhs.gov/ohrp/sachrp-committee/index.html

Tennessee Department of Health
Institutional Review Board
Application Submission Guidelines

Determination of Research Checklist

Section A - General Guidelines and Definitions
Section B – Human Subjects Determination Questions
Section C – Research and Institutional Review Board Review Determination Questions
Section D – Non-Research Examples
Section E – Resources/Reference Sites

Section A – General Guidelines and Definitions

If the definitions of research and human subjects are appliable to your project, then an Institutional Review Board (IRB) submission will be necessary. This checklist is designed as a guide to assist in deciding if an IRB Initial Application should be submitted for review. If you have additional questions or would like additional information, please contact the Tennessee Department of Health Institutional Review Board at 615-257-2557 or TDH-IRB.Health@tn.gov

Section B – Human Subjects Determination Questions

Does the activity involve human subjects? (45 CFR 46.102(f)) ***Human Subjects*** *means a living individual about whom an investigator (1) Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or bio-specimens; or (2) Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable bio-specimens.*			
	Yes	No	Not Sure
1. Is the data being obtained about living individuals?			
2. Is the data collected through intervention(s) or interactions with individuals?			
3. Does the data to be used contain identifiable private information?			

Identifiable private information *is private information for which the identity of the subject is or may readily be ascertained by the investigator or associated with the information.*			
• If ANY answer in Section B is "YES", continue to Section C. • If ANY answer in Section B is "Not Sure", continue to Section C. • If ALL answers in Section B are "NO", the activity does not involve human research, IRB review is not required. A Data Request may be made at: https://www.surveygizmo.com/s3/5819792/TDH-Data-Request- Form			

Section C – Research and IRB Review Determination Questions

Is this activity research? ***Research*** *means a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. Activities that meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program that is considered research for other purposes. For example, some demonstration and service programs may include research activities.*			
	Yes	No	Not Sure
1. Is the activity a systematic investigation, including research development, testing, and evaluation? ***Systematic Investigation*** *means an activity that includes research development (research question), testing, evaluation or data collection to answer the research question.*			
2. Is the activity designed to generate or contribute to <u>generalizable knowledge?</u> ***Generalizable Knowledge*** *is information that expands the knowledge base of a scientific discipline or information that can be applied beyond the situation studied.*			
3. Does the interview or survey focus on experiences, opinions, and sensitive information about people?			
4. Is the activity a class related project that will lead to publication or poster presentation?			

- If ANY answer in Section B is “YES” and ANY answer in Section C is “YES” an IRB Initial Application is required. This may be completed at https://www.tn.gov/health/health-program-areas/tennessee-department-ofhealth-institutional- review-board
- If ALL answers in section C are “NO”, IRB Review is NOT required. A data request may be made at https://www.surveygizmo.com/s3/5819792/TDH-Data-Request-Form
- If ANY answer in Section C is “NOT SURE” contact TDH-IRB.Heath@tn.gov

Section D: Examples of Non-Research Activities

https://www.hhs.gov/ohrp/education-and-outreach/revised-common-rule/revised-common-rule- resources/index.html

Public Health surveillance activities, including the collection and testing of information or biospecimens conducted, supported, requested, ordered, required, or authorized by a public health authority. Such activities are limited to those necessary to allow a public health authority to identify, monitor, assess, or investigate potential public health signals, onsets of disease outbreaks, or conditions of public health importance (including trends, signals, risk factors, patterns in diseases, or increases in injuries from using consumer products). Such activities include those associated with providing timely situational awareness and priority setting during the course of an event or crisis that threatens public health (including natural or man- made disasters). Public health surveillance activities are deemed not to research.	Scholarly and journalistic activities (e.g. oral history, journalism, biography, literally criticism, legal research, and historical scholarship), including the collection and use of information that focus directly on the specific individual about who the information is collected.

Course related activities/class assignments (may not be research where the data collected, and findings are not intended for use outside of the classroom).	Publically available data.
Research involving cadavers, except genetic studies providing private or medical information about relatives.	Coded specimen and/or data sets that were not collected for the currently proposed projects do not need IRB review as long as the investigator receiving the data/specimens cannot link the data/specimens back to the individual subject.
Biography or oral history.	Case histories.
Information gathering interviews e.g. What do you think about the new policy?	Data collection for internal purposes.

This checklist is a guide to assist researchers in determining if an activity should be reviewed by the IRB. The checklist is not an IRB determination. Decisions on whether IRB review is required for activities can only be made by the TDH IRB. For an official determination, please submit the TDH IRB application.

Section E: Resource/Reference Sites

Common Rule https://www.hhs.gov/ohrp/education-and-outreach/revised-common-rule/revised-common-rule-resources/index.html

Federal Policy for Protection of Human Subjects (Common Rule) https://www.ecfr.gov/cgi-bin/retrieveECFR?gp=&SID=83cd09e1c0f5c6937cd9d7513160fc3f&pitd=20180719&n=pt45.1.46&r=PART&ty=HTML

Office of Human Research Protection https://www.hhs.gov/ohrp

Office of Human Research Protection https://ori.hhs.gov/content/chapter-3-The-Protection-of-Human-Subjects-Definitions

Tennessee Department of Health IRB Resource Folder https://www.tn.gov/health/health-program-areas/tennessee--department-of-health-institutional-review-board.html

IRB Terminology

Continuous Quality Improvement (CQI)*:* A methodology employed by the IRB Teams, when needed, to improve existing processes by identifying the root cause of a problem, developing and implementing an action plan, and evaluating the outcome to assure problem resolution.

