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

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RESPONSIBILITY AND SCOPE OF THE UT TYLER IRB

All human subject research will be reviewed, prospectively approved, and subject to continuing oversight and review at least annually by the UT Tyler IRB. The IRB will have authority to approve, require modifications in, or disapprove the covered human subject research.

The UT Tyler IRB functions under the regulations of “45 CFR 46” which is the Federal Policy for the protection of human subjects that governs the research funded by the Department of Health and Human Services (DHHS). These regulations also apply to research conducted at UT Tyler not funded by federal organizations.

UT Tyler operates by DHHS-assigned Federal Wide Assurance (FWA) number 00009775

Regulations in the Code of Federal Regulations (CFR) known as Part 46 is further divided into subparts:

- **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

**Institutional Official:** Dr. Michael Odell, Director, Office of Research and Technology Transfer

**Reporting Structure:** The Institutional Review Board (IRB) reports directly to the Research Council, who reports to the Director of the Office of Research and Technology Transfer
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 46.101. 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 Form on file with the Office of Research and Technology Transfer before a proposal can be processed.

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 46.101.

- Be responsible for complying with all UT Tyler IRB decisions, conditions, and requirements.

- Be responsible for providing a copy of the IRB-approved and signed 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.

- 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, but no less than once
per year, using the Continuing Review form or the Discontinuance Form, whichever is appropriate one year post approval.

- Be responsible for notifying the UT Tyler IRB if the project is terminated or discontinued prior to one year, by using the Discontinuance Form. (additional information is available on the Submission and Review policies and procedures). 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:

- 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
- 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 REVIEWS BY THE UT TYLER IRB

Five different types of reviews of protocols are done by the UT Tyler IRB: full board, expedited, exempt, modification requests, and continuing review. Even though an exempt protocol is considered exempt from review, 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.

Any UT Tyler faculty member who is a co-investigator on a research project with another institution must also have UT Tyler approval prior to involvement with the research project. This is a simple process that requires the UT Tyler faculty member to send approval documents (approval letter, IRB application of original institution or proposal) to the UT Tyler IRB. The approval process is usually waived once approval documentation is received.

Students must have a faculty sponsor, and all approvals must be renewed at least annually.

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 monthly meetings, and do not meet criteria for exempt or expedited research. Administrative reviewers may deem an expedited protocol eligible for full board review.

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. Approvals of expedited protocols by the IRB Chair or designated person will be reported at the next regularly scheduled IRB meeting

3. Criteria for expedited reviews (additional details are on back of expedited forms):

**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) supragingival 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 CFR46.101, http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm

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 (additional details on back of exempt forms):

- 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 the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless: (i) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and (ii) any disclosure of the human subjects’ responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects’ financial standing, employability, or reputation.

- 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 (2) if (i) the human subjects are elected or appointed public officials or candidates for public office; or (ii) federal statute(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.

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. 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 approved proposals must undergo continuing review at least annually, or more often as is deemed necessary by the IRB due to the level of risk to research subjects.
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 study 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. 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.
**RETROSPECTIVE EXISTING DATA REVIEW**

Five different types of reviews of protocols are done by the UT Tyler IRB: full board, expedited, exempt, modification requests, and continuing review. Even though an exempt protocol is considered exempt from review, 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.

Retrospective, anonymous existing data protocols: If a faculty member is requesting approval for retrospective research using existing 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.

Any UT Tyler faculty member who is a co-investigator on a research project with another institution must also have UT Tyler approval prior to involvement with the research project.
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
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 the UT Tyler IRB Training Post. The course may be accessed at the following link: http://www.uttyler.edu/research/compliance/irb/
   B. Submit certificates electronically to the IRB Chair.

II. Responsibilities Of PIs:
   A. All Principal Investigators (PIs) are responsible for abiding by obligations stated in “Responsibilities of the Principal Investigator.”
   B. PIs must have an approved, current, signed Conflict of Interest Form on file with the Office of Research and Technology Transfer before a grant funded proposal can be processed.

