

The University of Texas at Tyler
IRB Handbook for the Institutional Review Board (IRB)

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THE UNIVERSITY OF TEXAS AT TYLER INSTITUTIONAL REVIEW BOARD

OVERVIEW OF THE UT TYLER IRB

Institutional Official: Dr. Kouider Mokhtari, Interim Associate Provost, Office of Research and Scholarship

Reporting Structure: The Institutional Review Board (IRB) reports directly to the Research Council, who reports to the Office of Research and Scholarship.

The UT Tyler Federal Wide Assurance Number: 00009775

The UT Tyler operates under a Federal Wide Assurance (FWA # 00009775). This is a number assigned to UT Tyler and it essentially means that UT Tyler has a signed contract with the federal government that all human subjects research at UT Tyler will comply with terms and conditions set forth by the DHHS and is committed to adhering to conditions and regulations of the Common Rule regardless of funding source.

Responsibility and Scope of the UT Tyler IRB

The purpose of The UT Tyler IRB is to approve research that involves live human beings **prior** to initiating sample recruitment and subsequent steps of the research process.

This review is conducted according to federal rules and regulations set forth by the Department of Health and Human Services (DHHS) "[45 CFR 46](#)". These regulations are enforced by the Office of Human Research and Protections (OHRP).

Key Definitions: Human Research and Human Subject

a. Human Research

As of January 20, 2019 human research is defined by the DHHS as:

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

Four categories of activities are considered **NOT** to be research:

- a. Scholarly and journalistic activities; for example;
 - i. Oral history, journalism, biography, literary criticism, legal research, and historical scholarship), includes the collection and use of information, that focus directly on the specific individuals about whom the information is collected.
- b. Public health surveillance activities; for example:
 - i. 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).
 - ii. 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).
- c. Collection of information and biospecimens for a criminal justice agency or criminal investigatory purposes; and
- d. Operational activities in support of national security or intelligence missions).

*It is up to individual IRBs how to define “generalizable”.

b. Human Subject

1. **A living individual about whom an investigator is conducting research**
 - i. (1) Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or
 - ii. (2) Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens

§_.102(e)(1)

Related Definitions

- a. **Clinical trial** means a research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of the interventions on biomedical or behavioral health-related outcomes.
- b. **Department or agency head** means the head of any Federal department or agency, for example, the Secretary of HHS, and any other officer or employee of any Federal department or agency to whom the authority provided by these regulations to the department or agency head has been delegated.
- (c) **Federal department or agency** refers to a federal department or agency (the department or agency itself rather than its bureaus, offices or divisions) that takes appropriate administrative action to make this policy applicable to the research involving human subjects it conducts, supports, or otherwise regulates (e.g., the U.S. Department of Health and Human Services, the U.S. Department of Defense, or the Central Intelligence Agency).
- (d) **Intervention** includes both physical procedures by which information or biospecimens are gathered (e.g., venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes.
- (e) **Interaction** includes communication or interpersonal contact between investigator and subject.
- (f) **Private information** includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information that has been provided for specific purposes by an individual and that the individual can reasonably expect will not be made public (e.g., a medical record).
- (g) **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.
- (h) **An identifiable biospecimen** is a biospecimen for which the identity of the subject is or may readily be ascertained by the investigator or associated with the biospecimen.
- (i) **Institution** means any public or private entity, or department or agency (including federal, state, and other agencies).
- (j) **Legally authorized representative** means an individual or judicial or other body authorized under applicable law to consent on behalf of a prospective subject to the subject's participation in the procedure(s) involved in the research.

If there is no applicable law addressing this issue, *legally authorized representative* means an individual recognized by institutional policy as acceptable for providing consent in the non-research context on behalf of the prospective subject to the subject's participation in the procedure(s) involved in the research.

- (k) **Minimal risk** means that 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 examinations or tests.
- (l) **Public health authority** means an agency or authority of the United States, a state, a territory, a political subdivision of a state or territory, an Indian tribe, or a foreign government, or a person or entity acting under a grant of authority from or contract with such public agency, including the employees or agents of such public agency or its contractors or persons or entities to whom it has granted authority, that is responsible for public health matters as part of its official mandate.

The Federal Regulations that Govern UT Tyler IRB

The UT Tyler IRB operates under federal regulations set forth by the Department of Health and Human Services (DHHS) “[45 CFR 46](#)”. [Part 46](#) is divided into subparts that apply to human subjects research which are described below.

- **Subpart A**: Known as The Common Rule: These are the basic policies that cover all research dealing with human subjects.
- **Subpart B**: Additional Protections for Pregnant Women, Human Fetuses and Neonates Involved in Research
- **Subpart C**: Additional Protections for Prisoners involved in Research
- **Subpart D**: Additional Protections for Children involved in Research

Overview of Types of Review Conducted by the UT Tyler IRB

Protocols initially submitted are subject to 1 of 3 types of IRB review, ranging in order of higher to minimal risk: full board, expedited and exempt. Under the new federal regulations, any protocol that may be subject to “limited IRB review” will undergo an expedited review.

Even though an exempt protocol is considered exempt from regulatory oversight, it still must undergo an administrative review to determine it exempt. A PI or co-investigator may not determine the exempt nature of a potential IRB review. Only the IRB can do this.

Protocols Using Retrospective Data

If a faculty member is requesting approval for retrospective research using existing, publicly available, non-identifiable data, completing an application may not be necessary. An email to the IRB Chair with the following information can be sent to determine if an application is necessary:

1. Title of protocol
2. Purpose or research questions
3. Target population (people, existing records)
4. Health information involved? (this may require HIPAA form)
5. Identifiability of sample

The IRB Chair will respond regarding the need to complete an application and/or to submit other documents. If the data involves private health information, a HIPAA application must be submitted.

Collaborative Research

Any UT Tyler faculty member who is a co-investigator on a research project with another institution may need to have UT Tyler approval **prior** to involvement with the research project. This may entail a complete protocol submission and review by the UT Tyler IRB, **OR** a reciprocity agreement initiated either by UT Tyler or by the institution that approved the initial protocol. More information can be reviewed under “Reciprocity Agreements”.

Student PIs

Students who are principal investigators must have a faculty sponsor. More information regarding research as part of classroom assignments can be reviewed under the Undergraduate And Graduate Student Course-Related Research Projects policy.

THE UNIVERSITY OF TEXAS AT TYLER

Human Subjects Research Training for IRB Members, PIs and the Research Team

Ethical considerations are essential in planning and implementing any research study involving humans. The University of Texas at Tyler (UT Tyler) has a formal agreement known as the Federal Wide Assurance (FWA) with the Department of Health & Human Services that states UT Tyler will be responsible in protecting the rights and welfare of human subjects involved in research through adherence to related principles regarding research conducted with human subjects.

These principles are operationalized through established policies and procedures that are reflected in UT Tyler's IRB Handbook. Of utmost importance is the knowledge and skills required to do human subjects research within a solid ethical framework. In order to facilitate meeting this standard of knowledge, UT Tyler has purchased a license to the Collaborative Institutional Training Initiative (CITI), a comprehensive educational program that is used nationally and world-wide "to provide educational content that promotes the quality of and public trust in the research enterprise" (Mission statement: [CITI](https://www.citiprogram.org/)). The main website for CITI can be accessed at <https://www.citiprogram.org/>

- I. **Minimum training requirements** for Principal Investigators (PI), co-investigators, student assistants, and anyone else directly related to the implementation of the research protocol have been established and are as follows:
 - a. **For socio-behavioral PIs:** PIs, co-investigators, and any student or other assistant who will be involved with sample recruitment and other sampling procedures, data collection, and identifiable (via direct or indirect identifiers) data and/or data analyses are required to do the following if the IRB protocol is considered to be socio-behavioral research:
 - i. **Socio-Behavioral Course: 9 modules**
 1. Belmont Report and CITI Course Introduction
 2. History and Ethical Principles
 3. Defining Research with Human Subjects
 4. The Federal Regulations
 5. Assessing Risk
 6. Informed Consent
 7. Privacy and Confidentiality
 8. Unanticipated problems and Reporting Requirements in Social and Behavioral Research
 9. Populations in Research Requiring Additional Considerations and/or Protections

Additional supplemental course(s) may be required if a special population is used, such as cognitively impaired or research in primary/secondary schools, or special method is used, such as internet or community-based participatory action research, or a special topic, such as stem cells/tissue research.

- b. **For biomedical PIs:** PIs, co-investigators, and any student or other assistant who will be involved with sample recruitment and other sampling procedures, data collection, and identifiable (via direct or indirect identifiers) data and/or data analyses are required to do the following if the IRB protocol is considered to be biomedical research:

i. **Bio-Medical Course: 9 modules**

1. Belmont Report and CITI Course Introduction
2. History and Ethics of Human Subjects Research
3. Basic Institutional Review Board (IRB) Regulations and Review Process
4. Informed Consent
5. Social and Behavioral Research (SBR) for Biomedical PIs
6. Records-Based Research
7. Research and HIPAA Privacy Protections
8. Recognizing and Reporting Unanticipated Problems Involving Risks to Subjects or Others in Biomedical Research
9. Populations in Research Requiring Additional Considerations and/or Protections

Additional supplemental course(s) may be required if a special population is used, e.g., cognitively impaired or research in primary/secondary schools, or special method is used, such as internet or community-based participatory action research, or a special topic, such as stem cells/tissue research.

- c. Those individuals, e.g., student research assistants (RA), who are handling de-identified data for data analysis purposes are exempt from these requirements under the condition that the PI accepts responsibility for oversight and monitoring of the student RA for the ethical conduct of research as described in the required training for the PI and research team. The PI may require students to take any of the CITI modules as it relates to their functions on the research team.

2. **Minimum training requirements** for IRB members who are affiliated with UT Tyler, include the following:
 - a. Socio-behavioral course
 - b. Biomedical course
 - c. Any supplemental modules necessary to complete a thorough review of a particular protocol
3. **Minimum training requirements** for IRB members who are not affiliated with UT Tyler include the following module(s):
 - a. Community member
 - b. Any supplemental modules necessary to complete a thorough review of a particular protocol; for example, a physician external member may be required to have socio-behavioral and/or biomedical courses if review of a particular protocol requires that particular knowledge.
4. **The timing, frequency, and documentation of CITI training will be as follows:**
 - a. CITI training must be completed at least every three years or more often as required per protocol.
 - b. The Office of Research & Scholarship IRB Coordinator will verify certification prior to final protocol approval.

The CITI training site can be accessed at: <https://www.citiprogram.org/>

Once an account is established, completion of courses and modules can be done as required.

Responsibilities of The Principal Investigator

The Principal Investigator (PI) acknowledges and accepts responsibility for protecting the rights and welfare of human research subjects, for the scientific and ethical conduct of the research study, and for complying with all applicable Federal, State, local, and institutional regulations and guidelines.

The PI intending to involve human research subjects will not make the final determination of exemption from coverage under "[45 CFR 46](#)". This is the responsibility of the UT Tyler IRB after reviewing the exempt study application.

PIs must have an approved, current, signed Conflict of Interest (COI) form on file with the Office of Research & Scholarship before a funded proposal can be processed. If a proposal is not funded but there is reason to believe a conflict of interest exists, the PI must file the COI form

In addition, the PI shall:

- Ensure the PI, co-investigators, research assistants are properly trained in all aspects of the protocol, including any investigational product(s), and are knowledgeable concerning protection of the rights and welfare of human research subjects and for complying with all applicable UT Tyler, state and federal guidelines. See policy regarding education under "Submission of Proposals" section, Required Education, of this Handbook.
- Prepare a protocol/proposal giving a complete description of the proposed research. As per recommendations of the Office of Human Research Protection, written proposals must be submitted with the appropriate IRB application. The proposal may be brief but include details on the protocol itself. In addition, the protocol must reflect provisions for the adequate protection of the rights and welfare of prospective research subjects and insure that pertinent laws and regulations are observed. This requirement is applicable even in cases where the research is exempt under "[45 CFR 46](#)".
- Be responsible for complying with all UT Tyler IRB decisions, conditions, and requirements.
- Be responsible for providing a copy of the IRB-approved and informed consent document to each subject at the time of consent, unless the IRB has specifically waived this requirement, and for insuring that no human subject will be involved in the research prior to the obtaining of the consent. All signed consent documents are to be retained in a manner approved by the UT Tyler IRB.

- Only those documents approved by the IRB at the time of approval or through a protocol modification can be used in the study.
- Promptly report proposed changes in previously approved human subject research activities to the UT Tyler IRB using the Modification form. The proposed changes will not be initiated without IRB review and approval, except where necessary to eliminate apparent immediate hazards to the subjects.
- Be responsible for reporting progress of approved research to UT Tyler IRB, as often as and in the manner prescribed by the UT Tyler IRB.
- Be responsible for notifying the UT Tyler IRB once the project is terminated or discontinued, by submitting a closure form through Cayuse IRB. If the study is terminated per request of a sponsor or other entity, the PI must notify the UT Tyler IRB immediately.
- Promptly report to the UT Tyler IRB any injuries to human subjects, or other unanticipated problems involving risks to subjects and others, using the Unanticipated-Adverse Event Form, within timelines established in the Reporting of Unanticipated-Adverse Events policy and procedure.
- Forward a copy of all reports of audits performed by funding agencies, sponsor monitors, regulatory agencies, or any other external or internal entity to the IRB promptly upon receipt of the report from the auditing entity.
- Retain all study records for a minimum of three years following completion of the study.

CRITERIA FOR IRB APPROVAL

All protocols are reviewed using the following criteria:

- The principal investigator (PI) agrees to adhere to the responsibilities of the principal investigator
- Measures are in place to ensure risks are minimized
- Risks are reasonable in relation to anticipated benefits of the study
- Subject selection is equitable
- Informed consent is obtained from each subject/participant, either prospective or retrospective. Rationale must be provided for retrospective consent.
- Informed consent is documented

Additional criteria may be necessary depending on the nature of the research, and the following criteria will be used as appropriate:

- Data collection is monitored in order to ensure safety of subjects/participants
- Confidentiality/privacy of subjects/participants is protected
- Safeguards for vulnerable populations are instituted as appropriate

Types of IRB Reviews

A. Full Board Reviews

1. The IRB as a full committee reviews full board review research proposals (non-exempt, non-expedited). These reviews typically involve more than minimal risk to subjects, and may involve vulnerable populations. All protocols involving prisoners must be full board review.
2. Full board reviews are conducted at face to face meetings, and do not meet criteria for exempt or expedited research. Administrative reviewers may deem an expedited protocol eligible for full board review. Face to face meetings include those with members participating via web conferencing, phone or other device.

B. Expedited Reviews

1. An expedited review procedure consists of a review of research involving human subjects by the IRB chairperson or by one or more experienced reviewers designated by the chairperson from among members of the IRB in accordance with the requirements set forth in 45 CFR 46.110
2. Any protocol that may be covered under “limited IRB review” established as part of the DHHS revised federal regulations for research January 19, 2019 shall be reviewed under expedited review
3. Approvals of expedited protocols by the IRB Chair or designated person will be reported at the next regularly scheduled IRB meeting

Expedited reviews include:

1. Research activities that (1) present no more than minimal risk to human subjects, and (2) involve only procedures listed in one or more of the following categories, may be reviewed by the IRB through the expedited review procedure authorized by 45 CFR 46.110 and 21 CFR 56.110. The activities listed should not be deemed to be of minimal risk simply because they are included on this list. Inclusion on this list merely means that the activity is

eligible for review through the expedited review procedure when the specific circumstances of the proposed research involve no more than minimal risk to human subjects.

2. The categories in this list apply regardless of the age of subjects, except as noted.
3. The expedited review procedure may not be used where identification of the subjects and/or their responses would reasonably place them at risk of criminal or civil liability or be damaging to the subjects= financial standing, employability, insurability, reputation, or be stigmatizing, unless reasonable and appropriate protections will be implemented so that risks related to invasion of privacy and breach of confidentiality are no greater than minimal.
4. The expedited review procedure may not be used for classified research involving human subjects.
5. IRBs are reminded that the standard requirements for informed consent (or its waiver, alteration, or exception) apply regardless of the type of review--expedited or convened--utilized by the IRB.
6. Categories one (1) through seven (7) pertain to both initial and continuing IRB review.

RESEARCH CATEGORIES

CATEGORY #1- Clinical studies of drugs and medical devices only when condition (a) or (b) is met.

(a) Research on drugs for which an investigational new drug application (21 CFR Part 312) is not required. (Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review.)

(b) Research on medical devices for which (i) an investigational device exemption application ([21 CFR Part 812](#)) is not required; or (ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.

CATEGORY #2- Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:

(a) from healthy, nonpregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week; or

(b) from other adults and children [children are defined in the HHS regulations as "persons who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted." [45 CFR 46.402\(a\)](#)]., considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week.

CATEGORY #3- Prospective collection of biological specimens for research purposes by noninvasive means.