IRB Cooperative Agreement: A joint agreement, in which multiple institutions agree to participate in a research project while relying on the review of one Primary IRB's review and approval in order to avoid duplication of effort. The primary IRB responsibilities may be rotated among the participating intuitions.

Coordinating Center: An institution, department, or center which agrees to be responsible for the conduct, administrative, or coordinating function of a multi-center IRB research project.

Covered Entity: Covered entity means: (1) A health plan. (2) A health care clearinghouse. (3) A health care provider who transmits any health information in electronic form in connection with a transaction covered by this subchapter. 45 CFR §160.103.

Data Use Agreement (DUA): A TDH promulgated agreement document between TDH and data user that specifies the conditions allowed with use of data provided for research or for a study.

De-Identified Data Set: A data where all eighteen (18) identifiers have been removed. The eighteen (18) identifiers include:

1. Names;
2. Any geographic subdivision smaller than a State, including street address, city, county, precinct, zip code and their equivalent geocodes, except for the initial three digits of a zip code'
3. All elements of dates (except year) for dates directly related to an individual, including birth date, admission date, discharge date, date of death; and all ages over 89 and all elements of dates (including year) indicative of such age, except that such ages and elements may be aggregated into a single category of age 90 or older;
4. Telephone numbers;
5. Fax numbers;
6. Electronic mail addresses;
7. Social security numbers;
8. Medical record numbers;
9. Health plan beneficiary numbers;
10. Account numbers;
11. Certificate/license numbers;
12. Vehicle identifiers and serial numbers, including license plate numbers;
13. Device identifiers and serial numbers;
14. Web Universal Resource Locators (URLs);
15. Internet Protocol (IP) address numbers;

16. Biometric identifiers, including finger and voice prints;
17. Full face photographic images and any comparable images; and
18. Any other unique identifying number, characteristic, or code; and except as permitted with respect to a re-identification code.

Department of Health and Human Services (DHHS): The United States Government agency responsible for protecting the health of all Americans and providing essential human services, especially for those who are least able to help themselves.

Directed Audit: These audits are conducted by the IRB Process Improvement Team to assess the Investigator's compliance with federal regulations, state and local laws, and IRB policies and procedures. These audits of IRB approved research studies are in response to identified concerns(s). Concerns may be identified by the IRB Committee, an external source, or an internal source.

Exempt Review: Studies determined by the IRB to meet the exempt criteria as defined by the Federal regulations. The criteria for an exempt determination may be found at: https://www.ecfr.gov/cgi-bin/retrieveECFR?gp=&SID=83cd09e1c0f5c6937cd9d7513160fc3f&pitd=20180719&n=pt45.1.46&r=PART&ty=HTML

Expediated Review: Studies determined by the IRB to meet the expedited criteria as defined by the Federal regulations. The criteria for expedited review may be found at: https://www.ecfr.gov/cgi-bin/retrieveECFR?gp=&SID=83cd09e1c0f5c6937cd9d7513160fc3f&pitd=20180719&n=pt45.1.46&r=PART&ty=HTML

Expired Study: When continuing review of the research does not occur prior to the end of the approval period specified by the IRB, IRB approval expires automatically. The study expires on the data specified in the Data Use Agreement (DUA). No study activities can occur after the expiration date.

Finding of Non-Compliance: A proven or obvious incident of non-compliance with policies, rules and regulations or laws.

Food and Drug Administration (FDA): The office responsible for implementing regulations governing the use of investigational drugs, biologics, devices and radiological procedures including radioactive drugs in clinical investigations with humans.

Greater than Minimal Risk: Where the research involves greater than minimal risk to subjects, the mechanism of obtaining local research context differs depending on whether the local research context involves intervention or interaction with subjects and whether the principal risk associated with the local research context is limited to the potential harm resulting from a breach of confidentiality.

Human Subject*:* A living individual about whom an investigator (1) Obtains information or bio-specimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or bio-specimens; or (2) Obtains, uses, studies, analyzes, or generates identifiable private

information or identifiable bio-specimens.

Human Subjects Research: Any research that involves humans as subjects and any clinical investigation.

Independent Ethics Committee (IEC): A specifically constituted review body whose responsibility is to ensure the protection of the rights, welfare and safety of research participants. An IEC shares the same composition and operations as an Institutional Review Board.

Institutional Review Board (IRB): A specifically constituted review body established or designated by an entity to protect the rights and welfare of human subjects recruited to participate in biomedical or behavioral/social science research.

Interaction: Includes communication or interpersonal contact with a subject or their private identifiable information.

Intervention: Includes both physical procedures by which data are gathered (e.g., venipuncture) and manipulates the subjects' environment that are performed for research purposes.

Investigational Agents: A pharmaceutical form of an active ingredient or placebo being tested or used as a reference in a clinical trial. This includes products with a marketing authorization when used or assembled (formulated or packaged) in a way different from the approved form, products used for an unapproved indication, or products used to gain further information about an approved use.