III. 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.

IV. Electronic Submissions Must Include:
   A. IRB application (a full board, expedited, or exempt application form). Ensure all spaces are completed. When in doubt as to which application to complete, contact the IRB Chair.
   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. Dean/Department Chair form (submitted by Dean or Department Chair)

V. Other IRB Review-Related Policies
   A. Proposals will be approved for no more than a one year period of time, beginning from date of proposal approval letter mailing. Some exceptions may
be made for approvals being less than one year, and will be indicated so in approval letter. 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 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. 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. Investigations of Reported Allegations of Research Misconduct or Non-Compliance

The UT Tyler IRB acknowledges the UT Tyler Handbook of Operating Procedures in 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). Any allegation 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. In addition, allegations must be reported directly to the IRB Chair and Director of the Office of Research and Technology Transfer before or at the same time the incident is reported to the department Chair/Dean, or if appropriate, the President or designee.

The PI of the research program affected by the allegations will be notified by the department Chair/Dean, or if appropriate, the President or designee. While respecting and regarding the reputation of the involved parties, the departmental Chair/Dean, or if appropriate, the President or designee shall conduct a thorough
investigation of the circumstances and facts. The investigation must be completed within 60 days.

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 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.

The IRB has the authority to terminate approval of the research, especially that which is not being conducted in accordance with the IRB 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. Every effort will be taken to insure the confidentiality of all aspects of the investigation and any subsequent IRB actions relating to the incident(s).

Additional procedural responsibilities are delineated in the UT Tyler HOP: http://www2.uttyler.edu/ohr/hop/documents/3.2.8ResearchFraudMisconduct.pdf

C. Reporting of Investigations

Upon completion of the investigative process, the completed IRB Research Misconduct and Non-Compliance Review Form must be submitted to the person(s) conducting the investigation and to the presiding official for the Office of Research and Technology Transfer. If the research project is federally-funded or is associated with an FDA regulated investigational drug or device study, the ORTT presiding official will submit a report to the Office for Human Research Protections (OHRP) 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.

D. Record Keeping
All documents relating to the investigation will be retained by the IRB Office 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.

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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 and Technology Transfer 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](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 Research and Technology Transfer
- 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 and Technology Transfer 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

Informed consent is an ongoing process, not just a form. Information must be presented to enable persons to voluntarily decide whether or not to participate as a research subject without any form of direct or indirect coercion.

This policy refers to individuals who meet the criteria as adults. For information on consent-related procedures for children, please refer to those relevant sections on Protection of Children Involved in Research.

Three consent templates are available for research:

1. Informed Consent Template (this is to be used for research involving higher than minimal risk)
2. Informed Consent Abbreviated Signed for Minimal Risk (this is for protocols that need signed consents but are minimal risk)
3. Informed Consent for Anonymous Online (these are for online, anonymous surveys so that participants are aware they are being involved in a research study).

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 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 must be written at no higher than a 8th grade level of reading, and tailored to less than that as appropriate.
6. 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.

7. The IRB must approve the consent form before it is used, and it must approve any changes made to a previously approved consent.

8. Subjects must be given a copy bearing the IRB approval stamp.

9. The IRB has the authority to observe the consent process and may do so without prior notification to the PI.

10. All potential subjects, especially those situations in which language and/or intellectual level of understanding may be an issue, must be able to verbalize to the PI or representative, that the project is research, general purpose of the research, risks, the voluntary nature of beginning and/or ending participation with no undue consequences, and who to contact if necessary for further information about the research.

II. ONGOING INFORMED CONSENT

Informed consent is a communication process that continues during the entire study. Many of the elements of informed consent previously discussed apply throughout the study. The researcher 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. Researchers should consult the IRB for the requirements for study changes and re-consent procedures.

1. The IRB has a sample consent form which contains all the required elements of consent and is written at the 7.9 grade level:
   http://uttyler.edu/research/compliance/irb/docs/irb-informed-consent-template-032612.doc

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…”

III. BASIC ELEMENTS OF INFORMED CONSENT

The following are the required elements (extracted from 45 CFR Part 46.116 and 21 CFR 50.25):

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:

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.

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. Informed consent must be documented by the use of a written consent form reviewed and approved by the IRB.

2. The informed consent should be signed and dated by the subject or subject’s legally authorized representative and a witness.

3. By signing the form, the witness is attesting to the fact that the subject, or the subject’s legally authorized representative, actually signed the form and volunteered to participate in the research.

4. A copy must be given to the subject or person signing the form.

5. For Texas Department of Criminal Justice (TDCJ) inmates, a copy of the signed consent form should also be placed in the subject’s medical record.