Examples: (a) hair and nail clippings in a nondisfiguring manner; (b) deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction; (c) permanent teeth if routine patient care indicates a need for extraction; (d) excreta and external secretions (including sweat); (e) uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gumbase or wax or by applying a dilute citric solution to the tongue; (f) placenta removed at delivery; (g) amniotic fluid obtained at the time of rupture of the membrane prior to or during labor; (h) supra- and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques; (i) mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings; (j) sputum collected after saline mist nebulization.

CATEGORY #4- Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves.

Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally

eligible for expedited review, including studies of cleared medical devices for new indications.)

Examples: (a) physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject's privacy; (b) weighing or testing sensory acuity; (c) magnetic resonance imaging; (d) electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography; (e) moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.

CATEGORY #5- Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis).

(NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. [45 CFR 46.101\(b\)\(4\)](#). This listing refers only to research that is not exempt.)

CATEGORY #6-Collection of data from voice, video, digital, or image recordings made for research purposes.

CATEGORY #7- Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.

(NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. [45 CFR 46.101\(b\)\(2\) and \(b\)\(3\)](#). This listing refers only to research that is not exempt.)

CATEGORY #8- Continuing review of research previously approved by the convened IRB as follows:

(a) where (i) the research is permanently closed to the enrollment of new subjects; (ii) all subjects have completed all research-related interventions; and (iii) the research remains active only for long-term follow-up of subjects; or

(b) where no subjects have been enrolled and no additional risks have been identified; or

(c) where the remaining research activities are limited to data analysis.

CATEGORY #9- Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where categories two (2) through eight (8) do not apply but the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.

C. Exempt Research

1. Exempt research at UT Tyler shall be reviewed for compliance with [45 CFR 46.101](#),
2. Determination of exempt status may only be done by the IRB.
3. An exempt review procedure consists of a review of research involving human subjects by the IRB chairperson or by one or more experienced reviewers designated by the chairperson from among members of the IRB in accordance with the requirements set forth in [45 CFR 46.110](#), & <http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm>
4. Criteria for exempt reviews (reflects January 19, 2019 federal revisions)

Exemption 1:

- 1) Normal educational practices in established or commonly accepted educational settings
- 2) Research that involves normal educational practices that are not likely to adversely impact:**
 - a. Students' opportunity to learn required educational content, or
 - b. Assessment of educators who provide instruction §__.104(d)(1)

Exemption 2:

- 1) Research that **only includes** interactions involving educational tests, surveys, interviews, and observations of public behavior, exempt when:
 - i. Information recorded cannot be readily linked back to subjects, **or**
 - ii. Any information disclosure would not place subjects at risk of harm, **or**
 - iii. Identifiable information recorded, with limited IRB review for privacy and confidentiality protection under §__.111(a)(7) ; §__.104(d)(2)

Exemption #3:

- i. Research involving benign behavioral interventions (see definition under Related Terms) with adults who prospectively agree, when information collection is limited to verbal or written responses (including data entry) or audiovisual recording, **and:**
- ii. Information recorded cannot be readily linked back to subjects, **or**
- iii. Any information disclosure would not place subjects at risk of harm, **or**
- iv. Identifiable information recorded, with limited IRB review for privacy and confidentiality protection under §__.111(a)(7)

Exemption #4:

Secondary research use of identifiable private information or identifiable biospecimens if the research falls under one of four provisions.

- i. Identifiable private information or identifiable biospecimens are publicly available, **OR**
- ii. Information, which may include information about biospecimens, is recorded in unidentifiable manner and the investigator does not contact or re-identify the subjects, **OR**
- iii. Investigator's use is regulated under HIPAA as "health care operations," "research," or "public health", **OR**
- iv. Research is conducted by, or on behalf of, a Federal agency using information collected or generated by the government for non-research purposes, and the information is protected by federal privacy standards

Note: No requirement that all data be “existing” at outset of study
 §__.104(d)(4)

Exemption #5:

Public benefit and service programs research and demonstration projects

- i. Expanded to apply to such federally-supported research; no longer limited to federally-conducted research
- ii. Added requirement that Federal agency publish a list of projects covered by this exemption prior to commencing the research

§__.104(d)(5)

Exemption #6:

Taste and food quality evaluation and consumer acceptance studies

Relevant to Exemptions #7 and #8:

IT IS IMPORTANT TO NOTE THAT THE UT TYLER IRB WILL NOT ADOPT THE USE OF BROAD CONSENT AS IT RELATES TO EXEMPTIONS #7 AND #8 BELOW, AND THEREFORE EXEMPTIONS #7 AND #8 WILL NOT APPLY TO ANY PROTOCOL SUBMITTED TO THE UT TYLER IRB.

ANY PROTOCOL THAT FALLS UNDER CIRCUMSTANCES STATED IN EXEMPTIONS #7 AND #8 MUST GO THROUGH A FULL BOARD OR EXPEDITED REVIEW.

Exemption #7:

Storage or maintenance of identifiable private information or identifiable biospecimens for secondary research (Requires broad consent and/or limited review)

Exemption #8:

Secondary research using identifiable private information or identifiable biospecimens (Requires broad consent and/or limited review) §.104(d)(7) and (8)

NOTE: While use of broad consent as it applies to Exemptions #7 and #8 is not allowed, use of broad consent may be considered by the IRB under unique circumstances which will be reviewed on an individual basis.

D. Modification Requests

1. Any revisions of previously IRB approved research must be approved first by the UT Tyler IRB before changes can be instituted in the research, except when necessary to eliminate apparent immediate hazards to the subject.
2. Requests may be administratively approved by IRB Chair or designee
3. While a modification form is required for most protocol alterations, at times a minor modification of a protocol may be approved via email request to the IRB Chair. The IRB Chair will make a determination as to the need for a Modification form.
4. Approvals of modifications by the IRB Chair or designated person will be reported at the next regularly scheduled IRB meeting

E. Continuing Review

1. All full board approved proposals must undergo continuing review via submission of a renewal form on Cayuse IRB at least annually, or more often as is deemed necessary by the IRB due to the level of risk to research subjects. The IRB may also require annual continuing reviews on other non-full board reviews under certain circumstances. The PI will be notified upon initial approval of a requirement for continuing review. The IRB shall document the rationale for conducting continuing review for non-full board review protocols.
2. Though it is the responsibility of the PI to obtain approval for research studies beyond one year after initial approval, all attempts will be made by the IRB Chair or designee to notify PIs within at least 14 days of the annual due date.
3. No full board or other study requiring continuing review shall extend beyond the one year date unless approval by IRB Chair or designee is obtained for continuation of study for no more than an additional year or less as specified by the IRB.
4. All protocols will be verified by the Office of Research & Scholarship on an annual basis regarding their status, and documented as such.

5. The PI is to submit a closure form through Cayuse IRB once their project has concluded
6. The Chair or designee shall keep records of all studies where continuing review has been requested, approved or when studies have been terminated through request of the PI.

DECISIONS OF IRB REVIEWS

A simple majority of members present at the IRB meeting is required to approve a study. No votes will be accepted by mail. Members may participate by video-conference or conference call, and be counted as part of the quorum. The PI shall be notified of the IRB's decision by email, phone or voicemail within 48 hours of the review.

“Approved” – Approved as written with no conditions.

“Approved with Contingencies” – Approved with contingencies for minor changes that will be identified to the PI and must be completed and documented prior to beginning the research. A contingency letter is sent to the PI, which must be signed and returned to the IRB office with the requested corrections. For these contingencies, the IRB Chair or designated reviewer can, upon reviewing the PI's response(s) to contingencies, approve the research on behalf of the IRB.

“Deferred” – Generally, the protocol or consent form has deficiencies that prevent accurate determination of risks and benefits or requires significant clarifications, modifications or conditions that, when met or addressed, require full IRB review and approval of the PI's responses and revisions. The deficiencies will be specified to the PI, and on occasion the PI is asked to attend the full board meeting in order to clarify the points in question.

“Disapproved” – The protocol describes a research activity that is deemed to have risks which outweigh potential benefits or the protocol is significantly deficient in several major areas.

If the protocol disposition is “Approved” or “Approved with Contingencies” and the protocol requests inclusion of a vulnerable population(s), special determinations for the vulnerable population(s) are performed at this time.

Suspended” – All protocols must be ceased immediately upon notification of IRB, and not resume until further notice by IRB. The PI should address the contingencies promptly. Once a PI receives notice that a study is suspended, the PI will have ten (10) days to correct contingencies outlined in the suspension notice and to report in writing to the IRB how contingencies are corrected. If the IRB receives no response within the ten days of issuing the contingencies, the IRB chairperson shall write a memo to the PI inquiring as to whether he or she intends to continue the protocol. Also, the inquiry shall state that lack of a written response within a two-week period will result in discontinuation of the protocol. The IRB will be kept informed of the non-compliance with the contingencies and the administrative actions taken.

Once IRB reviews the written corrections, the PI will be notified in writing of the decision to submit further corrections, resume the study, or to terminate the study.

“Termination” – All protocols must be ceased immediately upon notification of IRB, and not resumed. It is the responsibility of the PI to notify all subjects as to the cessation of the study, and reasons for doing so. Written copies of subject notifications must be submitted to the IRB within one month of notification of study termination.

As per requirements of the Department of Health and Human Services, any suspension or termination of an IRB-approved protocol must be reported to the OHRP: <http://www.hhs.gov/ohrp/compliance/reports/index.html>

SUBMISSION OF PROPOSALS

I. Required Education:

- A. All PIs and co-investigators must have on file with the UT Tyler IRB a current certificate (initial certifications good for 3 years) from CITI. The course may be accessed at the following [CITI Program](#).

II. Submission Deadlines:

- A. All submissions are electronic with the exception of copyrighted surveys and questionnaires
- B. Any full board review must be submitted at least 2 weeks prior to the next IRB meeting.
- C. Contact current chair for meeting dates or other questions.

III. Electronic Submissions Must Include:

- A. IRB application with ALL spaces completed.
- B. Brief research proposal, enough to document background and significance, basic research design and methods for sample recruitment, data collection and analysis. Research designs are reviewed for rigor to ensure compliance with the “Respect for Persons” component of the Belmont Report.
- C. Documentation of CITI training

IV. Other IRB Review-Related Policies

- A. Proposals will be approved for an indefinite period of time unless the protocol is a full board, or if the IRB has mandated periodic reviews and progress reports. The IRB reserves the right at any time to verify from sources other than the investigators that no material changes have occurred since previous IRB review.
- B. Following the presentation and discussion of protocols receiving initial review, a listing of protocols reviewed and approved through exempt and expedited review procedures will be reported to the IRB at the regularly scheduled meetings.
- C. The UT Tyler IRB may, in its discretion, invite individuals with competence in special areas to assist in the review of issues which require expertise beyond or in addition to that available on the IRB. These individuals may not vote with the IRB.

- D. The engagement in human research activities of an independent investigator(s) who is not an employee or student of UT Tyler may be covered under the UT Tyler FWA only in accordance with a formal, written agreement of commitment to relevant human subject protection policies and UT Tyler IRB oversight.

If the independent investigator is affiliated with another institution, a reciprocity agreement shall be initiated by UT Tyler IRB that specifies UT Tyler will rely on the institution's IRB for oversight of the research. If a UT Tyler employee is a co-investigator on a collaborative research project with a PI at another institution, the agreement to rely on the IRB of the reviewing/approving IRB will also be initiated by UT Tyler IRB.

Independent investigators seeking IRB approval to conduct research with UT Tyler or on UT Tyler premises, the protocol must first be approved by UT Tyler IRB. In addition, the UT Tyler Unaffiliated Investigator Agreement must be completed for this purpose, and submitted to the IRB Chair. UT Tyler will maintain commitment agreements on file and provide copies to OHRP upon request.

Procedures for Investigating and Reporting Incidents of Research Misconduct and Non-Compliance

A. Definitions of Research Misconduct and Non-Compliance

Reported allegations of research misconduct and non-compliance will be subject to an investigation. These incidents include, but are not limited to, the following:

- Any reported research activity that is being conducted without prior IRB approval
- Any reported significant deviation in activities previously approved by the IRB
- Research misconduct as defined by the Office of Research Integrity (http://ori.dhhs.gov/misconduct/definition_misconduct.shtml):

Non-compliance is defined as any deviation from academic or regulatory agency rules and regulations regarding human research. Research misconduct means fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results.

- **Fabrication** is making up data or results and recording or reporting them.
- **Falsification** is manipulating research materials, equipment, or processes, or changing or omitting data or results such that the research is not accurately represented in the research record.
- **Plagiarism** is the appropriation of another person's ideas, processes, results, or words without giving appropriate credit.
- Research misconduct does not include honest error or differences of opinion.

B. Definitions of Relevant Individuals in this Policy and Procedure

- Presiding Officer of the Office of Research & Scholarship (ORS): this individual is the deciding officer who makes final determinations on allegations of research misconduct and any institutional administrative actions. This person must have no prior involvement in the institution's inquiry, investigation or allegation assessment.
- Complainant: The complainant is the person who makes allegations of research misconduct and is responsible for making allegations in good faith, maintaining confidentiality, and cooperating with the inquiry and investigation.

- Respondent: The respondent is the person involved in being charged with the allegations of misconduct and is responsible for maintaining confidentiality and cooperating with the conduct of an inquiry and investigation. The respondent(s) has numerous rights as outlined in this policy and procedure, including the following:
 - Be notified in writing before or at the time of an inquiry
 - Have the opportunity to respond in writing to the inquiry report
 - Be notified of the outcome of the inquiry report
 - Be notified of impending investigation before investigation begins
 - Be interviewed during the investigation
 - Have the right to respond in writing to the draft investigative report and have comments considered in the final report.
 - Have the right to admit to engaging in research misconduct either inadvertently or intentionally.

NOTE: In consideration of advice of involved institutional officials (e.g. the IRB, IACUC, department chairs, dean, etc.), the presiding officer of ORS may terminate review of an allegation pending acceptance of UT Tyler’s institutional officials and, if this is a PHS-funded study, any proposed settlement that must be approved by the Office of Research Integrity (ORI).

C. General Guidelines for Investigations of Reported Allegations of Research Misconduct or Non-Compliance

- Upon notification of reported allegation of research misconduct or non-compliance, all efforts must be targeted to ensure safety of subjects or animals involved in any research study under inquiry or investigation. This will be the responsibility of the IRB if human subjects are involved, and the IACUC if animals are involved.
- The UT Tyler Handbook of Operating Procedures states that “any inquiry or investigation of allegations of misconduct/fraud in research must proceed promptly and with due regard for the reputation and rights of individuals involved” (Section 3.2.8, p. 2).
 - Confidentiality of respondents, complainants and research subjects who are identifiable from research records or evidence must be protected at all times, including initial reporting of the misconduct charges, initiation of the investigation process, duration of the investigation process and conclusion of the investigation process.

- The complainant is responsible for making allegations in good faith, maintaining confidentiality, and cooperating with the inquiry and investigation. As a matter of good practice, the complainant should be interviewed at the inquiry stage and given the transcript or recording of the interview for correction.
- The investigation must be conducted by individuals with no unresolved personal, professional, or financial conflicts of interest with the complainant, respondent or witnesses.
- ORI must be notified if an investigation of research misconduct is warranted regarding any PHS-funded study (note: this applies only to those references in this policy to ORI notifications; if the study is not PH-funded, ORI is not to be notified, but all other notifications within the institution must be followed as described).

D. The investigation must reflect a thorough, competent, objective and fair response to allegations of the research misconduct within the time frames specified by **§93.105**.

- The respondent(s) must be notified in writing within two weeks of the finding that an investigation is warranted.
- Within 30 days of finding that an investigation is warranted, the Institutional Official who shall be the presiding official for the Office of Research and Scholarship, shall provide ORI with the written finding and a copy of the inquiry report
- The investigation must be initiated within 30 days after it is determined that an investigation is warranted.
- The respondent(s) must be given 30 days to respond in writing to the draft investigation report prior to preparation of the final report.
- **The investigation must be completed within 60 calendar days from the date of initiation unless circumstances are warranted. Circumstances must be documented if the investigation proceeds beyond 60 days.**
- All aspects of the investigation will be completed within 120 days of beginning it, including conducting the investigation, preparing the report of findings, providing the draft report for comment in accordance with Sec. 93.312, and sending the final report to ORI under Sec. 93.315. (93.311(a)).

- If any new allegations of research misconduct are reported during an existing inquiry or investigation, the respondent (s) will be notified in writing within two weeks of deciding to pursue allegations not addressed during the current inquiry or in the initial notice of investigation.

E. Investigation Proceedings:

- **Reporting and Notifications**

- Allegations of research misconduct or non-compliance must be reported to the department chair or dean, or, if the allegations involve a chair or dean, then the charges must be reported to the President or designee.
- The PI and/or other individuals (respondents) affected by the allegations will be notified in writing by the department Chair/Dean, or if appropriate, the President or designee at the time of the inquiry.
- In addition, allegations must be reported directly to the IRB Chair if the misconduct involves human subjects, and if it involves animals, it must be reported to the IACUC chair and to the presiding official of the Office of Research and Scholarship (ORS) before or at the same time the incident is reported to the department Chair/Dean, or if appropriate, the President or designee.
- The presiding official of the ORS will be the institutional official responsible for appointing an investigative team if an inquiry warrants an investigation.
- The respondent(s) must be notified whether the inquiry found that an investigation is warranted before the investigation begins. The notice must include a copy of the inquiry report and include a copy of UT Tyler's policies and procedures for Research Misconduct
- The respondent(s) must be given an opportunity to respond to the allegations in the inquiry within a specified timeframe in the written notification of allegations. This must be done prior to initiation of the investigation, and investigation cannot proceed until the deadline has passed for the respondent to respond to the inquiry.