Investigational Device: Any healthcare product that does not achieve its primary intended purpose by chemical action or by being metabolized. A medical device that is the subject of a clinical study designed to evaluate the effectiveness and/or safety of the device. Investigational use also includes clinical evaluation of certain modifications or new intended uses of legally marketed devices.

Investigational Device Exemption: An FDA approved investigational device exemption (IDE) permits a device that otherwise would be required to comply with a performance standard or to have pre-market approval to be shipped lawfully for the purpose of conducting investigations of that device.

Investigational Drugs/Investigational Biologics (Test Articles): A new drug or biologic that is used in a clinical investigation. The term investigational biologic also includes a biological product that is used in vitro for diagnostic purposes. Investigational drugs or biologics may include: a) Products that are not generally recognized as being safe and effective for any use under the conditions prescribed, recommended, or suggested by the FDA; or b) Products approved by the FDA as safe and effective for specific indications that are being studies for new indications (or doses, strengths, or frequency).

IRB of Record: An IRB is considered the IRB of record when it assumes IRB primary responsibilities for another institution and is designated to do so through an approved Assurance with OHRP.

Memorandum of Understanding is required, designating the relationship for the TDH IRB to serve as the IRB of Record.

Limited Data Set: A limited data set is protected health information from which certain specified direct identifiers of individuals and their relatives, household members, and employers have been removed. A limited data set may be used and disclosed for research, health care operations, and public health purposes, provided the recipient enters into a data use agreement promising specified safeguards for the protected health information within the limited data set.

Local Research Context: Knowledge of the institution and community environment in which human subjects research will be conducted.

Memorandum of Understanding (MOU): A formal agreement between TDH and another institution that identifies the TDH Institutional Review Board as the IRB of record for that institution. (MOU - A document that describes the broad outlines of an agreement that two or more parties have reached. MOUs communicate the mutually accepted expectations of the parties involved in a negotiation.)

Minimal Risk: The probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examination or test.

Non-Compliance: Failure to follow the determinations or requirements of the TDH IRB. An action or omission taken by an Investigator that any other reasonable Investigator would have reasonably and clearly seen as compromising the rights and welfare of a participant.

Non-Human Subjects Research: Any activity determined by the IRB to not represent Human Subjects Research.

Non-Significant Risk (NSR) Device Study: A study of a device that does not meet the definitions for a significant risk device and does not present a potential for serious risk to the health, safety, or welfare of participants.

Not Less Than Once Per Year: All research proposal must receive IRB continuing review at a minimum of once every 365 days, per Federal regulations. Categories within Exempt may need annual review.

Office for Human Research Protections (OHRP): The office under the Department of Health and Human Services responsible for implanting DHHS regulations (45 CFR 46) governing biomedical and behavioral/social science research involving human subjects.

Other Participating Institutions (OPI): A collaborating institution that has chosen to participate in a research study under an Agreement that will rely on the Primary Reviewing Institution as the IRB of records in order to avoid duplication of effort.

Performance Site: A site where research is performed.

Performance Sites(s) Engaged in Research: A performance site becomes “engaged” in human

subjects research when its employees or agents 1) intervene or interact with living individuals for research purposes, or 2) obtain individually identifiable private information for research purposes. Further, a performance site is considered to be "engaged" in human subjects research when it receives a direct Federal award to support the research.

Performance Sites(s) Not Engaged in Research: A performance site is "not engaged" in human subjects research it its employees or agents do not 1) intervention or interact with living individuals for research purposes, or 2) obtain individually identifiable private information for research purposes. If a TDH investigator or staff including site personnel contracted by TDH, perform all research related activities as well as screening, recruiting, or consenting at the performance site, the performance site would be considered "not engaged" in research, unless the non-TDH performance site releases identifiable private information to TDH researchers without first obtaining participant's permission.

Periodic Compliance Review: Random assessments of the internal IRB department and external departments or sites involved in the conduct of human subjects research conducted by the IRB Process Improvement Staff. These reviews are used to evaluate proper execution and accurate documentation of an IRB approved research project. Internal compliance reviews monitor the adherence to federal regulations, state and local law, and IRB policies and procedures as well as accurate documentation in the IRB database. External compliance reviews monitor the adherence to federal regulations, state and local law, TDH IRB procedures, adhere to the study protocol, accurate documentation and reporting of study related activities, and evaluation/observation of the informed consent process.

Primary Reviewing Institution (PRI): The institution serving as the IRB of record in a Reliance Agreement or Memorandum of Understanding with TDH IRB.

Private Information: Includes information about behavior that occurs in a setting in which an individual can reasonably expect that no observation or recording is taking place. It includes information, which has been provided for specific purposes by an individual, and the individual can reasonably expect will not be made public (e.g., a medical records). Private information must be individually identifiable in order to be considered information to constitute research involving human subjects. This may include identifiable private information obtained from a primary subject about a third party.

Prospective: Research utilizing human participants' specimens/data that will be collected after the research is approved by the IRB.

Quality Assurance Reviews: Quality Assurance reviews are performed by the IRB Teams to verify that the IRB electronic database is consistent with IRB procedures.

Related: An event is "related" if it is likely to have been caused by the research procedures.