6. It is assumed that the consent form is only part of the total consent process in which the PI, perhaps using the written consent form as an outline, describes all facets of the study and answers the subject’s questions.

7. The PI is responsible for insuring that research subjects understand the research procedures and risks. Failure of the subjects to ask questions should not be construed as understanding on the part of the subject.

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 AND INTERNET**

The Office of Human Research Protections does not mandate a specific method of electronic signatures. They do permit IRBs to adopt such technologies for use as long as the IRB considers applicable issues, such as, how the electronic signature is being created, if the signature can be shown to be legitimate, and if the consent or permission document can be produced in hard copy for review by the potential subject ([http://answers.hhs.gov/ohrp/questions/7260](http://answers.hhs.gov/ohrp/questions/7260)).

- **Internet Consents**

Of importance to note: regardless of the manner in which consent/assent is obtained, there must always be ample opportunity for the subject/participant to have any questions answered or concerns addressed prior to and after consenting/assenting to participating in any research. Documentation of the method for this must be integrated into the protocol.

1. Risks and complexities of the research must be taken into consideration when consent/assent are provided via the Internet. Three concerns are inherent to using the Internet for consent/assent; potential solutions for addressing these concerns can be found under Question 11 at: [http://www.hhs.gov/ohrp/sachrp/mtgings/2013%20March%20Mtg/internet_research.pdf](http://www.hhs.gov/ohrp/sachrp/mtgings/2013%20March%20Mtg/internet_research.pdf)

   a. verification of identification
   b. ensuring understanding per consent requirements
   c. obtaining appropriate documentation when needed

These concerns may be minimal, or substantial depending on the risks involved, and must be appropriately addressed in the IRB application and protocol.
b. Waiving or altering the required consent elements requires adherence to 46.116 (c) and (d) which state that:

The research presents no more than minimal risk; the waiver will not adversely affect subjects’ rights and welfare; the research could not practically be carried out without waiver; and, when appropriate, subjects will be provided with additional pertinent information after participation.

c. Children under the age of 13: If identifiable information may be collected about children under the age of 13, the COPPA requirement for parental consent will apply (there is no waiver provision).

COPPA information and guidelines are at: 
http://www.coppa.org/comply.htm

○ Electronic Signatures

1. Considerations to Address

a. First, the investigator and the IRB need to be aware of relevant laws pertaining to electronic signatures in the jurisdiction where the research is going to be conducted.

b. Unless the IRB waives the requirement for the investigator to obtain a signed consent or permission form based on the HHS regulations at 45 CFR 46.117(c), a written consent or permission form, which may be an electronic version, must be given to and signed by the subjects or the subjects’ legally authorized representatives or the parents of subjects who are children.

c. Some form of the consent document must be made available to the subjects or the parents of subjects who are children in a format they can retain. OHRP would allow electronic signature of the document if such signatures are legally valid within the jurisdiction where the research is to be conducted.

d. If at all possible, use a system for electronic or digital signature that provides an encrypted identifiable “signature.”

○ Telephone Consents
1. The informed consent process should be an active process of sharing information between the investigator and the prospective subject.

2. An oral approval does not satisfy the 21CFR56.109(c) requirement for a signed consent document, as outlined in 21CFR50.27(a).

3. However, it is acceptable to send the informed consent document to the subject by facsimile, standard mail, or electronically, and conduct the consent interview by telephone when the subject can read and return the consent as it is discussed. If the subject agrees, he/she can sign the consent and return the signed document by facsimile, electronically, or standard mail.

4. 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.

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

**Telephone Surveys**

1. In some cases, the informed consent process may be altered from the written standard where a telephone survey methodology is used.

2. Where research is considered to be minimal risk, often consent may be obtained via telephone. The following items minimally must be included in the consent script:

   i. the purpose of the research, the researcher's name and his or her association with UT Tyler IRB
   ii. how confidentiality of their responses will be maintained, and
   iii. a statement that participation is voluntary, the participant can refuse to answer any questions or terminate his or her participation at any time.

   iv. Additional items may be required based on the subject matter and risks to subjects.
   v. Determinations regarding what information must be included and if the research qualifies for a waiver of signed consent will be made by the UT Tyler IRB.