- Written notice must be provided to ORI of any decision to open an investigation on or before the date on which the investigation begins
- The respondent must be given the opportunity to be interviewed as part of the investigations, and the interview be recorded, and transcripts to be corrected if needed by the respondent prior to preparation of the draft report.
- The respondent(s) will be given an opportunity to respond in writing to the draft report of the investigation. Respondent comments will be considered and addressed by the institutional investigation committee prior to issuing the final investigative report.
- Respondent(s) will be notified in writing of any new allegations and any decisions to pursue investigations of new allegations during the time of an existing inquiry or investigation.

F. IRB and IACUC Responsibilities

- If the research involves human subjects, the IRB Chair will submit all materials relevant to the investigation to the person(s) conducting the investigation. The IRB Chair shall complete the UT Tyler Research Misconduct and Non-Compliance Review Form and brief the IRB at the next convened meeting or at a specially convened meeting, on the details of research misconduct or non-compliance. The IRB will recommend any additional measures to prevent future similar occurrences.
- If the research involves animals, the IACUC Chair will submit all materials relevant to the investigation to the person(s) conducting the investigation. The IACUC Chair shall complete the UT Tyler Research Misconduct and Non-Compliance Review Form and brief the IACUC at the next convened meeting or at a specially convened meeting, on the details of research misconduct or non-compliance. The IACUC will recommend any additional measures to prevent future similar occurrences.
- The IRB and the IACUC have the authority to terminate approval of the research, especially that which is not being conducted in accordance with the IRB or IACUC requirements or that has been associated with unexpected serious harm to subjects. The PI will be notified in writing of the requirements or conditions necessary to assure compliance with the restrictions, conditions or decisions of the IRB or IACUC. Every effort will be

taken to insure the confidentiality of all aspects of the investigation and any subsequent IRB/IACUC actions relating to the incident(s).

G. Reporting of Investigations

- Upon completion of the investigative process, the Misconduct and Non-Compliance Review Form must be submitted by either the respective Chairs of the IRB or IACUC to the person(s) conducting the investigation and to the presiding official for the ORS.
- If the research project is PHS-funded and/or is associated with an FDA regulated investigational drug or device study, the ORS presiding official will submit a report to the Office for Human Research Protections (OHRP), the Office of Research Integrity and to the FDA.

The reports should indicate how the incident(s) were brought to the attention of the IRB and the specific allegations or observations that were relayed. Reports that are necessary to resolve the incident(s) of misconduct/non-compliance must also include the date(s) the investigation was accomplished, the identity of those involved in the investigation, the results of the investigation in detail, and the restrictions, conditions, or other actions recommended by the departmental Chair, Dean, or if appropriate, President or designee. Finally, the report should also delineate the actions taken by the IRB and/or PI to prevent future occurrences.

- In the event of involvement of a PHS-funded study, UT Tyler officials involved in the inquiry and/or investigation shall provide full and continuing cooperation with ORI during its oversight review under Subpart D of 42 C.F.R. Part 93 or any subsequent administrative hearings or appeals under Subpart E of Part 93. This includes providing all research records and evidence under the institution's control, custody, or possession and access to all persons within its authority necessary to develop a complete record of relevant evidence (§93.304(m))
- H.** All involved in the inquiry and/or investigation will make all reasonable and practical efforts to protect or restore the reputation of persons alleged to have engaged in research misconduct but against whom no finding of research misconduct is made.
- I.** All reasonable and practical efforts will be made to protect or restore the position and reputation of any complainant, witness, or committee member

and to counter potential or actual retaliation against these complainants, witnesses, and committee members

J. Record Keeping

All documents relating to the investigation will be retained by the ORS in a secure location and will be made available to authorized individuals for further reference. Records are held for at least 10 years.

SUSPENSION AND/OR TERMINATION OF INVESTIGATIONS

Grounds for suspension and/or termination of any investigation include, but are not limited, to the following:

- Any reported research activity that is being conducted without prior IRB approval
- Any reported deviation from activities previously approved by the IRB
- Any report of harm, illness, or any other adverse condition possibly occurring as a result of the investigation

UNANTICIPATED PROBLEMS OR ADVERSE EVENT/DEATH

A. Definitions

The UT Tyler IRB and the Office of Human Research Protection consider **unanticipated problems**, in general, to include any incident, experience, or outcome that meets **all** of the following criteria:

- (1) unexpected (in terms of nature, severity, or frequency) given (a) the research procedures that are described in the protocol-related documents, such as the IRB-approved research protocol and informed consent document; and (b) the characteristics of the subject population being studied;
- (2) related or possibly related to participation in the research (in this guidance document, *possibly related* means there is a reasonable possibility that the incident, experience, or outcome may have been caused by the procedures involved in the research); and
- (3) suggests that the research places subjects or others at a greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized.

The term **adverse event** in general is used very broadly and includes any event meeting the following definition:

Any untoward or unfavorable health-related occurrence in a human subject, including any abnormal sign (for example, abnormal physical exam or laboratory finding), symptom, or disease, temporally associated with the subject's participation in the research, whether or not considered related to the subject's participation in the research (modified from the definition of adverse events in the 1996 International Conference on Harmonization E-6 Guidelines for Good Clinical Practice).

Adverse events encompass both physical and psychological harms. They occur most commonly in the context of biomedical research, although on occasion, they can occur in the context of social and behavioral research

B. Reporting

Reporting requirements depend on the nature of the adverse event. If the adverse event was an anticipated one within the context of the research study (one that was specified in the informed consent and in the protocol approved by the IRB), the PI reports this to the IRB Chair using the Report Of Unanticipated Problem or Adverse Event/Death within 5 days of the event.

When a subject who is participating in a research study experiences an unanticipated problem, **the PI must report the incident within 24 hours of the PI becoming aware of the incident** to:

- Chair of the UT Tyler IRB via e-mail and phone voicemail
- Institutional Official (IO): the Director of the Office of Research & Scholarship at UT Tyler
- FDA if the PI holds the Investigational New Drug (IND) or New Device Exemption (IDE)
- Funding agency
- Department chair/administration
- Chair and/or IO report the incident to the Office of Human Research Protections (OHRP) as per Health and Human Services requirements
- (<http://www.hhs.gov/ohrp/compliance/reports/index.html>)

The PI must complete the Report of Unanticipated Problem or Adverse Event/Death and submit to the IRB Chair within 48 hours of the event.

Policy on Management of Human Subject Complaints and Assurance of Confidentiality

It is recognized that during the course of any research project that a research participant may have issues or complaints regarding the research study in which they are a part. Appropriate routing of relevant information and communication is critical in successful resolution of these issues. The goal is to protect subject rights and at the same time maintain confidentiality. As such, the following protocol should be followed whenever there is an awareness of such a situation by the UT Tyler administration, faculty, and/or staff: The following individuals should be notified in the order listed below prior to any action taken or contact with the subject:

- The PI
- Director of Office of & Scholarship
- Chair of the Research Council
- Chair of the IRB
- The PI's Dean

It is imperative that all parties maintain absolute confidentiality of the subject's identity in communications; subject identifying information should only be included when absolutely necessary to resolve conflicts.

Once notified, the PI shall report to the Director of the Office of Research & Scholarship and to the Chairs of the Research Council and IRB regarding the issue/complaint and options for successful resolution. These parties shall collaborate together to resolve the issue successfully. Once the issue is resolved, the PI's Dean will be notified of the outcome.

INFORMED CONSENT

AS OF JANUARY 21, 2019, the following will be in effect regarding informed consent:

- A. The purpose is to enhance participant autonomy and to make informed consent process more meaningful by ensuring they have the key information to make an informed choice to participate based on their own values
- B. The *reasonable person* standard must be used to determine what information to include on the consent form.
- C. Information must be presented in sufficient detail, and organized and presented in a way that facilitates the participant's understanding of why one may or may not want to participate in the research. This means that a list of facts will be insufficient.
- D. Verbiage should reflect how the person should think about what participation in the research would mean to them. The goal is to make the informed consent easier for the participant to process what is involved with participation in the research.
- E. The PI must be fully aware that Informed consent is not valid unless the prospective subject understands the information that has been provided. This is a major responsibility of the PI to ensure.

The following considerations will guide the PI in determining the appropriate way to present the information.

- 1) characteristics of the proposed subject population's levels of cognition and literacy,
- 2) the complexity of the information to be conveyed,
- 3) each subject's emotional state, and
- 4) the setting under which the consent process will take place.

F. *Informed consent is an ongoing process:*

The PI and research team involved in sample recruitment, consenting and data collection must be fully aware that a participant's initial decision to take part in research is not binding. Especially for protocols involving any type of sensitive topic, the PI should periodically ask if the participant is fine to continue in the study. Participants may choose to stop participating for any reason or without cause.

G. Certain key information must be provided first on the form, especially if this is a clinical trial in which consent forms tend to be lengthy.

- Key information can include, **in simple language**, about why one might want or not want to participate. This often includes information about purposes, risks, benefits and alternatives (when appropriate).
- This must be presented in a concise, focused manner.
- Information from a research proposal or application should not be copied and pasted into a consent form as this is typically higher level language.

H. If there is ANY chance that participant data could be used for future research and will be stripped of identifiers prior to that, this must also be explicitly stated in the consent form.

I. The following 3 elements must be included in any consent form if applicable:

- i. Notice about possible commercial profit: A statement that the subject's biospecimens (even if identifiers are removed) may be used for commercial profit and whether the subject will or will not share in this commercial profit
- ii. Notice about whether clinically relevant research results will be given to participants
- iii. Notice about whether research might include whole genome sequencing for biospecimens

J. For federally-funded clinical trials, one IRB-approved consent form used to enroll participants must be posted on a designated federal website

- i. Must be posted after recruitment closes, no later than 60 days after

- the last study visit
- ii. Federal department or agency may permit or require redactions.

K. Waiver of Consent for research with identifiable private information or identifiable biospecimens.

- i. The IRB must determine that the research cannot be *practicably* carried out without using such information or biospecimens in an identifiable format, and that the IRB determines that benefits outweigh risks of identifiability of biospecimens.
- ii. However, out of respect for participant autonomy, non-identifiable data should be used whenever possible.

L. Waiver of Consent for Screening, Recruiting, or Determining Eligibility

- i. The IRB may approve a proposal to obtain information or biospecimens to screen, recruit, or determine eligibility of prospective subjects without informed consent, if obtained through:
- ii. Oral or written communication with subject or LAR
- iii. Accessing records or stored identifiable biospecimens

I. **GENERAL REQUIREMENTS**

1. Except as described in Section III below, PIs may not enroll human subjects in research unless they have obtained the legally effective, written, informed consent of the subject or the subject's legally authorized representative who is responsible for clinical decision authorization *prior* to enrollment of the subject in the research.
2. PIs submitting protocols where health information of participants is involved must also refer to the HIPAA Policy in Research. PIs and anyone else involved with the study must be cognizant of the federal regulations regarding protection of health information for participants in research. Participants will need to sign a HIPAA Consent Form in addition to the written informed consent form.
3. PIs are responsible for insuring that subjects, or their representatives, are given sufficient opportunity to consider whether or not to participate and must seek to avoid coercion or undue influence.
4. Information given to potential subjects or their representatives must be in language that is understandable to the subject or representative.
5. A typical informed consent should be written at no higher than an 8th grade level of reading, and tailored to less than that as appropriate. The IRB uses the Flesch-Kincaid Grade Level readability formula on

<https://readabilityformulas.com/freetests/six-readability-formulas.php> to assess readability.

6. Any time literacy levels are questioned and understanding of the informed consent process by a potential participant may be questionable, the PI should assure verbal understanding of the potential participant of the following: general purpose of the research; voluntary nature of participating and ceasing participation with no adverse consequences; who to contact other than the PI if questions about the research; expectations of potential participation; and risks.
7. No process of obtaining consent may include exculpatory language through which the subject waives any of his/her legal rights, or releases or appears to release the PI, sponsor, or institution or its agents from liability for negligence.
8. The IRB must approve the consent form before it is used, and it must approve any changes made to a previously approved consent.
9. Subjects must be given a copy bearing the IRB approval stamp.
10. The IRB has the authority to observe the consent process and may do so without prior notification to the PI.

II. ONGOING INFORMED CONSENT

Informed consent is communication process that continues during the entire study. Many of the elements of informed consent previously discussed apply throughout the study. The PI and research team should:

- Feel confident that the participant maintains the ability to understand information, make an informed decision, and voluntarily continue to participate.
- Provide written and oral information about emerging study details in a manner understandable to the participant.
- Be satisfied that the participant understands the information provided, has had an opportunity to discuss the information and ask questions, and understands that he or she may withdraw from the study at any time.

When changes in the study occur, and/or significant new findings develop during the course of the study that may affect the participant and his or her willingness to continue participation, additional informed consent may be necessary. Continuation of the study may require having participants sign a new consent form (obtaining re-consent). All proposed changes in the protocol and the consent must be submitted to the IRB. PIs should consult the IRB for the requirements for study changes and re-consent procedures.

1. The IRB has a sample consent forms which contains all the required

- elements of consent: (a) for anonymous surveys; (b) expedited research; (c) full board .
2. The UT Tyler IRB requires that all consent forms be written in the second person, e.g., “you should understand that...”
 3. The signature page may be written in the first person, e.g., “I understand that...” The following are the required elements (extracted from 45 CFR Part 46.116 and 21 CFR 50.25):
 4. Basic Elements of Informed Consent:
 - a. A statement that the study involves research, an explanation of the purposes of the research, the duration of the subject’s participation, a description of the procedures to be followed, and identification of any procedures which are experimental;
 - b. A description of any reasonably foreseeable risks or discomforts that the subjects may encounter, and, if appropriate, a statement that some risks are currently unforeseeable;
 - c. A description of possible benefits, if any, to the subject and others which may be reasonably expected. It should be stated that since it is an experimental treatment or procedure, no benefits can be guaranteed;
 - d. A discussion of possible alternative procedures or treatments, if any, that might be advantageous to the subject. One alternative might be to choose not to participate in the research;
 - e. A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained and that notes the possibility that the FDA, the sponsor, the UT Tyler IRB, or others may inspect the records;
 - f. For research involving more than minimal risk, an explanation as to whether any compensation and/or any medical treatments are available if a research-related injury occurs and, if so, what they consist of, or where further information may be obtained;
 - g. An explanation of whom to contact for answers to pertinent questions about (i) the research (generally the PI or another staff member closely associated with the study), (ii) the rights of the research subject (usually the IRB chairperson), and (iii) any research-related injury to the subject (generally the PI or another staff member closely associated with the study). For item (iii), this should be a telephone number or numbers whereby the research subject can reach an appropriate person 24 hours a day, not just during normal working

hours; and

- h. A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.
- i. A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is becomes pregnant), which are currently unforeseeable;
- j. Anticipated circumstances under which the subject's participation may be terminated by the PI without regard to the subject's consent;
- k. A description of any additional costs for which the subject will be responsible, that may result from participation in the research study;
- l. The consequences of a subject's decision to withdraw from the research and the procedures for orderly termination of participation by the subject;
- m. A statement that significant new findings developed during the course of the research, which may relate to the subject's willingness to continue participation, will be provided to the subject;
- n. A description of any compensation or reimbursement for time, inconvenience, travel, and other similar costs to the subject; and
- o. The anticipated number of subjects that will be involved with the study, both totally and at UT Tyler.

IV. WAIVER OF INFORMED CONSENT

The IRB may waive the requirements for obtaining informed consent or approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent listed above, provided that:

Subject's signature can be waived if:

- i. Subjects are members of a distinct community in which signing forms is not the norm

- ii. Research involves no more than minimal risk
- iii. An alternative method for documenting consent is used

The 4 criteria for waiver of consent:

1. The research involves no more than minimal risk to the subjects;
2. The waiver or alteration will not adversely affect the rights and welfare of the subjects;
3. The research could not practicably be carried out without the waiver or alteration; and
4. Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

The IRB may waive requirements for obtaining signed informed consents under the following circumstances:

- i. The only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality, or
- ii. The research presents no more than minimal risk of harm to the subjects and involves no procedures for which written consent is normally required outside of the research context.
- iii. Subjects are members of a distinct community in which signing forms is not the norm
- iv. An alternative method for documenting consent is used

There are more stringent and specific requirements for the IRB waiver of informed consent in emergency situations in which the research involves more than minimal risk to the subjects. Information on the requirements and procedures may be obtained from the IRB Chair.