Reliance Agreement (RA): An agreement between TDH IRB and another institution that specifies the lead IRB for approved research/studies. This agreement outlines the responsibilities of TDH IRB and another IRB in relation to the research/study approved.

Repository: A storage site or mechanism by which identifiable human tissue, blood, genetic material or data are stored or archived for research by multiple Investigators or multiple research projects.

Research: A systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. Activities that meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program that is considered research for other purposes. For example, some demonstration and service programs may include research activities.

Retrospective Research: Research utilizing human participants' specimens/data that were previously collected (e.g., on the shelf) before the research was approved by the IRB.

Risk-Potential Benefit Profile: An evaluation of the risks and potential benefits that have occurred during the course of the study.

Serious: An event is "serious" if it involved a harm to one or more persons (who may or may not be participants) or required intervention to prevent one or more persons from experiencing serious harm.

Serious Adverse Event: As defined by the FDA(https://www.fda.gov/safety/reporting-serious-problems-fda/what-serious-adverse-event), any undesirable expertise associated with the project. Any of the following are considered serious and reportable:

1. Death;
2. Life-Threatening – substantial risk of dying at the time of the event;
3. Hospitalization – initial or prolonged hospitalization as a result of the event and emergency room visit that do not result in admission to the hospital should be evaluated for one of the other serious outcomes (e.g., life-threatening; required intervention to prevent permanent impairment or damage; or other serious medically important event).
4. Disability or Permanent Damage – substantial disruption of a person's ability to conduct normal life functions;
5. Congenital Anomaly/Birth Defection – exposure to a product prior to conception or during pregnancy may have resulted in an adverse outcome in the child.
6. Required Intervention to Prevent Permanent Impairment or Damage – medical or surgical intervention was necessary to preclude permanent impairment of a body function, or prevent permanent damage to a body structure, either situation suspected to be due to the use of a medical product;
7. Other Serious Events – if the event does not fit the other outcomes but may jeopardize the patient.

Significant Risk (SR) Device Study: A study of a device that presents a potential for serious risk to health, safety, or welfare of a participant and 1) is intended as an implant; 2) is used in supporting or sustaining human life; or otherwise prevents impairment of human health; 3) is of substantial importance in diagnosing, curing, mitigating or treating otherwise presents a potential for serious risk to the health, safety, or welfare of a participant.

Sponsor-Imposed Suspension: A determination from the sponsor of the study to place specific research activities on hold. This determination may be made for interim data analysis; inadequate drug availability; response to a Data and Safety monitoring Board report/recommendations; or a preplanned stopping point.

Standard Review: Studies reviewed by the full, convened IRB Committee with a recorded vote and corresponding minutes to document the discussion.

Suspension for Cause: An action initiated by the IRB to stop temporarily some or all research procedures pending future action by the IRB or by the Investigator or his/her stud personnel.

Tennessee Department of Health (TDH): The State of Tennessee government's agency to promote, protect, and improve the health of persons living in, working in, or visiting the State of Tennessee.

Termination for Cause: An action initiated by the IRB to stop permanently some or all research procedures proposed in an approved study as related to some adverse unanticipated causal factor(s).

Test Article: Any drug (including a biological product for human use), medical device for human use, human use, human food additive, color additive, electronic product, or any other article subject to FDA regulation.

Treatment of IDE: A mechanism through the FDA for providing eligible participants with investigational devices for the treatment of serious or life-threatening illness for which there are no satisfactory alternative.

Unanticipated: An event is "unanticipated" when it was unforeseeable at the time of its occurrence. The word unanticipated, is not a synonym for unexpected. A research protocol can monitor for an unexpected event but cannot monitor for an unforeseen event. All unanticipated events are unexpected, but not vice versa.

Unanticipated Adverse Device Effect: Any serious adverse effect on health or safety or any life-threatening problem or death cause by, or associated with, a device, if that effect, problem, or death was not previously identified in nature, severity, or degree of incidence in the investigational plan or application (including a supplementary plan or application), or any other unanticipated serious problems to participants or other associated with a device that relates to the rights, safety, or welfare of participants.

Unanticipated Problem Involving Risks to Participants or Others: Any event that was 1) unanticipated, 2) serious, and 3) related.

Unexpected: An event is "unexpected" when it is specifically, nature, severity or incidence are not accurately reflected in the information previously reviewed and approved by the IRB.

Unexpected Adverse Event: Any adverse event, which is not consistent with the current Investigator

Brochure; or , if an Investigator Brochure is not required or available, the specificity or severity of what is not consistent with the risk information described in the general investigational plan or elsewhere in the current approved application. For example, under this definition, hepatic necrosis would be unexpected (by virtue of greater severity) if the Investigator Brochure only listed cerebral vascular accident. Clarification Note: "Unexpected," as used in this definition refers to an adverse event that has not been previously observed (e.g., included in the investigator brochure) rather than from perspective of such experience not being anticipated from the pharmacological properties of the pharmaceutical product and not listed in the Investigator's Brochures.

Whistleblower: An individual who reports sensitive information to the TDH IRB regarding potential non-compliance issues or research activities that have potentially placed participants or others at increased risks in relationship to the conduct of the research.

Tennessee Department of Health Data Fees

The Tennessee Department of Health will make available record level or individual level data for approved data requesters subject to the fees described below.