**Family of Origin Research and Third Party Consent Issues**

When an investigator conducting research obtains identifiable private information about that living individual, that individual becomes a research subject. For example, when asking for family medical history, if the subject is asked to identify if his/her mother or father has a condition or ailment and the original subject is identifiable, the parent then becomes a research subject. This parent would be
referred to as a “third party subject” or “secondary subject” and would need to be consented regarding the information being obtained.

An agreement to participate in research constitutes valid consent only if voluntarily given by the individual whose identifiable private information is obtained by the researcher. Thus the regulations require consideration of all living individuals about whom a researcher obtains identifiable private information, be they family members, or not.

**Incentives**

Federal regulations governing research with human subjects contain little specific guidance for IRB review of payment practices. However, the UT Tyler IRB will make sure that prospective subjects realize that their participation is voluntary, and that choosing not to participate will not adversely affect their relationship with the institution or its staff in any way.

To make this determination, the UT Tyler IRB will know who the subjects will be, what incentives are being offered, and the conditions under which the offer will be made. Informed consent documents must contain a detailed account of the terms of payment, including a description of the conditions under which a subject would receive partial or no payment.

Determining the appropriateness of the incentive is another matter. For research that requires subjects to undergo only minor inconvenience or discomfort, a modest payment will usually be adequate. Reimbursement for travel, babysitting, and so forth may also be provided. In more complex research projects, IRBs tend to base their assessment on the prevailing payment practices within their institution or general locale. Volunteers are often compensated for their participation according to an established fee schedule, based upon the complexity of the study, the type and number of procedures to be performed, the time involved, and the anticipated discomfort or inconvenience. Extra payments are usually provided for a variety of additional inconveniences (e.g., the imposition of dietary restrictions). Payments may vary according to a number of factors, and therefore, the UT Tyler IRB will be familiar with accepted standards within the community as well as the anticipated discomforts and inconveniences involved in a particular study to judge the appropriateness of payments.

It should be noted that providing subjects with monetary awards through UT Tyler IRB can create a problem of maintaining strict confidentiality. If the award is made through funding from a contract or grant, usually subjects receive a check for the predetermined (and approved) amount. UT Tyler IRB must have the subject’s Social Security number in order to issue the check. Such payroll records are not available to the public, but do constitute a link between the subject and the research.
X. PRIVACY AND CONFIDENTIALITY AND FERPA

In reviewing some protocols, the UT Tyler IRB may have to consider whether an invasion of privacy is involved. The IRB will base decisions on its sense of propriety and the particular circumstances of the study. Among the several relevant factors are:

- the private nature of the information sought,
- the likelihood that the subjects would regard the release of information as an invasion of privacy, the importance of the research, and
- the availability of alternative ways to do the study.

Investigators sometimes want access to existing records to identify people suitable for inclusion in a study. The UT Tyler IRB will always need to know if the subjects' names will be recorded by the investigator for follow-up (either for further record review or for personal contact).

This is because the level of review may be affected, and the UT Tyler IRB will need to determine whether the consent of subjects should be sought (e.g., by the institution holding the records) before the researcher gains access to the records.

Factors used in deciding if consent must be sought include the sensitivity of the information reviewed, the vulnerability of the subject population, and the purpose for which the investigator wants access to the information.

The Buckley Amendment [the General Education Provisions Act (20 USC 1232)], also known as FERPA, requires parental consent for release of records or identifiable information about children in public schools; instructional materials to be used in connection with any research or experimental program must be open to inspection by the parents or guardians of the children to be involved.

In most research, ensuring confidentiality is only a matter of following some routine practices:

- substituting codes for identifiers,
- removing face sheets (containing such items as names and addresses) from survey instruments containing data,
- properly disposing of computer sheets and other papers,
- limiting access to identified data,
- impressing on the research staff the importance of confidentiality, and
- storing records in locked cabinets.

Most researchers are familiar with the routine precautions that should be taken to maintain the confidentiality of data. More elaborate procedures may be needed in some studies, either to give subjects the confidence they need to participate and answer
questions honestly, or to enable researchers to offer strong, truthful assurances of confidentiality.

Such elaborate procedures may be particularly necessary for studies in which data are collected on sensitive matters such as sexual behavior or criminal activities. When information linked to individuals will be recorded as part of the research design, the UT Tyler IRB will make sure that adequate protections will be taken to safeguard the confidentiality of the information.