V. DOCUMENTATION OF INFORMED CONSENT

1. Documentation of Consent
(added in the appropriate section below)
2. Electronic Signatures on Consent Forms are acceptable
3. Legally Authorized Representatives (LAR)

Current policy reflected in #1 below

VI. RECORD RETENTION REQUIREMENTS FOR SUBJECT CONSENT FORMS

1. The PI shall maintain, in a designated location, all executed subject consents.
2. These consent forms are to be available for inspection by authorized officials of the UT Tyler administration and IRB, as well as the FDA, DHHS, and other regulatory agencies and sponsors.
3. For FDA regulated test article studies, all signed subject consent forms shall be retained by the PI for the appropriate period(s) specified below.

Drugs: Three (3) years following the date a marketing application is approved or the study is discontinued.

Devices: Three (3) years after a study is terminated or completed, or longer if the records are needed to support FDA approval.

4. Should a PI depart from UT Tyler prior to the completion of an activity, the PI is responsible for initiating mutually satisfactory arrangements with his or her department and the UT Tyler administration as to the disposition of executed subject consents.

VII. INFORMED CONSENT OBTAINED BY TELEPHONE

An oral approval does not satisfy the [21CFR56.109\(c\)](#) requirement for a signed consent document, as outlined in [21CFR50.27\(a\)](#). However, it is acceptable to send the informed consent document to the subject by facsimile or standard mail and conduct the consent interview by telephone when the subject can read the consent as it is discussed. If the subject agrees, he/she can sign the consent and return the signed document by facsimile or standard mail.

When the subject makes the first study visit, informed consent must be obtained again. This is to ensure that the patient understands the study and in fact still wants to participate. Both informed consents should be kept on file.

Any questions regarding this process should be directed to the IRB Chair.

The University of Texas at Tyler
Institutional Review Board
Certificates of Confidentiality

NOTE: This information was extracted from the NIH Certificates of Confidentiality site:
<https://humansubjects.nih.gov/coc/background>

This policy also has numerous exceptions and conditions to be noted.

Purpose

Certificates of Confidentiality are issued by the National Institutes of Health (NIH) to protect the privacy of research subjects by protecting investigators and institutions from being compelled to release information that could be used to identify subjects with a research project. Certificates of Confidentiality are issued to institutions or universities where the research is conducted. They allow the investigator and others who have access to research records to refuse to disclose identifying information in any civil, criminal, administrative, legislative, or other proceeding, whether at the federal, state, or local level.

Identifying information is broadly defined as any item or combination of items in the research data that could lead directly or indirectly to the identification of a research subject.

By protecting PIs and institutions from being compelled to disclose information that would identify research participants, Certificates of Confidentiality help achieve the research objectives and promote participation in studies by assuring privacy to subjects.

Statutory Authority

Under section 301(d) of the Public Health Service Act ([42 U.S.C. 241\(d\)](#)) the Secretary of Health and Human Services may authorize persons engaged in biomedical, behavioral, clinical, or other research to protect the privacy of individuals who are the subjects of that research. This authority has been delegated to the National Institutes of Health (NIH).

Persons authorized by the NIH to protect the privacy of research subjects may not be compelled in any Federal, State, or local civil, criminal, administrative, legislative, or other proceedings to identify them by name or other identifying characteristic.

Extent and Limitations of Coverage

Certificates can be used for biomedical, behavioral, clinical or other types of research that is sensitive. By sensitive, we mean that disclosure of identifying information could have adverse consequences for subjects or damage their financial standing, employability, insurability, or reputation.

Examples of sensitive research activities include but are not limited to the following:

- Collecting genetic information;
- Collecting information on psychological well-being of subjects;
- Collecting information on subjects' sexual attitudes, preferences or practices;
- Collecting data on substance abuse or other illegal risk behaviors;
- Studies where subjects may be involved in litigation related to exposures under study (e.g., breast implants, environmental or occupational exposures).

In general, certificates are issued for single, well-defined research projects rather than groups or classes of projects. In some instances, they can be issued for cooperative multi-site projects. A coordinating center or "lead" institution designated by the NIH program officer can apply on behalf of all institutions associated with the multi-site project. The lead institution must ensure that all participating institutions conform to the application assurances and inform participants appropriately about the Certificate, its protections, and the circumstances in which voluntary disclosures would be made.

A Certificate of Confidentiality protects personally identifiable information about subjects in the research project while the Certificate is in effect. Generally, Certificates are effective on the date of issuance or upon commencement of the research project if that occurs after the date of issuance. The expiration date should correspond to the completion of the study.

The Certificate will state the date upon which it becomes effective and the date upon which it expires. A Certificate of Confidentiality protects all information identifiable to any individual who participates as a research subject (i.e., about whom the investigator maintains identifying information) during any time the Certificate is in effect.

An extension of coverage must be requested if the research extends beyond the expiration date of the original Certificate. **However, the protection afforded by the Certificate is permanent.** All personally identifiable information maintained about participants in the project while the Certificate is in effect is protected in perpetuity.

Protection is permanent despite expiration date of study; even data before is also protected; data after expiration date is not protected.

Some projects are ineligible for a Certificate of Confidentiality. Not eligible for a Certificate are projects that are:

- not research,
- not collecting personally identifiable information,
- not reviewed and approved by the IRB as required by these guidelines, or
- collecting information that if disclosed would not significantly harm or damage the participant.

While Certificates protect against involuntary disclosure, investigators should note that research subjects might voluntarily disclose their research data or information. Subjects may disclose information to physicians or other third parties. They may also authorize in writing the investigator to release the information to insurers, employers, or other third parties.

In such cases, PIs may not use the Certificate to refuse disclosure. Moreover, PIs are not prevented from the voluntary disclosure of matters such as child abuse, reportable communicable diseases, or subject's threatened violence to self or others. (For information on communicable disease reporting policy, see [Communicable Diseases Policy](#)). However, if the PI intends to make any voluntary disclosures, the consent form must specify such disclosure.

Certificates do not authorize PIs to refuse to disclose information about subjects if authorized DHHS personnel request such information for an audit or program evaluation. Neither can PIs refuse to disclose such information if it is required to be disclosed by the Federal Food, Drug, and Cosmetic Act.

In the informed consent form, investigators should tell research subjects that a Certificate is in effect. Subjects should be given a fair and clear explanation of the protection that it affords, including the limitations and exceptions noted above. Every research project that includes human research subjects should explain how identifiable information will be used or disclosed, regardless of whether or not a Certificate is in effect. The Office of Human Subjects Protection ([OHRP](#)) provides guidance on the content of informed consent documents.

I. An Important Caveat

Certificates of Confidentiality do not take the place of good data security or clear policies and procedures for data protection, which are essential to the protection of research participants' privacy. PIs should take appropriate steps to safeguard research data and findings. Unauthorized individuals must not access the research data or learn the identity of research participants.

HIPAA Privacy Rule in Research Policy

Guidelines for this policy were taken from the DHHS at the following site:

<http://www.hhs.gov/ocr/hipaa/guidelines/research.pdf> new link:
<https://www.hhs.gov/hipaa/for-professionals/special-topics/research/index.html>

Definitions: Selected definitions are below; if any other terms are not clear, please contact the IRB Chair for clarification. The Health Information Portability Accountability Act (HIPAA) Policy may also be referred to as the "Privacy Rule" and is directed toward privacy of individual protected health information (PHI)

Accounting for Disclosures:

This is also known as "tracking disclosures"

Upon request, a covered entity must provide the individual with an accounting of each disclosure by date, the Protected Health Information (PHI) disclosed, the identity of the recipient of the PHI, and the disclosure. Additional information is found below in II.D.3.

<https://www.hhs.gov/hipaa/for-professionals/privacy/laws-regulations/index.html>

Covered Entity (CE):

Under HIPAA, this is a health plan, a health care clearinghouse, or a health care provider who transmits any health information in electronic form in connection with a HIPAA transaction. Also see Part II, [45 CFR 160.103](#).

Covered Workforce:

Any UT Tyler employee, full time, part time, or adjunct, student, or person with a research-associated contract

Data Element:

Under HIPAA, this is the smallest named unit of information in a transaction. Also see Part II, [45 CFR 162.103](#).

De-identified information:

Health information that has no identifiers with it and cannot be linked to an individual

Disclosure: Release or divulgence of information by an entity to persons or organizations outside of that entity. Also see Part II, [45 CFR 164.501](#).

Forms and Policies Relating to Enforcement of the UT Tyler Privacy Rule:

- **Protected Health Information Use In Research (policy):** This policy is a general policy for using PHI in research at UT Tyler.
- **Waiver Of Authorization To Use Protected Health Information (policy):** This policy presents guidelines to use when requesting permission to use PHI without participant authorization

- **Protected Health Information Use IRB Application (form):** This is a form that all PIs must complete and submit with their review applications to the IRB when participants are authorizing release of PHI from the covered entities to the PI.
- **Research Participant Authorization To Use Protected Health Information (form):** This form is an amendment to the written informed consent form that participants sign when health information is to be collected and used during a study. It does not include obtaining PHI from a covered entity; it only authorizes use of PHI during the study and authorizes release of PHI to other entities, e.g., study sponsors, the FDA, or any other regulatory agency.
- **Request for IRB Approval of Waiver of Authorization to Use Protected Health Information (form):** This form is to be submitted with the review application to the IRB when requesting PHI without participant authorization. Review of the **Waiver Of Authorization To Use Protected Health Information** (policy) is required. <https://www.hhs.gov/hipaa/for-professionals/special-topics/research/index.html>

Identifiers:

- Names
- All geographic subdivisions smaller than a state, including street address, city, county, precinct, zip code and their equivalent geocodes
- All elements of dates (except year) for dates directly related to an individual, including birth date, admission date, discharge date, date of death
- Telephone numbers
- Fax numbers
- Electronic mail addresses
- Social security numbers
- Medical record numbers
- Health plan beneficiary numbers
- Account numbers
- Certificate/license numbers
- Vehicle identifiers & serial number, including license plate numbers
- Device identifiers & serial numbers
- Web universal resource locators (URLs)
- Internet protocol (IP) address numbers
- Biometric identifiers, including finger and voice prints
- Full face photographic images and any comparable images
- Any other unique identifying number, characteristic or code

Minimum Necessary:

The Privacy Rule stipulates that covered entities limit the amount of information disclosed to the minimum necessary to achieve the specified goal [45 CFR 164.514(d)(1)]. This requirement would not apply if the disclosure were required by law, authorized by the individual, or for treatment purposes.

Protected Health Information (PHI):

The Privacy Rule defines PHI as "...as individually identifiable health information, held or maintained by a covered entity or its business associates acting for the covered entity, that is transmitted or maintained in any form or medium (including the individually identifiable health information of non-U.S. citizens). This includes identifiable demographic and other information relating to the past, present, or future physical or mental health or condition of an individual, or the provision or payment of health care to an individual that is created or received by a health care provider, health plan, employer, or health care clearinghouse. For purposes of the Privacy Rule, genetic information is considered to be health information."

https://privacyruleandresearch.nih.gov/pr_07.asp

Health information held by a covered entity that is NOT considered protected is individually identifiable health information that is maintained in education records covered by the Family Educational Right and Privacy Act (as amended, 20 U.S.C. 1232g) and records described at 20 U.S.C. 1232g(a)(4)(B)(iv), and employment records containing individually identifiable health information that are held by a covered entity in its role as an employer.

Treatment:

Is the provision, coordination, or management of health care and related services by one or more health care providers, including the coordination or management of health care by a health care provider with a third party; consultation between health care providers relating to a patient; or the referral of a patient for health care from one health care provider to another.

UT Tyler HIPAA Requirements

PIs, co-investigators and anyone else involved with protected health information must be knowledgeable about the federal regulations regarding protecting the privacy of research participant health information.

When health information is involved as a part of the research study, participants must sign a HIPAA Consent Form in addition to the written informed consent form.

I. Background

- A. The Health Information Portability Accountability Act (HIPAA) Privacy Rule establishes the conditions under which protected health information may be used or disclosed by covered entities for research purposes.
- B. Research is defined in the Privacy Rule as, “a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge.” See 45 CFR 164.501.
- C. A PI may use or disclose for research purposes health information which has been de-identified (in accordance with 45 CFR 164.502(d), and 164.514(a)-(c) of the Rule) without regard to the provisions below.

For example, if a list of diagnoses are being reviewed with no identifying information on them, including names, birthdates, and other personal information, then HIPAA policies do not apply.

- D. Accounting for Disclosures: The Privacy Rule also defines the means by which individuals will be informed of uses and disclosures of their medical information for research purposes, and their rights to access information about them held by covered entities
- E. Where research is concerned, the Privacy Rule protects the privacy of individually identifiable health information, while at the same time ensuring that PIs continue to have access to medical information necessary to conduct vital research. Currently, most research involving human subjects operates under the Common Rule ([45 CFR Part 46, Subpart A](#)) and/or the Food and Drug Administration’s (FDA) human subject protection regulations ([21 CFR Parts 50 and 56](#)), which have some provisions that are similar to, but separate from, the Privacy Rule’s provisions for research.
- F. The Privacy Rule creates equal standards of privacy protection for research governed by the existing Federal human subject regulations and research that is not.

- G. The Privacy Rule applies to all situations involving protected health information, regardless of research funding or setting.

II. Application of the Privacy Rule in Research

- A. In the course of conducting research, PIs may obtain, create, use, and/or disclose individually identifiable health information with full disclosure of this intent to the IRB prior to these actions.
- B. Under the Privacy Rule, covered entities are permitted to use and disclose protected health information for research under one of the following circumstances: (a) with individual authorization, or (b) without individual authorization under limited circumstances set forth in the Privacy Rule.
- C. **Research Use/Disclosure Without Authorization:** To use or disclose protected health information without authorization by the research participant, the PI must first complete the **UT Tyler IRB Approval Of Waiver Of Authorization To Use Protected Health Information** form and submit to the IRB with the review application. In order to proceed with obtaining protected health information from an entity, e.g., health care facility, the investigator must have:

1. Documented Institutional Review Board (IRB) Approval.

- a. **Documentation that an alteration or waiver of research participants' authorization for use/disclosure of information about them for research purposes has been approved by the UT Tyler IRB [\[See 45 CFR 164.512\(i\)\(1\)\(i\)\]](#).**

This provision of the Privacy Rule might be used, for example, to conduct records research, when PIs are unable to use de-identified information, and the research could not practicably be conducted if research participants' authorization were required.

- b. **A covered entity (e.g., a health care facility that houses the protected health information) may use or disclose protected health information for research purposes following an approved waiver of authorization by the UT Tyler IRB, provided it has obtained documentation of *all* of the following:**
 - Identification of the IRB approval and the date on which the waiver of authorization was approved;
 - A statement that the IRB has determined that the waiver of authorization, in whole or in part, satisfies the three criteria in the Privacy Rule;

- A brief description of the protected health information for which use or access has been determined to be necessary by the IRB;
- A statement that the alteration or waiver of authorization has been reviewed and approved under either normal or expedited review procedures; and
- The signature of the chair or other member, as designated by the chair, of the IRB or the Privacy Board, as applicable.

c. The following three criteria must be satisfied for the UT Tyler IRB to approve a waiver of authorization under the Privacy Rule:

- The use or disclosure of protected health information involves no more than a minimal risk to the privacy of individuals, based on, at least, the presence of the following elements:
 - *an adequate plan to protect the identifiers from improper use and disclosure;
- an adequate plan to destroy the identifiers at the earliest opportunity consistent with conduct of the research, unless there is a health or research justification for retaining the identifiers or such retention is otherwise required by law;
 - *adequate written assurances that the protected health information will not be reused or disclosed to any other person or entity, except as required by law-- for example, authorized oversight of the research project by the IRB may necessitate review of the health information or for other research for which the use or disclosure of protected health information would be permitted by the Privacy Rule.
- The research could not practicably be conducted without the waiver; and
- The research could not practicably be conducted without access to and use of the protected health information.

Other criteria that may meet waiver of authorization (must be in addition to the three listed above): Preparatory to Research; Decedents; Limited Data Sets

2. Access to PHI as Preparatory to Research

- a. HIPAA provides a mechanism to access personally identifiable information for the purpose of "reviews preparatory to research". This provision might be used to design a research study, to assess the feasibility of conducting a study, or to assemble a database of individuals who indicate a willingness to be considered for participation in future research studies.

*Note that this mechanism does not permit the collection of data for conducting actual research or the removal of information from a covered entity.