Vital Statistics Data Fees

Vital Statistics data are regulated by Rules of Tennessee Department of Health Chapter 1200-07-01. Requests may be for selected variables from the entire catalogs of the vital statistics files – birth, fetal death, death, linked infant death, marriage, or divorce – or for a limited dataset with pre-selected variables. File options include:

Vital Statistics File	Available Variables
Tennessee Death File	All record-level data elements or user-selected fields
Tennessee Death Roster File	Limited dataset with pre-selected fields recommended for records auditing purposes
Tennessee Fact of Death Report	Limited dataset with pre-selected fields recommended for records auditing purposes; individual records included with restriction to TDH data linkage
Tennessee Birth File	All record-level data elements or user-selected fields
Tennessee Birth Roster File	Limited dataset with pre-selected fields recommended for records auditing purposes
Tennessee Fetal Death File	All record-level data elements or user-selected fields
Tennessee Marriage File	All record-level data elements or user-selected fields
Tennessee Divorce File	All record-level data elements or user-selected fields

Data and data processing fees are as follows:

Data System	Data Type	Materials Fees (per data year)	***Plus***, Processing Fee
DEATH	Death File	$75	$50 per hour staff time (2-hour minimum)
	Death Roster File	$50	
	Fact of Death Report	$50	
BIRTH	Birth File	$150	
	Birth Roster File	$75	
FETAL DEATH	Fetal Death File	$75	
MARRIAGE	Marriage File	$75	
DIVORCE	Divorce File	$75	

Hospital Discharge Data System Data Fees

Hospital Discharge Data System data are regulated by Rules of Tennessee Department of Health Chapter 1200-07-03. Data fees are as follows:

Data System	Materials Fees (per data quarter ¼ of calendar year)
Record Level Data	$300
Inpatient Record Level Data	$300
Outpatient Record Level data	$300

Ambulatory Surgical Treatment Center (ASTC) Data System & Outpatient Diagnostic Center (ODC) Data System Data Fees

ASTC and ODC Data System data are regulated by Rules of Tennessee Department of Health Chapter 1200-07-04. Data fees are as follows:

Data System	Materials Fees (per data quarter ¼ of calendar year)
Ambulatory Surgical Treatment Centers	$250
Outpatient Diagnostic Centers	$250

IRB Frequently Asked Questions

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1. How do I know if I need an IRB?

Answer: If your project meets the definition of Human subject and Research, then an IRB review is required. These definitions are:

Human Subject - means a living individual about whom an investigator (1) Obtains information or bio-specimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or bio-specimens; or (2) Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable bio-specimens.

Research - means a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge.

If both research and human subject criteria are met, then the study requires review by the TDH IRB.

2. Where and how do I begin to make an IRB submission?

Answer: https://tdh.imedris.net

3. May I start my research before the IRB review and decision is complete?

Answer: No activities may be initiated prior to the IRB review determination and approval of a Data Use Agreement (DUA) required for use of TDH data. An Outcome Letter will be available following the review along with an approved DUA – research may then begin.

4. How long will it take to complete the IRB review?

Answer: A completed IRB application is submitted for pre-review and through an iterative process questions, clarifications and modifications are included in the review process. Once the study materials have been completed for the submission the study is referred to the appropriate reviewing body. This is dependent upon the review categorical classification for IRB Studies and reviewers may be an Administrative/Appointed IRB individual, IRB Subcommittee, or the Full IRB Committee. The Full IRB Committee is convened monthly. Since this is an iterative process, the length of time for approval varies based upon the number of rounds (times study is sent back to Principal Investigator for clarifications, corrections, and/or modifications) prior to review.

5. What does the IRB review process entail?

Answer: Once an application is submitted the IRB staff pre-reviews and communicates with the study personnel regarding additional materials/clarifications or questions regarding the study. When this process is completed the Data Stewards reviews data request and either recommends or does not recommend requested data be used for the proposed study. The Data Steward may need additional information to complete their review and will request responses from the study personnel. Once these steps are completed, the submission will either be referred for the IRB review. Reviewing individuals and committees have two (2) weeks to complete their review after receipt of the study materials.

6. How long will my IRB approval last?

Answer: IRB approval is for a 12-month period from the original approval date. A continuing review submission application should be submitted at least 30 days prior to the original study expiration date. If the continuation is approved is granted on the submitted application for continuation it is for a 12-month period.

7. What if my study changes after my approval?

Answer: To submit changes to your study (including adding procedures, research personnel, or documentation) log into iMedRIS and submit an “Amendments” form. This form gives you the opportunity to modify your original application and submit new documentation to the IRB for review and approval. These changes cannot be implemented prior to the approval of the submission.

8. What training is required by the IRB?

Answer: All study staff are required to have CITI training. A basic course in biomedical research, social/behavioral research, or research with records of lab specimens only must be completed with a score of 80% or above on each module. CITI provides a report (modules listed) of completion which must be submitted with the IRB study application. CITI training may be accessed at https://www.citiprogram.org

A Few Tips for Successful TDH IRB Applications

1. Read and follow all directions. Review prior to submission to ensure everything is completed and consistent.

2. If you have an IRB at your resident (employer/academic home) institution, an IRB determination letter is required.

3. Make sure all your processes are clearly stated. Have someone outside your field of study review your application and materials to confirm it can be understood and is clearly written.