Sensitive information is sometimes obtained in the course of behavioral studies, research with the cognitively impaired, AIDS research, and research dealing with drug and alcohol abuse. There is a regulatory provision for waiving documentation of consent when a signed consent form would itself constitute a risk to the subjects [45 CFR §46.117(c)(1)].

Researchers must be aware that promising subject anonymity is misleading. Neither the researcher or the institution can promise anonymity, except when a Certificate of Confidentiality has been obtained from a federal agency. Otherwise, research records can be subpoenaed. For details about obtaining and using a Certificate of Confidentiality, see http://grants1.nih.gov/grants/policy/coc/faqs.htm#187

**XI. MANAGEMENT OF DATA FOR ENSURING SUBJECT SAFETY AND PRIVACY**

One of the areas to be reviewed in proposed research is the researcher’s plan for collection, storage, and analysis of data. Monitoring of the research by the researcher is important because preliminary data may signal the need to change the research design, change the information presented to subjects, or even to terminate the project before the scheduled ending date.

Both the timing and adequacy of the plan for analysis are important. If the data are not analyzed until the project is terminated, the chance for making mid-course corrections is lost. If the data are not properly analyzed, the research itself is not valid, and correct conclusions may not result.

For the UT Tyler IRB to approve proposed research, the protocol must, when appropriate, include plans for monitoring the data collected to ensure the safety of subjects (45 CFR §46.11(a)(6)). Investigators sometimes misinterpret this requirement as calling for annual reports so the UT Tyler IRB can monitor the project. However, it does in fact require, when appropriate, that researchers provide the IRB with a description of their plans for analyzing the data during the collection process.

Concurrent collection and analysis enable the researcher to identify flaws in the study design early in the project. At this point, researchers are able to reevaluate the risks to human subjects to assure they are no greater than initially predicted. Like other
considerations, the level of monitoring in the research plan should be related to the degree of risk posed by the research.
**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](http://www.hhs.gov/ocr/hipaa/guidelines/research.pdf)

**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.

**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 researcher.

- **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.

**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

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- 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." [http://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**

PIIs, 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 researcher 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 researchers 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, researchers 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:

   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 researchers are unable to use de-identified information, and the research could not practically 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 researcher, 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 researcher 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 researcher 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 researcher. Following this, the covered entity may disclose a limited data set to the researcher 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 researchers 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 or 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 at: http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm#subpartc, 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.

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

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.

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 (http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm#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 UT Tyler IRB shall carry out such other duties as may be assigned by the Secretary.

(c) 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.

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.

*Investigators must become certified through the Secretary to conduct DHHS funded research. For assistance with this, contact the Office of Research and Technology Transfer 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

Under this policy, children include all those who have not yet reached their 18th birthday (i.e., 0 through 17 years old).

The special vulnerability of children makes consideration of involving them as research subjects particularly important.

To safeguard their interests and to protect them from harm, special ethical and regulatory considerations apply for reviewing research that involves children.

Exceptions to the “17 year old” rule depend on the jurisdiction in which the research will take place. In Texas, the following are considered adults and thus are not children (Title 4, Tex. Health & Safety Code § 313.002(1); Title 6, Tex. Civ. Practice & Remedies Code § 129.001). A minor can have the disabilities of minority removed by a legal proceeding under Title 2, Tex. Family Code § 31.001:

(1) one who is 18 years of age or older; or
(2) someone under age 18 who has had the disabilities of minority removed by court order (what is commonly referred to as being “emancipated” though that word is not used in the statute). [Note: If there is a question as to whether a potential participant is emancipated or whether the removal of disabilities was limited and does not include health care decision-making, the researcher should read the actual court order.]

The IRB and researchers must be familiar with Texas and other relevant state laws regarding emancipation and other criteria that affect consent procedures for individuals under the age of 18 years.

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

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 non-substantive, 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.

The exceptions, additions, and provisions for waiver as they appear in paragraphs (c) through (i) of §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 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. Consent and Assent: Requirements For Permission By Parents Or Guardians And For Assent By Children

A. Adequate Provisions for Child’s Assent

The UT Tyler IRB must make adequate provisions for soliciting the assent of child subjects when the children are capable of providing assent. In determining whether children are capable of assenting, the IRB should 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. The child should be given an explanation of
the proposed research procedures in a language that is appropriate to the child’s age, experience, maturity, and condition.