The following is needed from the PI:

- b. HIPAA Disclosures from the PI, either in writing or orally, that:
 - the use or disclosure of the protected health information is solely to prepare a research protocol or for similar purposes preparatory to research,
 - the PI will not remove any protected health information from the covered entity, *and*
 - protected health information for which access is sought is necessary for the research purpose. See [45 CFR 164.512\(i\)\(1\)\(ii\)](#).
3. Research on Protected Health Information of Decedents: The PI must provide to the covered entity:
 - a. Representations, either in writing or orally, that the use or disclosure being sought is solely for research on the protected health information of decedents
 - b. Documentation that the protected health information being sought is necessary for the research
 - c. Documentation, at the request of the covered entity, of the death of such individuals See [45 CFR 164.512\(i\)\(1\)\(iii\)](#).
4. Limited Data Sets with a Data Use Agreement

- a. A limited data set excludes specified direct identifiers of the individual or of relatives, employers, or household members of the individual.
- b. A data use agreement must first be entered into by both the covered entity and the PI. Following this, the covered entity may disclose a limited data set to the PI for research, public health, or health care operations. See [45 CFR 164.514\(e\)](#).
- c. The data use agreement must:
 - Establish the permitted uses and disclosures of the limited data set by the recipient, consistent with the purposes of the research, and which may not include any use or disclosure that would violate the Privacy Rule
 - Limit who can use or receive the data; and
 - Require the recipient to agree to the following:
 - Not to use or disclose the information other than as permitted by the data use agreement or as otherwise required by law;
 - *Use appropriate safeguards to prevent the use or disclosure of the information other than as provided for in the data use agreement;
 - *Report to the covered entity any use or disclosure of the information not provided for by the data use agreement of which the recipient becomes aware;
 - *Ensure that any agents, including a subcontractor, to whom the recipient provides the limited data set agrees to the same restrictions and conditions that apply to the recipient with respect to the limited data set; and
 - *Not to identify the information or contact the individual.

D. Research Use/Disclosure with Individual Authorization

1. The Privacy Rule also permits covered entities to use or disclose protected health information for research purposes when a research participant authorizes the use or disclosure of information about him or herself.

2. In addition to the research protocol consent form, participants must sign a **Research Participant Authorization To Use Protected Health Information** form and have available for covered entity and IRB review.
3. Accounting for Research Disclosures.
 - a.. In general, the Privacy Rule gives individuals the right to receive an accounting of certain disclosures of protected health information made by a covered entity. (See 45 CFR 164.528).
 - b. This accounting must include disclosures of protected health information that occurred during the six years prior to the individual's request for an accounting, or since the applicable compliance date (whichever is sooner), and must include specified information regarding each disclosure.
 - c. However, where the covered entity has, during the accounting period, made multiple disclosures to the same recipient for the same purpose, the Privacy rule provides for a simplified means of accounting. In such cases, the covered entity need only identify the recipient of such repetitive disclosures, the purpose of the disclosure, and describe the PHI routinely disclosed. The date of each disclosure need not be tracked. Rather, the accounting may include the date of the first and last such disclosure during the accounting period, and a description of the frequency of such disclosures.
 - d. A covered entity is not required to account for all disclosures of PHI.
 - e. An accounting is **not required** for
 - Research disclosures made pursuant to an individual's authorization;
 - Disclosures of the limited data set to PIs with a data use agreement under [45 CFR 164.514\(e\)](#).

POLICY ON PROTECTION OF PREGNANT WOMEN, HUMAN FETUSES AND NEONATES IN RESEARCH

These policies below are derived from the following:

<http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm#subpartb> and include the duty of the UT Tyler IRB in connection with research involving pregnant women, fetuses, and neonates to be the following:

In addition to other responsibilities assigned to the UT Tyler IRB under this part the UT Tyler IRB shall review research covered by this policy and approve only research which satisfies the conditions of all applicable sections of this policy and the other subparts of this part.

* The term “part” in this policy refers to PART 46 PROTECTION OF HUMAN SUBJECTS: <http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm>

I. To What Do These Regulations Apply?

(a) Except as provided in paragraph (b) of this section, this policy applies to all research involving pregnant women, human fetuses, neonates of uncertain viability, or nonviable neonates conducted or supported by the Department of Health and Human Services (DHHS). This includes all research conducted in DHHS facilities by any person and all research conducted in any facility by DHHS employees.

(b) The exemptions at [§46.101\(b\)\(1\) through \(6\)](#) which are the same as UT Tyler’s Categories of Exempt Categories listed in the UT Tyler Exempt Research Application are applicable to this policy.

(c) The provisions of §46.101(c) through (i) are applicable to this policy, and include the following:

- Department or agency heads retain final judgment as to whether a particular activity is covered by this policy.
- Department or agency heads may require that specific research activities or classes of research activities conducted, supported, or otherwise subject to regulation by the department or agency but not otherwise covered by this policy, comply with some or all of the requirements of this policy.
- Compliance with this policy requires compliance with pertinent federal laws or regulations which provide additional protections for human subjects.

- This policy does not affect any state or local laws or regulations which may otherwise be applicable and which provide additional protections for human subjects.
- This policy does not affect any foreign laws or regulations which may otherwise be applicable and which provide additional protections to human subjects of research.
- When research covered by this policy takes place in foreign countries, procedures normally followed in the foreign countries to protect human subjects may differ from those set forth in this policy.

[An example is a foreign institution which complies with guidelines consistent with the World Medical Assembly Declaration (Declaration of Helsinki amended 1989) issued either by sovereign states or by an organization whose function for the protection of human research subjects is internationally recognized.] In these circumstances, if a department or agency head determines that the procedures prescribed by the institution afford protections that are at least equivalent to those provided in this policy, the department or agency head may approve the substitution of the foreign procedures in lieu of the procedural requirements provided in this policy. Except when otherwise required by statute, Executive Order, or the department or agency head, notices of these actions as they occur will be published in the FEDERAL REGISTER or will be otherwise published as provided in department or agency procedures.

- Unless otherwise required by law, department or agency heads may waive the applicability of some or all of the provisions of this policy to specific research activities or classes of research activities otherwise covered by this policy. Except when otherwise required by statute or Executive Order, the department or agency head shall forward advance notices of these actions to the Office for Human Research Protections, Department of Health and Human Services (HHS), or any successor office, and shall also publish them in the FEDERAL REGISTER or in such other manner

(d) The requirements of this policy are in addition to those imposed under the other subparts of this part.

II. Definitions

(a) Dead fetus means a fetus that exhibits neither heartbeat, spontaneous respiratory activity, spontaneous movement of voluntary muscles, nor pulsation of the umbilical cord.

(b) Delivery means complete separation of the fetus from the woman by expulsion or extraction or any other means.

(c) Fetus means the product of conception from implantation until delivery.

(d) Neonate means a newborn.

(e) Nonviable neonate means a neonate after delivery that, although living, is not viable.

(f) Pregnancy encompasses the period of time from implantation until delivery. A woman shall be assumed to be pregnant if she exhibits any of the pertinent presumptive signs of pregnancy, such as missed menses, until the results of a pregnancy test are negative or until delivery.

(g) Secretary means the Secretary of Health and Human Services and any other officer or employee of the Department of Health and Human Services to whom authority has been delegated.

(h) Viable, as it pertains to the neonate, means being able, after delivery, to survive (given the benefit of available medical therapy) to the point of independently maintaining heartbeat and respiration. The Secretary may from time to time, taking into account medical advances, publish in the FEDERAL REGISTER guidelines to assist in determining whether a neonate is viable for purposes of this policy. If a neonate is viable then it may be included in research only to the extent permitted and in accordance with the requirements of subparts A and D of this part.

III. Research Involving Pregnant Women Or Fetuses

Pregnant women or fetuses may be involved in research if all of the following conditions are met:

- Where scientifically appropriate, preclinical studies, including studies on pregnant animals, and clinical studies, including studies on nonpregnant women, have been conducted and provide data for assessing potential risks to pregnant women and fetuses;
- The risk to the fetus is caused solely by interventions or procedures that hold out the prospect of direct benefit for the woman or the fetus; or, if there is no such prospect of benefit, the risk to the fetus is not greater than minimal and the purpose of the research is the development of important biomedical knowledge which cannot be obtained by any other means;
- Any risk is the least possible for achieving the objectives of the research;
- If the research holds out the prospect of direct benefit to the pregnant woman, the prospect of a direct benefit both to the pregnant woman and the fetus, or no prospect of benefit for the woman nor the fetus when risk to the fetus is not greater than minimal and the purpose of the research is the development of important biomedical knowledge that cannot be

obtained by any other means, her consent is obtained in accord with the informed consent provisions of subpart A of this part;

- If the research holds out the prospect of direct benefit solely to the fetus then the consent of the pregnant woman and the father is obtained in accord with the informed consent provisions of subpart A of this part, except that the father's consent need not be obtained if he is unable to consent because of unavailability, incompetence, or temporary incapacity or the pregnancy resulted from rape or incest.
- Each individual providing consent under paragraph (d) or (e) of this section is fully informed regarding the reasonably foreseeable impact of the research on the fetus or neonate;
- For children as defined in §46.402(a) who are pregnant, assent and permission are obtained in accord with the provisions of subpart D of this part;
- No inducements, monetary or otherwise, will be offered to terminate a pregnancy;
- Individuals engaged in the research will have no part in any decisions as to the timing, method, or procedures used to terminate a pregnancy; and
- Individuals engaged in the research will have no part in determining the viability of a neonate.

IV. Research Involving Neonates

(a) Neonates of uncertain viability and nonviable neonates may be involved in research if all of the following conditions are met:

- Where scientifically appropriate, preclinical and clinical studies have been conducted and provide data for assessing potential risks to neonates.
- (2) Each individual providing consent under paragraph (b)(2) or (c)(5) of this section is fully informed regarding the reasonably foreseeable impact of the research on the neonate.
- Individuals engaged in the research will have no part in determining the viability of a neonate.
- The requirements of paragraph (b) or (c) of this section have been met as applicable.

(b) Neonates of uncertain viability. Until it has been ascertained whether or not a neonate is viable, a neonate may not be involved in research covered by this policy unless the following additional conditions have been met:

- The IRB determines that:

(i) The research holds out the prospect of enhancing the probability of survival of the neonate to the point of viability, and any risk is the least possible for achieving that objective, or

(ii) The purpose of the research is the development of important biomedical knowledge which cannot be obtained by other means and there will be no added risk to the neonate resulting from the research; and

- The legally effective informed consent of either parent of the neonate or, if neither parent is able to consent because of unavailability, incompetence, or temporary incapacity, the legally effective informed consent of either parent's legally authorized representative is obtained in accord with subpart A of this part, except that the consent of the father or his legally authorized representative need not be obtained if the pregnancy resulted from rape or incest.

(c) Nonviable neonates. After delivery nonviable neonate may not be involved in research covered by this policy unless all of the following additional conditions are met:

- Vital functions of the neonate will not be artificially maintained;
- The research will not terminate the heartbeat or respiration of the neonate;
- There will be no added risk to the neonate resulting from the research;
- The purpose of the research is the development of important biomedical knowledge that cannot be obtained by other means; and the legally effective informed consent of both parents of the neonate is obtained in accord with subpart A of this part, except that the waiver and alteration provisions of §46.116(c) and (d) do not apply. However, if either parent is unable to consent because of unavailability, incompetence, or temporary incapacity, the informed consent of one parent of a nonviable neonate will suffice to meet the requirements of this paragraph (c)(5), except that the consent of the father need not be obtained if the pregnancy resulted from rape or incest. The consent of a legally authorized representative of either or both of the parents of a nonviable neonate will not suffice to meet the requirements of this paragraph (c)(5).

(d) Viable neonates. A neonate, after delivery, that has been determined to be viable may be included in research only to the extent permitted by and in accord with the requirements of subparts A and D of this part.

V. Research Involving, After Delivery, The Placenta, The Dead Fetus Or Fetal Material

(a) Research involving, after delivery, the placenta; the dead fetus; macerated fetal material; or cells, tissue, or organs excised from a dead fetus, shall be conducted only in accord with any applicable federal, state, or local laws and regulations regarding such activities.

(b) If information associated with material described in paragraph (a) of this section is recorded for research purposes in a manner that living individuals can be identified, directly or through identifiers linked to those individuals, those individuals are research subjects and all pertinent subparts of this part are applicable.

VI. Research Not Otherwise Approvable Which Presents An Opportunity To Understand, Prevent, Or Alleviate A Serious Problem Affecting The Health Or Welfare Of Pregnant Women, Fetuses, Or Neonates

The Secretary will conduct or fund research that the IRB does not believe meets the requirements of [§46.204](#) or [§46.205](#) only if:

(a) The IRB finds that the research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of pregnant women, fetuses or neonates; and

(b) The Secretary, after consultation with a panel of experts in pertinent disciplines (for example: science, medicine, ethics, law) and following opportunity for public review and comment, including a public meeting announced in the FEDERAL REGISTER, has determined either:

- That the research in fact satisfies the conditions of Section III above, as applicable; or
- The following:
 - (i) The research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of pregnant women, fetuses or neonates;
 - (ii) The research will be conducted in accord with sound ethical principles; and
 - (iii) Informed consent will be obtained in accord with the informed consent provisions of subpart A and other applicable subparts of this part.

PROTECTION OF PRISONERS IN RESEARCH

The regulations in this policy are derived from SubPart C of The Code of Federal Regulations Title 45, Public Welfare, Department of Health and Human Services, Part 46, Protections of Human Subjects, and are applicable to all biomedical and behavioral research conducted or supported by the Department of Health and Human Services and The University of Texas at Tyler involving prisoners as subjects.

Nothing in this policy shall be construed as indicating that compliance with the procedures set forth in this policy will authorize research involving prisoners as subjects, to the extent such research is limited or barred by applicable state or local laws.

Any protocol involving prisoners as subjects shall be conducted only through a full board review process.

The requirements of this policy are in addition to those imposed under the Common Rule, Basic HHS Policy for Protection of Human Research Subjects (<http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm#subparta>)

I. Purpose

Prisoners may be under constraints because of their incarceration which could affect their ability to make a truly voluntary and uncoerced decision whether or not to participate as subjects in research. It is the purpose of this subpart (Subpart C) to provide additional safeguards for the protection of prisoners involved in activities to which this subpart is applicable.

II. Definitions

(a) *Secretary* means the Secretary of Health and Human Services and any other officer or employee of the Department of Health and Human Services to whom authority has been delegated.

(b) *DHHS* means the Department of Health and Human Services.

(c) *Prisoner* means any individual involuntarily confined or detained in a penal institution. The term is intended to encompass individuals sentenced to such an institution under a criminal or civil statute, individuals detained in other facilities by virtue of statutes or commitment procedures (forensic psychiatric clients or persons ruled incompetent to stand trial) which provide alternatives to criminal prosecution or incarceration in a penal institution, and individuals detained pending arraignment, trial, or sentencing.

(d) *Minimal risk* is the probability and magnitude of physical or psychological harm that is normally encountered in the daily lives, or in the routine medical, dental, or psychological examination of healthy persons.

III. Composition of Institutional Review Boards Where Prisoners Are Involved

In addition to satisfying the requirements in [§46.107](#) which involves IRB membership as it relates to research regarding prisoners, the UT Tyler IRB carrying out responsibilities under this part* with respect to research covered by this subpart, shall also meet the following specific requirements:

- (a) A majority of the UT Tyler IRB (exclusive of prisoner members) shall have no association with the prison(s) involved, apart from their membership on the UT Tyler IRB.
- (b) At least one member of the UT Tyler IRB shall be a prisoner, or a prisoner representative/advocate with appropriate background and experience to serve in that capacity.

IV. Additional Duties of the UT Tyler IRB Where Prisoners Are Involved

(a) In addition to all other responsibilities prescribed for the UT Tyler IRB under this part, the UT Tyler IRB shall review research covered by this subpart and approve such research only if it finds that:

- The research under review represents one of the categories of research permissible under Section V of this policy, (a)(2nd bullet);
- Any possible advantages accruing to the prisoner through his or her participation in the research, when compared to the general living conditions, medical care, quality of food, amenities and opportunity for earnings in the prison, are not of such a magnitude that his or her ability to weigh the risks of the research against the value of such advantages in the limited choice environment of the prison is impaired;
- The risks involved in the research are commensurate with risks that would be accepted by non-prisoner volunteers;
- Procedures for the selection of subjects within the prison are fair to all prisoners and immune from arbitrary intervention by prison authorities or prisoners. Unless the principal investigator provides to the UT Tyler IRB justification in writing for following some other procedures, control subjects

must be selected randomly from the group of available prisoners who meet the characteristics needed for that particular research project;

- The information is presented in language which is understandable to the subject population;
- Adequate assurance exists that parole boards will not take into account a prisoner's participation in the research in making decisions regarding parole, and each prisoner is clearly informed in advance that participation in the research will have no effect on his or her parole; and
- Where the UT Tyler IRB finds there may be a need for follow-up examination or care of participants after the end of their participation, adequate provision has been made for such examination or care, taking into account the varying lengths of individual prisoners' sentences, and for informing participants of this fact.

(b) The institution shall certify to the Secretary, in such form and manner as the Secretary may require, that the duties of the UT Tyler IRB under this section have been fulfilled. Federally funded, IRB-approved research involving prisoners must be reviewed by the Office for Human Research Protections (OHRP) before the study may be initiated. In addition, research that falls into categories 3 or 4 described above requires federal consultation and approval. If research is not conducted or supported by HHS, these requirements do not apply.

(c) The UT Tyler IRB shall carry out such other duties as may be assigned by the Secretary.