4. Ensure all study personnel have current CITI training (within 3 years), in one of the following: 1) Social Behavioral; 2) Biomedical; or 3) Research with Specimens or Data ONLY. CITI training may be accessed at http://www.citiprogram.org.

5. Make sure your application has all the needed signatures or it will be returned.

6. Make sure all your surveys or questionnaires are with the application.

7. Make sure your numbers (i.e., sample size), compensation, time commitment, and protocols are consistent across all the documents in the application.

8. Explain any study jargon or acronyms used in the application and documents. IRB reviewers include non-scientific members, and everyone should be able to understand your application to avoid unnecessary delays in the approval process.

9. If you are using ads or flyers for recruitment, make sure they contain all of the following: individuals are being asked to participate in research, the name and institution of the researcher, purpose of the research, inclusion or exclusion criteria, brief statement of procedures, time commitment, compensation, location of research and contact number, or UCCS email. Do not emphasize (bold, underline, etc.) any financial benefit as incentives for participation.

10. State risks and benefits to the participants clearly and completely. Do not understate the risks.

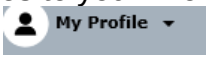
11. If you need a letter(s) of access to a special population or data sources outside Tennessee Department of Health make sure approval for use is documented and is submitted with the application. If documentation is not included, it will be requested, and your approval may be delayed.

12. Make sure all the elements of consent/assent document are included and clear. Ensure all consent/assent documents are written at the 8th grade reading level.

13. State whether you will be requesting a waiver of consent/assent. Clearly state the reason(s) for requesting a waiver.

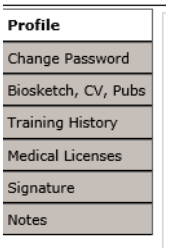
IRB Initial Application Process

Go to : https://tdh.imedris.net and Request new Account or log into the system.

1. The first time you log in or when there are changes to your information select the *My Profile* button on the top right-hand side of the screen. 

2. From the My Profile drop down menu, select *My Account*. 

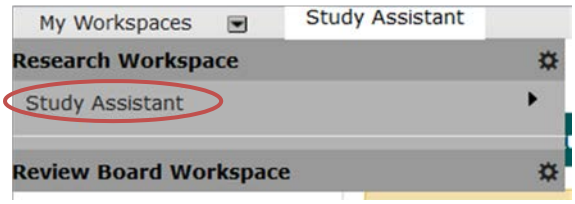
3. On the left-hand side of the screen this list will appear.



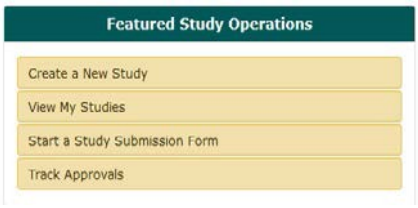
Under *Profile*, you will complete the mailing address and physical address. Under *Change Password*, you will change your password here.
Under *Biosketch, CV, Pubs* you must upload your CV or Biosketch here. Under *Training History*, you will upload CITI trainings/transcripts.
Under *Medical Licenses*, you will upload the appropriate license. Under *Signature*, you will upload your electronic signature.
Under *Notes*, you may use this as you desire.

4. After your account is established and you are logged into the system go to *My Workplaces.*

5. The drop-down arrow will provide two areas in bold print *Research Workspace* and *Review Board Workspace*. You will not have access to the Review Board Workspace; however, it will show in this area. Select *Study Assistant.*

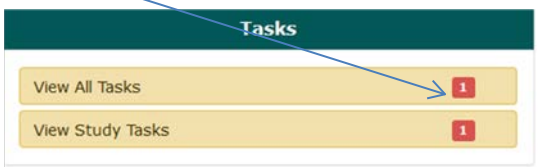


6. This will display your work/home screen. There are five sections on this screen. The first two are *Featured Study Operations* and *Tasks.*



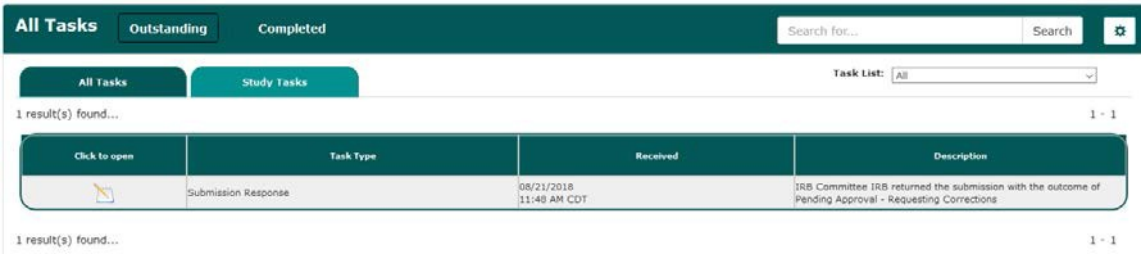
Featured Study Operations allows you to create a new study. The other three options allow you to view all your studies; start a submission form (one that is already listed in your studies, and track approvals. Each of these last three options will take you to the last section on this work/home screen.