B. Age Requirements for Assent

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

- 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.

Researchers must justify their decision as to whether or not to obtain children’s assent.

When assent is obtained, documentation must reflect the manner in which it was obtained.

C. Waiver of Assent

If the UT Tyler IRB determines any of the following to be true, then the assent of the children is not a necessary condition for proceeding with the research:

a) the capability of some or all of the children is so limited that they cannot reasonably be consulted, or

b) when the research offers the child the possibility of a direct benefit that is important to the health or well-being of the child and is available only in the context of the research.

c) in such circumstances a child's dissent, which should normally be respected, may be overruled by the child's parents, at the discretion of the UT Tyler IRB. Even where the UT Tyler IRB determines that the child subjects are capable of assenting, the IRB may still waive the assent requirement under circumstances in which consent may be waived for adults, as is reflected in §46.116.

D. Adequate Provisions for Parent or Guardian Permission

The investigator must make adequate provisions for soliciting the permission of each child’s parents or legally authorized representative.

Some circumstances exist that only one parent’s permission is needed and others where both, except under special circumstances described below, signatures would be required.
a) Permission of one parent is sufficient for research to be conducted under either of the following circumstances, as is reflected in §46.404, §46.405, and §46.407

i. §46.404: Research not involving greater than minimal risk

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. An example of minimal risk is the risk of drawing a small amount of blood from a healthy individual for research purposes (because the risk of doing so is no greater than the risk of doing so as part of a routine physical examination).

ii. §46.405: Research involving greater than minimal risk but presenting the prospect of direct benefit to the individual subjects (§46.405) when the IRB finds that the intervention or procedure 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, and if the UT Tyler IRB determines that:

a) the risk is justified by the anticipated benefit to the subjects,

b) that the relation of the anticipated benefit to the risk is at least as favorable to the subjects as that presented by available alternative approaches,

c) that adequate provisions are made for soliciting the assent of the children and permission of their parents or guardians.

b) Permission is to be obtained from both parents 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, under the two following circumstances that reflect §46.406 and §46.407:

i. §46.406: 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.

When the research involves greater than minimal risk to children and involves 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.
Additionally, the UT Tyler IRB must find that:

i) the risk represents a minor increase over minimal risk

ii) that 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

iii) that 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

iv) adequate provisions are made for soliciting assent of the children and permission of their parents or guardians.

E. Waiver of Parental or Guardian Permission

If parental or legally authorized representative permission is not a reasonable requirement to protect the subjects (for example, neglected or abused children), the investigator may request that the UT Tyler IRB waive the consent requirements described above, provided both an appropriate mechanism for protecting the children who will participate as subjects in the research is substituted, and 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.

F. Documentation

Permission by parents or guardians shall be documented in the same manner as required for other subjects. When the UT Tyler IRB determines that assent of a child is required, it shall also determine whether and how assent must be documented.
V. Wards

For research involving wards of the state of Texas, “ward” includes foster children (Title 5, Tex. Family Code, §266.001(2), (4)), children residing at a Texas Youth Commission facility (Title 3, Human Resources Code, §§ 63.001-63.028) and children who are otherwise in the care and control of the state or a state agency.

(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.
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., researchers, 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.
SPECIAL SUBJECT POPULATIONS: STUDENTS

Students 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 instructor or someone who might be in a position to influence their future.

Students 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 better grades, recommendations, employment, 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 students are involved in human subjects research.

NOTE: PIs and co-investigators must take the supplementary CITI module: Students in Research (ID: 1321) in addition to the SBR or Biomedical Courses.

General Guidelines and FERPA

In general, research involving students in academic settings who receive funds from the U.S. Department of Education must adhere to any procedures involving the Family Educational Rights and Privacy Act (FERPA) regulations.

This information is provided at the end of these guidelines.

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 or highly motivated or because participation in research is a course requirement.

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

Various alternatives have been used to reduce the possibility of unintended coercion while still permitting students to participate as subjects in research.