V. Permitted Research Involving Prisoners

(a) Biomedical or behavioral research conducted or supported by DHHS may involve prisoners as subjects only if:

- The institution responsible for the conduct of the research has certified to the Secretary that the Institutional Review Board has approved the research under Section IV of this policy; and
- In the judgment of the Secretary the proposed research involves solely the following:
 - (i) Study of the possible causes, effects, and processes of incarceration, and of criminal behavior, provided that the study presents no more than minimal risk and no more than inconvenience to the subjects;

(ii) Study of prisons as institutional structures or of prisoners as incarcerated persons, provided that the study presents no more than minimal risk and no more than inconvenience to the subjects;

(iii) Research on conditions particularly affecting prisoners as a class (for example, vaccine trials and other research on hepatitis which is much more prevalent in prisons than elsewhere; and research on social and psychological problems such as alcoholism, drug addiction, and sexual assaults) provided that the study may proceed only after the Secretary has consulted with appropriate experts including experts in penology, medicine, and ethics, and published notice, in the FEDERAL REGISTER, of his intent to approve such research; or

(iv) Research on practices, both innovative and accepted, which have the intent and reasonable probability of improving the health or well-being of the subject. In cases in which those studies require the assignment of prisoners in a manner consistent with protocols approved by the IRB to control groups which may not benefit from the research, the study may proceed only after the Secretary has consulted with appropriate experts, including experts in penology, medicine, and ethics, and published notice, in the FEDERAL REGISTER, of the intent to approve such research.

(b) Except as provided in paragraph (a) of this section, biomedical or behavioral research conducted or supported by DHHS shall not involve prisoners as subjects.

VI. Specific Items to include in the IRB Application

- A. A statement to indicate the research involves one of the following:
1. The study of the possible causes, effects, or processes of incarceration and of criminal behavior, provided that the study presents no more than minimal risk and no more than an inconvenience to the participants.
 2. The study of prisons as institutional structures or of prisoners as incarcerated persons, provided that the study presents no more than minimal risk and no more than inconvenience to the participants.
 3. Research on the conditions particularly affecting prisoners as a class of people (for example, research on hepatitis which is much more prevalent in prisons than elsewhere; and research on social and psychological problems such as alcoholism, drug addiction, and sexual assaults). [HHS

funded or conducted research in this category may proceed only after the Secretary (through OHRP) has consulted with the appropriate experts including experts in penology, medicine, and ethics, and published notice in the Federal Register, of the intent to approve such research. For research that is not HHS funded or conducted, the need to convene an expert panel will be determined on a protocol per protocol basis.]

4. Research on practices, both innovative and accepted, which have the intent and reasonable probability of improving the health or well-being of the participant. [In cases in which the study protocol design is such that it is required to assign prisoners to control groups which may not benefit from the research, HHS funding of conducted research may proceed only after the Secretary (through OHRP) has consulted with the appropriate experts including experts in penology, medicine, and ethics, and published notice in the Federal Register, of the intent to approve such research. For research that is not HHS funded or conducted, the need to convene an expert panel will be determined on a protocol per protocol basis.]
- B. A statement describing the correctional facility(ies) where the research will occur. Include the name, type of facility, and indicate if it is a local, state, or federal facility.
 - C. A description of the criteria that was used in selecting the correctional facility(s).
 - D. A description of the procedures for the selection of participants. The selection process within the correctional facility must be fair to all prisoners and not expose participants or non-participants (those declining to participate) to stigmatization, harassment, prejudice, or retaliatory treatment. Assurance that the procedures for assignment to various groups (e.g. experimental, control) within the research should also be designed to be fair.
 - E. A description of the possible advantages for prisoners if they participate. Advantages must not be of the magnitude that they will unduly influence the prisoner's ability to weigh the risks of the research against the value of such advantages.
 - F. A description of the risks to prisoners involved in the research and compare the similarities and differences to the risks that would be likely be deemed minimal or reasonable by non-prisoner volunteers.
 - G. Description of how the PI will ensure there is no arbitrary influence or intervention by prison authorities regarding the selection, assignment, and withdrawal of prisoners during the study.

- H. Description of the provisions made to ensure that parole board will not have access to information related to the prisoners' participation in the research. If the parole board will have access to the information, the PI must verify that the parole board will not use the information when considering the prisoners' parole.
- I. A statement concerning whether the PI anticipates the need for follow-up examinations or care for participants after the end of their participation; even if a prisoner does not complete the study (e.g. psychological counseling). Also, describing the provisions for the follow-up examinations or care after participation has ended (e.g. how often, how long will the care be available, and under what conditions).
- J. Describe the protocol for prisoners that are released, transferred, or moved from the primary research site during their research participation and before completing the study. (For example, would there be follow-up, would data continue to be collected?)

Investigators must become certified through the Secretary to conduct DHH funded research. For assistance with this, contact the Office of Research & Scholarship or the IRB Chair.

POLICY ON INFORMED CONSENT OF CHILDREN

This policy applies to all research involving children as subjects, conducted or supported by the Department of Health and Human Services and/or The University of Texas at Tyler. In addition to this policy, refer to UT Tyler's Protection Of Children Involved In Research for any research involving human subjects under the age of 18 years.

I. Definitions

(a) *Children* are persons who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted.

(b) Assent means a child's affirmative agreement to participate in research. Mere failure to object should not, absent affirmative agreement, be construed as assent.

(c) *Permission* means the agreement of parent(s) or guardian to the participation of their child or ward in research.

(d) *Parent* means a child's biological or adoptive parent.

(e) *Guardian* means an individual who is authorized under applicable State or local law to consent on behalf of a child to general medical care.

II. Age Requirements for Assent

Due to variations in child development maturity levels, these are to serve as guidelines.

- For children 6 years of age and under: No actions, parental consent only
- For children 7-12 years of age: Child must be able to provide verbal agreement in addition to parental consent; if child verbally disagrees, no coercion must take place by parent or other
- For children 13-17 years of age: Written assent by child and written consent by parent required

III. Documentation means of the Assent shall be established by the IRB

PROTECTION OF CHILDREN INVOLVED IN RESEARCH

The policies in this document are derived from: <http://www.hhs.gov/ohrp/children/>

I. To What Do These Regulations Apply?

- a. This policy applies to all research involving children as subjects, conducted or supported by the Department of Health and Human Services and/or The University of Texas at Tyler.
 - This includes research conducted by Department/UT Tyler employees, except that each head of an Operating Division of the Department may adopt such nonsubstantive, procedural modifications as may be appropriate from an administrative standpoint.
 - It also includes research conducted or supported by the Department of Health and Human Services outside the United States, but in appropriate circumstances, the Secretary may, under paragraph (i) of [§46.101](#) of subpart A (see <http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm#46.101>), waive the applicability of some or all of the requirements of these regulations for research of this type.

- b. Exemptions to this policy include [taken from 46.101(b)(1) and (b)(3) through(b)(6)], and partial exemption to (b)(2) are listed below. However, only the IRB must make final determination as to any exemptions that may be covered.
 - Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.
 - Research involving survey or interview procedures or observations of public behavior does not apply to research covered by this policy except for research involving observation of public behavior when the investigator(s) do not participate in the activities being observed.
 - Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under paragraph (b)(2) of this section, if the federal statute(s) require(s) without exception that the

confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

- Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.
 - Research and demonstration projects which are conducted by or subject to the approval of department or agency heads, and which are designed to study, evaluate, or otherwise examine:
 - (i) Public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs.
 - Taste and food quality evaluation and consumer acceptance studies, (i) if wholesome foods without additives are consumed or (ii) if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.
- c. The exceptions, additions, and provisions for waiver as they appear in paragraphs (c) through (i) of [§46.101](http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm#46.101) of [subpart A](#) (see: <http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm#46.101>) are applicable to this policy.

II. Definitions

The definitions in [§46.102](http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm#46.102) of subpart A (see: <http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm#46.102>) shall be applicable to this policy as well. In addition, as used in this policy:

- *Children* are persons who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted.
- *Assent* means a child's affirmative agreement to participate in research. Mere failure to object should not, absent affirmative agreement, be construed as assent.
- *Permission* means the agreement of parent(s) or guardian to the participation of their child or ward in research.

- *Parent* means a child's biological or adoptive parent.
- *Guardian* means an individual who is authorized under applicable State or local law to consent on behalf of a child to general medical care.

III. UT Tyler IRB Duties

In addition to other responsibilities assigned to the UT Tyler IRB under this part, the UT Tyler IRB shall review research covered by this policy and approve only research which satisfies the conditions of all applicable sections of this policy. Expert consultants shall be part of the review process for all categories except “a”.

A. Research not involving greater than minimal risk

HHS/UT Tyler will conduct or fund research in which the UT Tyler IRB finds that no greater than minimal risk to children is presented, only if the IRB finds that adequate provisions are made for soliciting the assent of the children and the permission of their parents or guardians, as set forth in [§46.408](#). Therefore, no research proposals using children as subjects will be considered as exempt from IRB review.

B. Research involving greater than minimal risk but presenting the prospect of direct benefit to the individual subjects

HHS/UT Tyler will conduct or fund research in which the UT Tyler IRB finds that more than minimal risk to children is presented by an intervention or procedure that holds out the prospect of direct benefit for the individual subject, or by a monitoring procedure that is likely to contribute to the subject's well-being, only if the IRB finds that:

1. The risk is justified by the anticipated benefit to the subjects;
2. The relation of the anticipated benefit to the risk is at least as favorable to the subjects as that presented by available alternative approaches; and
3. Adequate provisions are made for soliciting the assent of the children and permission of their parents or guardians, as set forth in [§46.408](#)

C. Research involving greater than minimal risk and no prospect of direct benefit to individual subjects, but likely to yield generalizable knowledge about the subject's disorder or condition.

HHS/UT Tyler will conduct or fund research in which the UT Tyler IRB finds that more than minimal risk to children is presented by an intervention or procedure that does not hold out the prospect of direct benefit for the

individual subject, or by a monitoring procedure which is not likely to contribute to the well-being of the subject, only if the IRB finds that:

1. The risk represents a minor increase over minimal risk;
2. The intervention or procedure presents experiences to subjects that are reasonably commensurate with those inherent in their actual or expected medical, dental, psychological, social, or educational situations;
3. The intervention or procedure is likely to yield generalizable knowledge about the subjects' disorder or condition which is of vital importance for the understanding or amelioration of the subjects' disorder or condition; and
4. Adequate provisions are made for soliciting assent of the children and permission of their parents or guardians, as set forth in [§46.408](#).

D. Research not otherwise approvable which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children

HHS/UT Tyler will conduct or fund research that the IRB does not believe meets the requirements of Sections (a), (b), or (c) only if:

(a) The UT Tyler IRB finds that the research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of children; and

(b) The DHHS Secretary, after consultation with a panel of experts in pertinent disciplines (for example: science, medicine, education, ethics, law) and following opportunity for public review and comment, has determined either:

- That the research in fact satisfies the conditions of Sections (IIIa), (IIIb), or (IIIc), as applicable, or
- The following:
 - (i) The research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of children;
 - (ii) The research will be conducted in accordance with sound ethical principles;

(iii) Adequate provisions are made for soliciting the assent of children and the permission of their parents or guardians, as set forth in Section IV.

IV. Requirements for Permission by Parents or Guardians and for Assent by Children

(a) In addition to the determinations required under other applicable sections of this policy, the UT Tyler IRB shall determine that adequate provisions are made for soliciting the assent of the children, when in the judgment of the IRB the children are capable of providing assent.

- See UT Tyler Informed Consent of Children Policy in addition to below
- In determining whether children are capable of assenting, the IRB shall take into account the ages, maturity, and psychological state of the children involved.
- This judgment may be made for all children to be involved in research under a particular protocol, or for each child, as the IRB deems appropriate.
- If the IRB determines that the capability of some or all of the children is so limited that they cannot reasonably be consulted or that the intervention or procedure involved in the research holds out a prospect of direct benefit that is important to the health or well-being of the children and is available only in the context of the research, the assent of the children is not a necessary condition for proceeding with the research.
- Even where the IRB determines that the subjects are capable of assenting, the IRB may still waive the assent requirement under circumstances in which consent may be waived in accord with [§46.116](#) of [Subpart A](#) (see <http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm#46.116> as it relates to informed consent).

(b) In addition to the determinations required under other applicable sections of this subpart, the UT Tyler IRB shall determine, in accordance with and to the extent that consent is required by [§46.116](#) of [Subpart A](#) (see: <http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm#46.116>), that:

- Adequate provisions are made for soliciting the permission of each child's parents or guardian.
- Where parental permission is to be obtained, the IRB may find that the permission of one parent is sufficient for research to be conducted under Section (IIIa) or Section (IIIb) of this policy.

- Where research is covered by Section (IIIc) and Section (III d) of this policy and permission is to be obtained from parents, both parents must give their permission unless one parent is deceased, unknown, incompetent, or not reasonably available, or when only one parent has legal responsibility for the care and custody of the child.

(c) Exceptions to parental or guardian permission: In addition to the provisions for waiver contained in [§46.116](#) of [subpart A](#), (see: <http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm#46.116>):

- If the UT Tyler IRB determines that a research protocol is designed for conditions or for a subject population for which parental or guardian permission is not a reasonable requirement to protect the subjects (for example, neglected or abused children), it may waive the consent requirements in Subpart A of this part (Basic HHS Policy for Protection of Human Research Subjects: see: <http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm#subparta>) and paragraph (b) of this Section, provided an appropriate mechanism for protecting the children who will participate as subjects in the research is substituted, and provided further that the waiver is not inconsistent with federal, state, or local law. The choice of an appropriate mechanism would depend upon the nature and purpose of the activities described in the protocol, the risk and anticipated benefit to the research subjects, and their age, maturity, status, and condition.

(d) Permission by parents or guardians shall be documented in accordance with and to the extent required by [§46.117](#) of [subpart A](#) (see: <http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm#46.117>).

(e) When the UT Tyler IRB determines that assent is required, it shall also determine whether and how assent must be documented.

V. Wards

(a) Children who are wards of the state or any other agency, institution, or entity can be included in research approved under Section III(c) and Section III(d) of this policy only if such research is:

- Related to their status as wards; or
- Conducted in schools, camps, hospitals, institutions, or similar settings in which the majority of children involved as subjects are not wards.

(b) If the research is approved under paragraph (a) of this Section, the UT Tyler IRB shall require appointment of an advocate for each child who is a ward, in addition to any other individual acting on behalf of the child as guardian or in loco parentis. One individual may serve as advocate for more than one child. The advocate shall be an individual who has the background and experience to act in, and agrees to act in, the best interests of the child for the duration of the child's participation in the research and who is not associated in any way (except in the role as advocate or member of the IRB) with the research, the investigator(s), or the guardian organization.

Policy on Clinical Trial Registration and Results Dissemination for Federally Funded Studies

This policy was taken from the following sites:

https://grants.nih.gov/grants/policy/nihgps/html5/section_4/4.1.3_clinical_trials_registration_and_reporting_in_clinicaltrials.gov_requirement.htm

<https://grants.nih.gov/policy/clinical-trials/reporting/understanding/nih-policy.htm>

Effective for grant applications submitted on or after January 18, 2017, that request support for the conduct of a clinical trial that is initiated on or after the policy's effective date, the NIH Policy on Dissemination of NIH-funded Clinical Trial Information establishes the expectation that all NIH-funded recipients and investigators conducting clinical trials, funded in whole or in part by the NIH, **will ensure that their clinical trials are registered at, and that summary results information is submitted to, ClinicalTrials.gov for public posting.**

The purpose of the policy is to promote broad and responsible dissemination of information from NIH-funded clinical trials through ClinicalTrials.gov. Disseminating this information supports the NIH mission to advance the translation of research results into knowledge, products, and procedures that improve human health.

This policy is complementary to requirements in the Clinical Trial Registration and Results Information Submission regulation at 42 CFR Part 11, hereinafter referred to as the regulation.

This policy applies to all NIH-funded clinical trials regardless of study phase, type of intervention, or whether they are subject to the regulation. For example, NIH-funded phase 1 clinical trials of an FDA-regulated product are covered by this policy as are clinical trials studying interventions not regulated by the FDA, such as behavioral interventions. As such, the policy encompasses all NIH-funded clinical trials, including [applicable clinical trials](#) subject to the regulation. **All NIH-funded clinical trials will be expected to register and submit results information to ClinicalTrials.gov according to the timelines described in the regulation.**

This policy does not apply to a clinical trial that uses NIH-supported infrastructure but does not receive NIH funds to support its conduct.

Applicants seeking NIH funding for clinical trials will be required to submit a plan that will address how the expectations of this policy will be met. Recipients and investigators conducting clinical trials funded in whole or in part by the NIH are required to comply with all terms and conditions of award, including following their plan for the dissemination of NIH-funded clinical trial information.

The signature of the AOR on the grant or progress report form certifies that, for any clinical trials funded under the NIH award, the recipient and all investigators are in compliance with the recipient's clinical trial information dissemination plan.