The *Tasks* section will identify any items that the PI needs to address. For example, if the submission has been sent back for additional information, etc. The number of task due will show on the right in red.



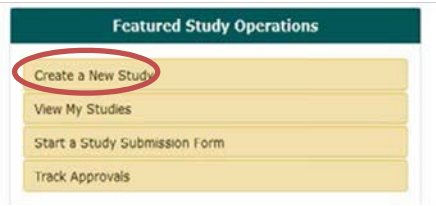
The third section on the work/home screen is the *Study Assistant.* The *Find a Study* button allows you to look for a specific study by name or number.

The fourth section of the work/home is *All Tasks* this identifies the details of required tasks. This should reflect the same as the Tasks area discussed above.



The last section *IRB Studies* will list all the studies associated with the user.

7. To create a new study select *Create a New Study* on the Featured Study Operations section.



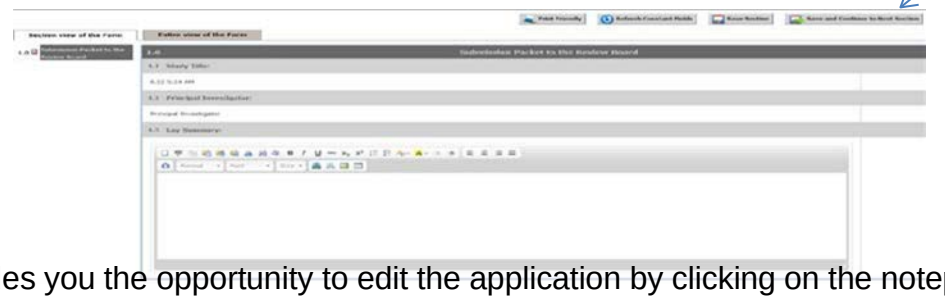
8. This begins the initial application process. After each page you will select the *Save and Continue to the Next Section* button.

During the process, you may stop and return later by selecting the Save Section button.

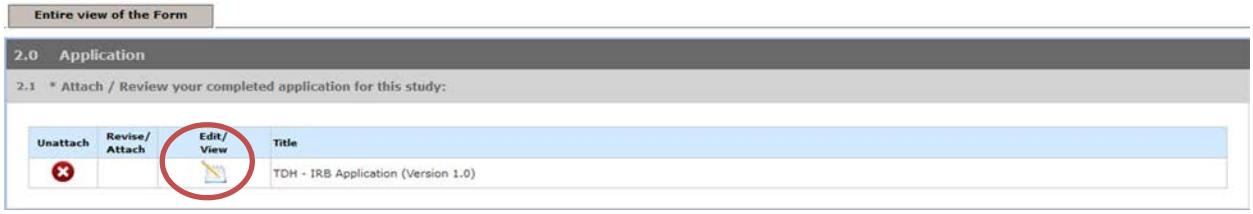
The Section view of the Application will identify each section that has been completed and allows you to return to a specific section by selecting it.

Continue to complete the application sections. The final section is 14.4 and is required. Select the Save and Continue to Next Section button to finalize submission.

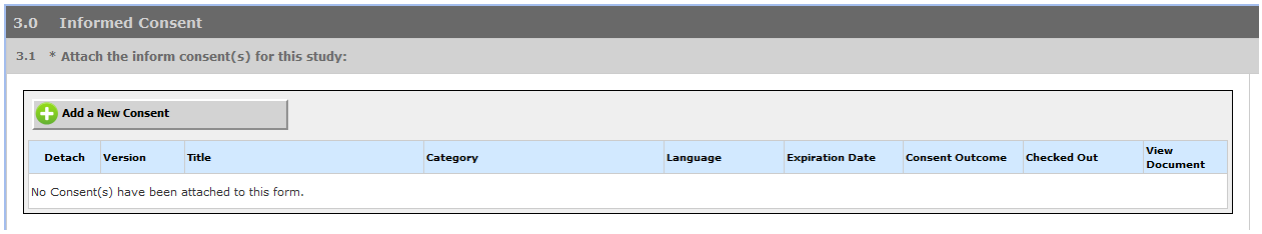
9. The first section of the finalization allows you to place a lay summary in the text box. This is not required; however, it is available if there is something you would like to add. Select the Save and Continue to Next Section button.



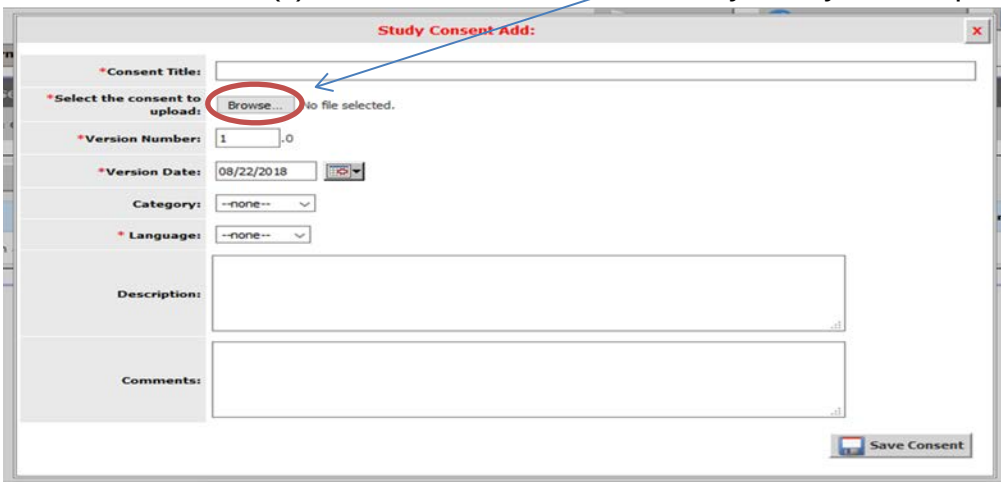
10. This provides you the opportunity to edit the application by clicking on the notepad under the *Edit/View* button. Select the *Save and Continue to Next Section* button on the upper right-hand side of the screen.



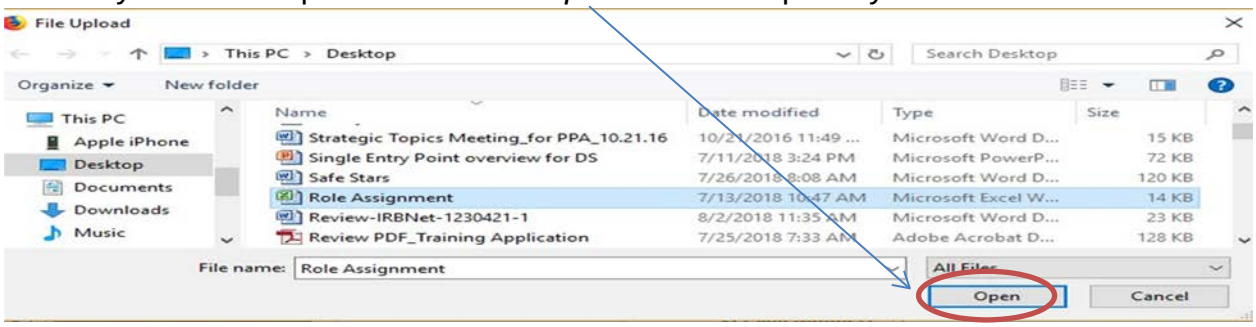
11. If your submission has informed consent forms, they will be uploaded next. Select the *Add a New Consent* button to begin.



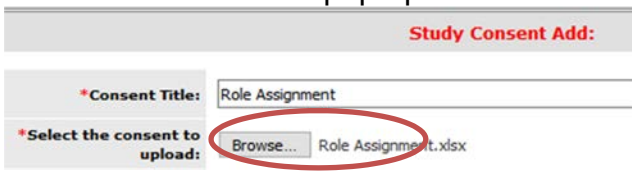
12. Complete the information on the screen and use the *Browse* button to locate your informed Consent document(s). The *Browse* button will take you to your computer files.



13. Select the file you wish to upload and select *Open*. This will upload your file.



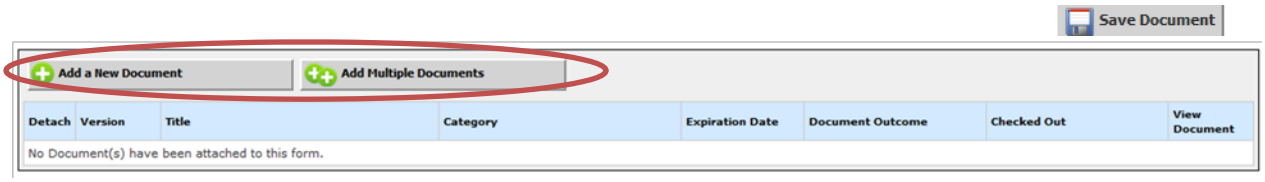
The file name will be beside the *Browse* button in the pop-up screen.



14. Select the *Save Consent* button on the right-hand side of the pop-up screen. 

15. Select the *Save and Continue to Next Section* button on the upper right-hand side of the screen.

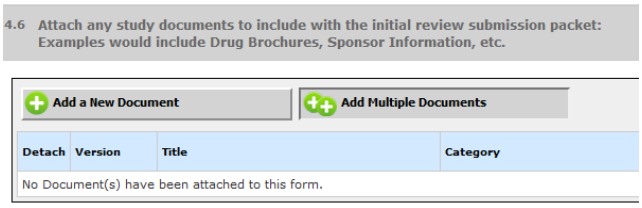
16. This section Study Document allows you to upload additional items that are required by TDH IRB. The first section allows you to upload award letter(s). Select *Add a New Document* OR *Add Multiple Documents*. Next, follow the steps 10-13 listed above. Note: step #12 has a button that states *Save Consent*. In this section the button will now say *Save Document.*



17. The next section is for the confidentiality pledges for all staff associated with the submission. The Confidentiality Pledge form is located under the Help button at the top right-hand side of the screen. Select Help then select Confidentiality Pledge and Print. Each Confidentiality Pledge requires an ink or electronic signature.

After each staff member completes the pledge, follow the steps 10-13 listed above.

18. Any additional items associated with the submission may be uploaded in the next section.



19. Select *Signoff and Submit*

. This will direct you to the option to *Approve* or *Deny* this submission. Select *Approve* and insert your User ID and Password. Next select *Save Signoff*.

The submission is complete.