Responsibilities of recipients and investigators will fall within one of the following three categories:

1. If the NIH-funded clinical trial is an [applicable clinical trial](#) under the regulation and the recipient is the responsible party, the recipient will ensure that all regulatory requirements are met.
2. If the NIH-funded clinical trial is an [applicable clinical trial](#) under the regulation but the recipient is not the responsible party, the recipient will coordinate with the responsible party to ensure that all regulatory requirements are met.
3. If the NIH-funded clinical trial is not an [applicable clinical trial](#) under the regulation, the recipient will be responsible for carrying out the tasks and meeting the timelines described in regulation. Such tasks include registering the clinical trial in ClinicalTrials.gov and submitting results information to ClinicalTrials.gov.

In addition, informed consent documents for clinical trials within all three categories are to include a specific statement relating to posting of clinical trial information at ClinicalTrials.gov.

Each NIH-funded clinical trial should have only one entry in ClinicalTrials.gov that contains its registration and results information. Recipients need not and should not create a separate record of the [applicable clinical trial](#) to comply with this policy.

Definitions

Clinical Trial. For purposes of this policy, a "clinical trial" means "a research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes."³ This definition encompasses phase 1 trials of FDA-regulated drug and biological products, small feasibility studies of FDA-regulated device products, and studies of any intervention not regulated by the FDA, e.g., behavioral interventions. This definition of

"clinical trial"⁴ is broader than the term "applicable clinical trial" as defined in the regulation.⁵

Responsible Party. In the policy, the awardee or the investigator is responsible for meeting the expectations of this policy. In the regulation, a "responsible party" means, in part, "with respect to a clinical trial, the sponsor of the clinical trial, as defined in 21 CFR 50.3 (or any successor regulation); or the principal investigator of such clinical trial if so designated by a sponsor, grantee, contractor, or awardee, so long as the principal investigator is responsible for conducting the trial, has access to and control over the data from the clinical trial, has the right to publish the results of the trial, and has the ability to meet all of the requirements under [42 CFR Part 11] for the submission of clinical trial information."⁶

Primary Completion Date. In the policy, this term has the same meaning as the term "primary completion date" in the regulation, which is "the date that the final subject was examined or received an intervention for the purposes of final collection of data for the primary outcome, whether the clinical trial concluded according to the pre-specified protocol or was terminated."⁷

Registration Information. In the policy, this term has the same meaning as the term "registration information" in the regulation. In the regulation, registration information consists of descriptive information, recruitment information, location and contact information, and administrative data.⁸

Results Information. In the policy, this term has the same meaning as the term "results information" in the regulation. In the regulation, results information includes participant flow, demographic and baseline characteristics, outcomes and statistical analyses, adverse events, the protocol and statistical analysis plan, and administrative information.⁹

Compliance

If the clinical trial is NIH-funded in whole or in part, expectations for clinical trial registration and summary results submission will be included in the terms and conditions of the award. Failure to comply with the terms and conditions of the NIH award may provide a basis for enforcement actions, including termination, consistent with 45 CFR 75.371 and/or other authorities, as appropriate. If the NIH-funded clinical trial is also an applicable clinical trial, non-compliance with the requirements specified in 42 USC 282(j) and 42 CFR Part 11 may also lead to the actions described in 42 CFR 11.66.

Effective Date

This policy is effective January 18, 2017.

Footnotes

1. ClinicalTrials.gov is operated by the National Library of Medicine within the NIH.
2. The Clinical Trial Registration and Results Information Submission regulation at 42 CFR Part 11 was issued in the Federal Register in September 2016. The regulation implements section 402(j) of the Public Health Service Act.
3. Further information about this definition is available from the NIH Office of Science Policy at <http://osp.od.nih.gov/office-clinical-research-and-bioethics-policy/clinical-research-policy/clinical-trials>.
4. Note that the regulation also includes a definition of "clinical trial." That definition is "a clinical investigation or a clinical study in which human subject(s) are prospectively assigned, according to a protocol, to one or more interventions (or no intervention) to evaluate the effect(s) of the intervention(s) on biomedical or health related outcomes" (see 42 CFR 11.10 (a)). For the purposes of this policy, the regulatory definition and the definition in this policy are treated as synonymous.
5. In the regulation, applicable clinical trial is defined as an applicable device clinical trial or an applicable drug clinical trial. The regulation defines an applicable device clinical trial to mean, in part, "a prospective clinical study of health outcomes comparing an intervention with a device product subject to section 510(k), 515, or 520(m) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(k), 21 U.S.C. 360e, 21 U.S.C. 360j(m)) against a control in human subjects (other than a small clinical trial to determine the feasibility of a device product, or a clinical trial to test prototype device products where the primary outcome measure relates to feasibility and not to health outcomes)." The regulation defines an applicable drug clinical trial to mean, in part, "a controlled clinical investigation, other than a phase 1 clinical investigation, of a drug product subject to section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) or a biological product subject to section 351 of the Public Health Service Act (42 U.S.C. 262), where "clinical investigation" has the meaning given in 21 CFR 312.3 (or any successor regulation) and "phase 1" has the meaning given in 21 CFR 312.21 (or any successor regulation).
6. See 42 CFR 11.10 (a) and 42 CFR 11.4.
7. See the complete definition at 42 CFR 11.10 (a).
8. See 42 CFR 11.10 (b) and 42 CFR 11.28 for the specific data elements.
9. See 42 CFR 11.28 for complete results information and specific data elements.

Policy for Data and Safety Monitoring of Human Subject Research Studies

Purpose

The National Institutes of Health (NIH) requires the monitoring activities of all NIH-sponsored or -conducted clinical studies to be commensurate with their risks, nature, size, and complexity.

It is recognized that Institutes (I) and Centers (C) within NIH may have varying guidelines for DSM activities that are mandated for receipt of NIH IC specific funding. Hence, it is the PIs responsibility to check with individual institutes and centers for specific requirements. This policy presents broad guidelines and related definitions and procedures to follow when a DSM protocol is needed for an NIH study.

Definitions

Data and Safety Monitoring Plan (DSMP) - A written description of the procedures for reviewing accumulated data in an ongoing research protocol to ensure the safety of research participants and the continuing validity and scientific merit of the protocol.

NIH Definition of a Clinical Trial - A research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes.

Data and Safety Monitoring Board (DSMB) (also known as a Data and Safety Monitoring Committee [DSMC] or Data Monitoring Committee [DMC]) - A formal committee made up of experts, who are not the trial organizers or investigators, which reviews on a regular basis accumulating data from one or more ongoing clinical trials.

Policy Details

Human Studies Requiring a DSMP

Appropriate mechanisms for data and safety monitoring may range from monitoring by the Principal Investigator (PI) or co-investigator (Co-I), to monitoring by an independent DSMB.

For example:

1. Monitoring by the PI or Co-PI or other designated individual may be appropriate for protocols involving no more than minimal risk or a minor increase over minimal risk and that are conducted at a single site.
2. Monitoring by an individual or team that is independent of the protocol may be appropriate for protocols that pose more than minimal risk to the subjects, for multi-site protocols, for studies where an investigator has a potential conflict of interest, or for some FDA-regulated research.
3. Because individual ICs may have varying requirements for DSMPs, PIs and UT Tyler IRB must refer to that specific IC for outlining protocol-specific DSMP.

4. When required as part of a protocol the DSMP shall be part of the IRB application materials as a separate Word document.

Implementation

Broad Requirements for a DSMP include:

1. Monitoring study safety;
2. Minimizing research- associated risk;
3. Protecting the confidentiality of participant data; and
4. Identifying, reviewing, and reporting adverse events and unanticipated problems to the IRB(s), NIEHS, and Food and Drug Administration (FDA) (if applicable).

Specific Requirements for a DSMP will address the following as appropriate:

1. Monitoring mechanism
 - a. The individual(s) who will be responsible for the data and safety monitoring should be identified.
 - b. When a DSMB is the monitor, the PI will provide the names of the DSMB chair, secretary and members and who is establishing the DSMB.
2. Frequency of monitoring: Monitoring should be performed on a regular basis at intervals determined before the study begins.
3. Stop or change rules: Specific criteria to be used for interrupting enrollment or administration of study products or procedures and formal guidelines to be used for stopping one or more study arms should be provided.
4. Advanced plans for any interim analyses and/or futility analyses.
5. Information to be monitored: In describing what information will be monitored, consideration will be given to the following, as appropriate:
 - a. An evaluation of the progress of the research study, including assessments of data quality and timeliness and participant recruitment, accrual and retention consistent with plans for diversity and generalizability.
 - b. A review of adverse event and outcome data to determine whether there is any change to the risk/benefit ratio of the study, if a stop rule has been invoked, a study endpoint has been reached, and whether the study should continue as originally designed, be changed, or be stopped.

- c. An assessment of external factors or relevant information (e.g., developments in the literature, results of related studies, etc.) that may have an impact on the safety of participants or on the ethics of the research study.

6. Communication:

- a. The lines of communication between the PI, the study sites, research teams, the data and safety monitor/committee, the IRB, the FDA, and other individuals at the NIH should be identified.
- b. PIs for studies must submit, at a minimum, annual progress reports to the PO for extramural studies or to the CD for intramural studies that:
 - 1. Confirm adherence to the DSMP.
 - 2. Include a summary of any data and safety monitoring issues that occurred since the previous reporting period.
 - 3. Describe any changes in the research protocol or the DSMP that may or does affect risk.
 - 4. Provide all new and continuing IRB approvals.

Functions and Operations for DSMBs

DSMBs:

- 1. Are convened to protect the interests of research subjects and ensure that they are not exposed to undue risk.
- 2. Are advisory to the sponsor of the study and operate without undue influence from any interested party, including study investigators, UT Tyler IRB staff, or any IC.
- 3. Must be informed by the relevant IC of their ability to access unmasked data.
- 4. Are encouraged to review interim analyses of study data in an unmasked fashion as needed to assess the risks and benefits in the study.

For an extramural protocol, certification of IRB approval(s), and the DSMB plan if needed, must be sent electronically to the appropriate PO and approved before a proposed human subject research project may begin at a site. All other related documents for an extramurally funded study will also be sent to the PO and archived in the main grant file as a permanent repository of study decisions and progress.

For intramural studies, all supporting documents will be sent to the NIH IRB of record after approval by the CD.

For multi-site studies, the study sites initiating a protocol and the Data Coordinating Center (DCC) must submit certification of IRB approval as well as assurance that IRB approvals have been obtained from all study sites, are on file, and are available to the appropriate IC upon request.

For extramural studies, the DSMB members will be proposed, after PI consultation, by the awardee institution, who will assure that there are no conflicts of interest.

For intramural studies, board members will be proposed, after PI consultation, by the CD. The DSMB will meet after IRB approval of the study but before enrollment of subjects.

Each DSMB must operate according to the provisions of a formal charter (see the National Institute of Aging Template, attached). Charters should address appointment and responsibilities of members, terms of appointment, scheduling and format of meetings, quorum requirements, distribution and disposition of meeting materials, preparation of meeting summaries and written recommendations, management of conflict of interest, voting rights, and other procedural matters.

Use of Radioactive Equipment in Research

Any human subjects research using radiation shall be approved by The University of Texas at Tyler Institutional Review Board (IRB) as required by Title 45, Code of Federal Regulations (CFR), Part 46 and Title 21, CFR, Part 56. The IRB shall include at least one practitioner of the healing arts to direct any use of radiation in accordance with §289.231(b)(1) of this title.

Until further notice, Dr. _____ will serve as the medical practitioner consultant for any human subjects research review that involves the use of radiation equipment. No protocol involving human subjects and use of radiation will be approved without approval of Dr. _____. In the event Dr. _____ is not available as a consultant, another qualified health care practitioner will serve as consultant.

UNAFFILIATED INVESTIGATOR AGREEMENT

An independent investigator not employed at UT Tyler may engage in research under the UT Tyler FWA under the following conditions:

- Investigator is sponsored by an employee of UT Tyler who is certified in a UT Tyler approved human subjects course or program. The UT Tyler employee must agree to sponsor outside investigator by submitting an electronic to the UT Tyler IRB.
- Investigator agrees to abide by conditions established for human research by the FWA terms.
- Investigator abides by all other relevant policies established for human research by the UT Tyler IRB, including **Responsibilities of the Principal Investigator and Policy and Procedures for Proposal Submission, Review, Suspension and Termination of Research Proposals, and any other relevant policies that pertain to the proposed research project.**

All unaffiliated investigators must agree to the above and sign the “Unaffiliated Investigator Agreement” Form prior to IRB approval.

EXTERNAL REVIEWS CONDUCTED BY THE UNIVERSITY OF TEXAS AT TYLER INSTITUTIONAL REVIEW BOARD

The UT Tyler IRB may review proposals for human subjects protection for research conducted by PIs and co-investigators not affiliated with UT Tyler. The fee for conducting reviews will be negotiated with the PI at the time the request for the review is made.

A letter of agreement between the UT Tyler Office of Research & Scholarship and the PI must first be completed.

Any external proposal submitted to the UT Tyler IRB will undergo the same scrutiny as any other proposal, and the PI and all associated individuals and entities will be accountable for following the policies and procedures of the UT Tyler IRB and will be subject to compliance and monitoring procedures.

**THE UNIVERSITY OF TEXAS AT TYLER
Institutional Review Board**

Review of IRB Policies, Procedures and Forms

Reviews of all policies and procedures used by the UT Tyler IRB will be conducted bi-annually on odd-numbered years of the beginning academic years, or more frequently as needed.

All forms used by the UT Tyler IRB will be conducted annually or more frequently as needed.

At the first meeting of the academic year, the chair shall designate members to review policies/procedures for relevancy and currency, and all forms for clarity and practicality for determining human subject protection.

The University of Texas at Tyler

Undergraduate and Graduate Student Course-Related Research Projects

Federal regulations require that research protocols involving human subjects be reviewed by an Institutional Review Board for the Protection of Human Subjects in Research (IRB). These regulations also allow certain types of studies to be exempted from IRB review. The University of Texas at Tyler (UT Tyler) abides by an approved "Federal Wide Assurance" assuring the Office for Human Research Protections (OHRP) the rights and welfare of human research subjects recruited to participate in research activities conducted under the auspices of the university are adequately protected.

In the case of a student course-related research project assignment, it may be difficult at times to distinguish between that which would require IRB review and that which is designed simply to provide an experience in research methodology. In some courses, students collect data by using professional research methods, even though the student's work is not expected to contribute to generalizable knowledge. Some of the methods involve human subjects and, in some instances, subjects may be placed at risk.

In an effort to clarify the matter, the UT Tyler- IRB has drafted the following guidelines for determining when institutional review and approval is necessary for projects that are part of an academic course:

Student projects that are solely classroom directed exercises (purpose of the student investigation is solely for the fulfillment of a course requirement) do not require IRB review if they meet all of the following criteria:

- (a) involve the learning of research techniques; AND
- (b) involve no more than minimal risk; AND
- (c) the data is recorded anonymously by the students (i.e., with no names, social security numbers, or any other codes that can be linked to a list of names, or the recorded data will not identify the subject through their behavior); AND
- (d) the data will not be used beyond the classroom environment (**i.e. will not be published, orally presented, presented at a conference, colloquium, departmental colloquium, poster presentation or used in further research by the student, other class members or the instructor**); AND
- (e) the research review category would normally fall under the exempt or expedited review categories (defined by [CFR 45 Part 46](#)).

If protocols/projects meet ALL of the above criteria, these projects shall be deemed to be "classroom exercises" and are not subject to review by the IRB.

In these cases, **the primary responsibility for assuring that the rights and welfare of human subjects are protected is delegated to the faculty member/instructor in accordance with Attachment A.** The faculty member/instructor shall take responsibility for communicating to students ethical principals of research, review/approve student research protocols prior to initiation of the research project, monitor students' research activities and reports of findings, and assure that the students' own work does not violate human subjects' protection.

If the instructor is not certain that all of the criteria above have been met, they should contact the IRB Chair. If the instructor/student has reason to believe they may wish to present the results of this research in an activity such as a poster presentation or colloquium, the protocol must go before the Board for approval.

* This policy does not apply to master's theses or doctoral dissertations. Those protocols must follow standard IRB review policies and procedures.

**The University of Texas at Tyler-Institutional Review Board
Undergraduate Student Course-Related Research Projects***

ATTACHMENT A

1. Ethical Principles for the Protection of Human Subjects of Research

- 1.1. Every person has the right to determine what shall be done to him or her, what activities he or she shall engage in and what risks he or she will take. Consequently, research on human subjects cannot be carried out without the subjects' competent, voluntary and informed consent.
- 1.2. No person should be placed at risk as a subject of research unless the risks are reasonable in relation to the anticipated benefits of the research.
- 1.3. The risks and burdens to subjects should not be unjustly distributed. The recruitment and selection of subjects should be reasonably related to the research and should not impose inequitable risks and burdens on any segment of society.
- 1.4. Special consideration and protection should be given in research to persons who may lack full capacity to secure their own rights and interests, due to age, mental capacity, involuntary custody, cultural barriers or other special circumstances.

2. Definitions

- 2.1. "Student Research" means any observation or intervention by a student as part of a course which is designed to develop or contribute to student learning or to general knowledge, and for which publication of findings outside class will not take place.
- 2.2. "Human Subject" means an individual about whom an investigator conducting research obtains: (1) data through intervention or interaction with the person, or (2) personally identifiable information.
- 2.3. "Student PI" means any student enrolled in a course at The University of Texas at Tyler who conducts research on human subjects as an assignment or project in the course (excluding master's or doctoral theses research which are not designated as classroom projects).
- 2.4. "Minimal risk" is the probability and magnitude of harm that is normally encountered in the daily lives of healthy individuals, or in the routine medical, dental or psychological examination of healthy individuals. Minimal risk does not involve data that, if made public, could place the subject at risk of criminal or civil liability, be damaging to the subject's

financial standing, employability, insurability, reputation, or be stigmatizing.

3. Responsibility of Instructors

- 3.1. Instructors of courses in which students do research involving human subjects must complete the UT Tyler IRB required Training Post prior to review/approval of any student project.
- 3.2. Instructors of courses in which students do research involving human subjects are responsible for informing students of the ethical principles for the protection of the human subjects of research and applicable policies and procedures.
- 3.3. Instructors of courses in which students do research involving human subjects are responsible for prior review of that research in accordance with these policies and procedures.

4. Instructor Review of Student Research

- 4.1. If student research involves passive observation of public behavior, poses no more than minimal risk, and subjects will remain anonymous or their identity will be kept confidential, instructors shall review and approve the research. Informed consent of subjects is not required. Examples of such research are:
 - a) observation of public behavior except where it is recorded in such a way that the subject can be identified directly or by identifiers linked to the subject and the subject's responses, if they became known, could place the subject at risk of legal liability or financial loss, or deals with sensitive aspects of behavior or use of alcohol;
 - b) research involving the collection or study of existing data, documents, records or specimens, if they are publicly available or if they are recorded in such a manner that subjects cannot be identified; or
 - c) observation in established or commonly accepted educational settings.
- 4.2. If student research involves intervention but poses no more than minimal risk, the course instructor will be responsible for the review and approval of the research. Informed consent of subjects is required. If the research involves more than minimal risk, it must be reviewed by the IRB as described in Section 5.

- a). The instructor is responsible to assess whether risk is more than minimal as defined in 2.4. If there is any question or doubt about the degree of risk posed by the research and if there is any possibility of more than minimal risk, the protocol must be reviewed under Section 5 below.
- b). The instructor must review and approve the procedures for obtaining informed consent and assure that they meet the requirements of The University of Texas at Tyler, Institutional Review Board prior to their use by student PIs.
- c). The instructor must review and approve the instruments, methods and procedures of the research protocol in their final form prior to their use by student PIs.
- d). The instructor must keep a record for at least one calendar year of research protocols which includes the research project title, the student PIs' names and the date of the instructors' review and approval.
- e). Examples of research which may be approved by the procedures of this section are:
 - i) research conducted in established or commonly accepted educational settings involving normal educational practices;
 - ii) research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), if the information is recorded in such a manner that the subjects cannot be identified directly or through identifiers linked to the subject;
 - iii) research on individual or group behavior or characteristics or individuals such as studies of perception, cognition, game theory, or test development, where the investigator does not manipulate subjects' behavior and the research will not stress the subjects;
 - iv) research involving survey or interview procedures except where responses are recorded in such a way that the subjects can be identified directly or through identifiers linked to the subject AND the subject's responses, if they became known, could place the subject at risk of criminal or civil liability, be damaging to the subject's financial standing, employability, insurability, reputation, or be stigmatizing;
 - v) moderate exercise by health volunteers;
 - vi) recording of data from subjects 18 years or older using noninvasive procedures routinely employed in clinical practices.

5. IRB Review of Student Research

- 5.1. If student research involves more than minimal risk, the research protocol must be submitted to and approved by the IRB prior to any data collection activity.
- 5.2. If the research protocol is generic (i.e., all student PIs will use the same instruments, methods and consent procedures), the course instructor will submit a regular IRB application form. Once approved by the IRB, the generic protocol may continue to be used by student PIs without further review by the IRB unless:
 - a) the protocol is changed;
 - b) there is a complaint from a subject;
 - c) there is an adverse reaction by a subject; or
 - d) there is a change in the research environment or new information that would indicate greater risk to human subjects than that assumed when the protocol was initially reviewed and approved.
- 5.3. Approvals for full board protocols are only valid for up to one calendar year. Renewed approval must be sought for projects extending beyond one year.

THE UNIVERSITY OF TEXAS AT TYLER

Special Subject Populations: Students

In general, research involving students of UT Tyler must adhere to any procedures involving the Family Educational Rights and Privacy Act (FERPA) regulations, which may be found at <https://www2.ed.gov/policy/gen/guid/fpco/ferpa/index.html>.

When investigators propose to recruit students from their own classes to participate in research, they need to consider that student participation in such research may not be truly voluntary because of a desire on the part of the students to appear cooperative, highly motivated, or because participation in research is a course requirement. However, participation of students in research, both as a participant and researcher, often has an important and legitimate educational purpose. As such, there must be a balance between this purpose and the possibility of coercion to participate in the research.

In short, due to the potential for undue influence, researchers generally should avoid recruiting subjects from their own classes. When recruiting from their own class is the only feasible way to do a study, researchers are expected to design the research in such a way that the potential for students to feel pressure is minimized. These steps include:

1. Any faculty involved in assigning grades to students may not be involved in recruiting participants, directly collecting data, or handling identifiable data until after final grades are posted.
2. Posting IRB approved advertisements throughout the university to recruit subjects from a broad base of students
3. Providing a number of research projects from which to choose, if participating as a subject in research is a course requirement
4. Providing alternative and equal methods for meeting course credit (or extra credit) requirements, such as attending a series of research presentations by faculty, writing a brief paper, or conducting one's own research. Alternatives to participating in research for extra credit must be equal in effort and time as participation in the research project.
5. Research participation should be self-motivated. Receipt of extra credit in a course for student research participation as a research subject is discouraged.

6. If incentives for participation are offered (e.g., extra course credit), the incentives should not be so large as to cause undue influence. Typically, this means that any credit or extra credit must be only a small portion of the total grade.
7. If possible, design the study so that the instructor is blind to the identity of the participants (at least until after the final grades have been assigned). For example, another researcher can run the study and keep any identifying information from the instructor. If a researcher designs a study in this way the following points are crucial:
 - a. *Before being asked to participate, potential subjects should be informed that the instructor will not know who did and who did not participate (at least until after the final grades have been assigned).*
 - b. *The research should be designed so that the instructor cannot infer who participated through indirect means (e.g., by seeing who walks into the laboratory, by getting a list of who earned extra credit for participating in the study).*

THE UNIVERSITY OF TEXAS AT TYLER

Special Subject Populations: Employees

Employees who are asked to volunteer as participants in research are considered a potentially vulnerable subject population because they may feel some pressure to participate, especially if the requesting Investigator is their supervisor or someone who might be in a position to influence their future.

Employees may volunteer to participate out of a belief that doing so will place them in good favor with the Investigator (e.g., participating will result in receiving recommendations, promotions, and the like), or that failure to participate will negatively affect their relationship with the Investigator.

This guidance outlines special ethical considerations that investigators and the UT Tyler IRB must make when employees are involved in human subjects research.

NOTE: PIs and co-investigators must take the supplementary CITI module: Vulnerable Subjects-Research Involving Workers/Employees (ID: 483) in addition to the SBR or Biomedical Courses.

General Guidelines

When investigators propose to recruit employees from any occupational setting, they need to consider the potential coercive nature of their choice to participate or not to participate.

As a general rule, due to the potential for perceived or undue influence to participate, workers or employees who desire to participate in the research must not be under the direct supervision of anyone who has access to identified data (e.g., PIs, those collecting data).

In addition, employees must not be recruited from a person who has any line of authority (direct or indirect), and all efforts must be taken that no one in direct lines of authority know of an employee's choice to participate or not to participate.

General Information for IRB Members

Being a member of the UT Tyler IRB is an honor and privilege in that you are being asked to ensure that any research reviewed demonstrates that the rights of human subjects are being protected.

Being knowledgeable about application of the components of the Belmont Report, the Common Federal Rule: Part 46 that mandates federal regulations for the conduct of research involving human subjects, and the UT Tyler policies and procedures is essential.

The UT Tyler IRB reviews all research conducted by UT Tyler investigators and research that is not affiliated with UT Tyler. All members of the UT Tyler IRB must complete the required orientation and education before being a part of the review process. In addition, at the first meeting of the academic year, members must establish a mechanism for conducting safety and monitoring reviews for the year.

All members must read and sign the "IRB Member Agreement" form (next page).

IRB MEMBER AGREEMENT

I have received a copy of *The Belmont Report* and the regulations at [45 CFR Part 46](#), including the criteria for IRB approval of research and the required elements of informed consent. As a member of the IRB, I agree to comply with the ethical principles outlined in these documents, which protect the rights and welfare of human subjects in research.

I also have been informed of my responsibilities with regard to the following:

Attendance. Members of the IRB are responsible for attending all convened meetings and staying until business has been completed, whenever possible. When attendance is not possible, IRB members must notify the IRB Chair, allowing sufficient time in advance of the meeting to locate an alternate, if necessary, to reach a quorum.

Confidentiality. Service on the IRB includes the review of documents that contain personal, confidential, and proprietary information. Members of the IRB are responsible for maintaining all committee proceedings and documents in strict confidence. Such information may not be used for any purpose other than the IRB review and may not be disclosed to anyone outside of the IRB unless permission is granted in writing by the UT Tyler Director of the Office of Research & Scholarship, the Institutional Official (IO).

Conflict of Interest Disclosure. It is the expectation of the University that IRB members will: a) read and abide by the UT Tyler Policy on Conflict of Interest and Commitment and related policies; b) submit a completed Conflict of Interest and Commitment Form to the Office of Research & Scholarship annually, within 30 days of a change of financial interest, or upon request; and c) voluntarily recuse themselves from situations that create, or appear to create, a conflict of interest. For example, in a convened meeting of the Board, members must leave the room during discussion and vote when they:

- have a significant financial or management interest (as defined by UT Tyler's Conflict of Interest and Commitment Policy¹) in the extramural sponsor or provider of the drug, device or test product;
 - are primary investigators, faculty sponsors, or other investigators in the project under review, or their spouse or child holds one of these roles; or
 - perceive any other circumstances that may directly affect their objectivity.
- Also, members may not serve as the primary reviewer of a protocol if they have, or are perceived as having, a conflict of interest or commitment.

Failure of persons to disclose conflicts of interest as a PI or as a reviewer is subject to disciplinary action by the University.

Participation. Members are responsible for reading protocol submissions and other documents prior to the convened meetings. Primary reviewers are to

complete and turn in their comments electronically by noon on the day before the meeting so that the Chair can prepare draft minutes and stipulation memos. Exceptions (e.g., urgent University business, personal emergencies, etc.) should be discussed with the Chair as soon as possible.

Regulatory Compliance. Members of the IRB are responsible for keeping abreast of and acting in accordance with all applicable federal regulations and policies, state laws, and UT Tyler policies that pertain to human subject protection.

I have read this form and agree to serve under the expectations described above.

Signature	Printed Name	Date
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¹ “Significant financial interests” are defined as (1) any equity interest that, when aggregated for the Faculty Member, Family or Associated Entity, meets either of the following tests: (a) is equal to or greater than \$10,000 in value, or (b) represents more than 5% ownership interest in any single Business Entity; or (2) salary, royalties, or other payments from a single Business Entity over the next 12 months may reasonably be expected to be equal to or greater than \$10,000.

STREAMLINING IRB MEETINGS: WHAT YOU CAN DO?

1. **Be prepared.** Come to the meeting having already read your protocols and with some notes jotted down to focus your verbal comments.
2. **Don't read the study title.** We all have an agenda in front of us. If we all used protocol numbers instead of titles, we could shave 20 minutes off each meeting!
3. **Focus on questions and problems.** A brief overview of the design may be appropriate. But, since all members receive study packets, it is not necessary to provide an in-depth description of the study. We've all read our packets (right?).
4. **Don't discuss typos and grammatical errors unless they present a risk to the subject.** Only edits to the informed consent document that would affect a subject's comprehension are worth discussing. Please forward any other typo corrections directly to the Chair.
5. **Don't treat modifications like opportunities for protocol overhauls.** Focus on the proposed change(s) and any legitimate regulatory or subject safety problems. Let minor issues, like typos that don't affect comprehension, slide until continuing review.
6. **Communicate with the Chair.** Contact the chair with questions or problems (e.g., something left out of your packet, serious concerns about a protocol that were not raised in the administrative review, request for expert consultation, etc.). That's what they're there for.
7. **Talk with the PI before the meeting.** Clarifying issues with the PI in advance of the meeting can facilitate a more efficient discussion of the protocol and recommendations for action.
8. **Make a motion.** After all of the concerns have been discussed, the primary reviewer can help the group to stay on task by initiating a motion for committee vote.
9. **Keep interruptions to a minimum.** The committee loses momentum when cell phones and pagers interrupt discussion and voting. Please keep these devices on vibrate and be conscious of the quorum requirement when leaving the meeting to answer a call.
10. **Plan to attend and stay until the end.** Please respond to rsvp requests and plan to attend for the whole meeting unless something truly urgent requires your attention. It wastes time when we have to jump around the agenda.

Delegated Reviewer Guidelines

The IRB Chair or person delegated by IRB Chair will work with delegated reviewers (DR) who are in training through parallel protocol reviews. **For filing purposes, please copy IRB Chair on all email correspondence.**

Place in the Email Subject line of ALL email correspondence: the last name of PI followed by IRB#, for ex.: Duke F2016-01. This helps in organizing and locating files in the server and archives.

Step by step process for DR's:

- IRB Chair will assign IRB# and send protocol information to next rotating DR on list.
- DR accepts review via email to IRB Chair
- DR sends email to PI: "I am assigned as the delegated reviewer for your protocol: Duke F2016-01 and will provide input to you by xxxxx. (this should be no longer than one week).
- Suggestions for revisions should be made using comments (and if appropriate, tracking) on IRB documents. If DR is in training, this is reviewed by IRB Chair prior to being sent to PI.
- DR will forward requested revisions to PI and cc G. Duke (for filing purposes)
- When doing this, give instructions to PI in body of email, bolded and underlined: **"Please return revisions with all comments intact, and use tracking changes for revisions."**
- Once the PI returns the revised protocol, review for accuracy in addressing requested revisions.
- Once this is done, and DR is satisfied with revisions, forward the revisions to IRB Chair for final review (for those DRs considered to be in training).
- **Approval process:**
 - Accept all changes in documents and remove comments.
 - Complete the upper left box information (IRB#, your name, date) on applications.

- For consents, put IRB# and approval date.
- Send email to PI and to Barbara Bextine (or other designated ORS person assisting with IRB business—this can be verified with IRB Chair) and copy the IRB Chair

- **Put in subject line: “PI name, IRB#, approval.” For example, “Duke F2016-01 Approval.”**

- In body of email for approval, DR must indicate to ORS person type of review and if letter should indicate a waiver of signed consent or with signed consent. Examples are as follows:
 - “Ms. Bextine, please write approval letter for (Ms./Mr./Dr.) Smith for expedited with signed consent(s)
 - “Ms. Bextine, please write approval letter for (Ms./Mr./Dr.) Smith for exempt with signed consent(s)
 - “Ms. Bextine, please write approval letter for (Ms./Mr./Dr.) Smith for exempt with waiver of signed consent(s)
 - “Ms. Bextine please write approval letter for (Ms./Mr./Dr.) Smith for expedited with waiver of signed consent(s)

- Attach ALL approved documents: application, CITI certificates of PI and any co-investigators, and when applicable, survey(s), script/flyers, consents, or any other information related to protocol.
- **Copy IRB Chair on ALL communications**

NOTE: ANY MOUs INVOLVING MONETARY ISSUANCES MUST BE APPROVED THROUGH UT-TYLER COUNSEL PRIOR TO APPROVAL.

UNAFFILIATED INVESTIGATOR AGREEMENT FORM

As an independent investigator not employed at UT Tyler, I agree to engage in research under the UT Tyler FWA under the following conditions:

_____ I am sponsored by an employee of UT Tyler who is certified in a UT Tyler approved human subjects course or program. The UT Tyler employee has agreed to sponsor me by submitting an application for review to the UT Tyler IRB.

_____ I agree to abide by conditions established for human research by the FWA terms as set forth in the UT Tyler IRB Handbook.

_____ I agree to abide by all other relevant policies established for human research by the UT Tyler IRB, including **Responsibilities of the Principal Investigator** and **Policy and Procedures for Proposal Submission, Review, Suspension and Termination of Research Proposals, and any other relevant policies that pertain to the proposed research project.**

Name of Faculty Sponsor:

Name of Independent Investigator:

Employer of Independent Investigator:

Contact Information of Independent Investigator:

Signature of Independent Investigator (form submitted from independent investigator's email desk is considered signature, though electronic signature is preferred):