These include:

- Any faculty involved in assigning grades to students may not be involved in recruiting or handling identifiable data until after final grades are posted.
• Posting IRB approved advertisements throughout the university to recruit subjects from a broad base of students

• Providing a number of research projects from which to choose, if participating as a subject in research is a course requirement

• 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.

• 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.

Reducing the Potential for Undue Influence When Recruiting from Investigator’s Class

In the rare instances in which recruiting from one’s own class is permissible, researchers are expected to minimize the potential for students to feel pressured to participate. There are various strategies for minimizing the potential pressure to participate. One way that researchers have reduced the potential to cause undue influence is to 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:

1. 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).

2. 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).

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.
The Family Educational Rights and Privacy Act (FERPA)

The Family Educational Rights and Privacy Act (FERPA) (20 U.S.C. § 1232g; 34 CFR Part 99) is a Federal law that protects the privacy of student education records. The law applies to all schools that receive funds under an applicable program of the U.S. Department of Education.

FERPA gives parents certain rights with respect to their children's education records. These rights transfer to the student when he or she reaches the age of 18 or attends a school beyond the high school level. Students to whom the rights have transferred are "eligible students."

- Parents or eligible students have the right to inspect and review the student's education records maintained by the school. Schools are not required to provide copies of records unless, for reasons such as great distance, it is impossible for parents or eligible students to review the records. Schools may charge a fee for copies.

- Parents or eligible students have the right to request that a school correct records which they believe to be inaccurate or misleading. If the school decides not to amend the record, the parent or eligible student then has the right to a formal hearing. After the hearing, if the school still decides not to amend the record, the parent or eligible student has the right to place a statement with the record setting forth his or her view about the contested information.

- Generally, schools must have written permission from the parent or eligible student in order to release any information from a student's education record. However, FERPA allows schools to disclose those records, without consent, to the following parties or under the following conditions (34 CFR § 99.31):
  - School officials with legitimate educational interest;
  - Other schools to which a student is transferring;
  - Specified officials for audit or evaluation purposes;
  - Appropriate parties in connection with financial aid to a student;
  - Organizations conducting certain studies for or on behalf of the school;
  - Accrediting organizations;
  - To comply with a judicial order or lawfully issued subpoena;
  - Appropriate officials in cases of health and safety emergencies; and
  - State and local authorities, within a juvenile justice system, pursuant to specific State law.

Schools may disclose, without consent, "directory" information such as a student's name, address, telephone number, date and place of birth, honors and awards, and dates of attendance. However, schools must tell parents and eligible students about
directory information and allow parents and eligible students a reasonable amount of time to request that the school not disclose directory information about them. Schools must notify parents and eligible students annually of their rights under FERPA. The actual means of notification (special letter, inclusion in a PTA bulletin, student handbook, or newspaper article) is left to the discretion of each school.
COMPLIANCE AND MONITORING OF PROTOCOLS

The UT Tyler IRB is responsible for conducting the safety and monitoring process for all approved protocols. The researcher and team’s obligation to protect human research participants does not end with initial approval of the study or an informed consent (written or otherwise). In any research, the commitment to participants is to safeguard their interests throughout the study.

Data and safety monitoring plays an essential role in protecting the safety of participants and ensuring integrity of the research study.

The objectives of data and safety monitoring are to:
- Ensure that risks associated with research participation are minimized to the extent practical and possible.
- Avoid exposure of participants to excessive risk.
- Ensure data integrity.
- Stop a study: (1) if safety concerns arise; or (2) as soon as the study objectives have been met.

Monitoring should be commensurate with risks and with the size and complexity of the research.

IRB committee members protect the safety of participants by being familiar with the study and ensuring the integrity of the study by reviewing data on such aspects as participant enrollment, site visits, study procedures, forms completion, data quality, losses to follow-up, and other measures of adherence to protocol. In addition, monitoring of adverse events, discussion of concerns in this regard, and making of recommendations regarding appropriate study and operational changes are conducted.

The UT Tyler IRB reserves the right to conduct monitoring at any time without prior notification of visits.

During the process of compliance and monitoring and continuing reviews of a research project, material provided to the Institutional Review Board and the ORTT shall be considered privileged information and the Board shall assure the confidentiality of the data contained within any submitted documents that contains subject/participant identifying information.

All federally funded human subject clinical research protocols must have a data and safety monitoring plan. The plans must include a description of the reporting mechanism should an adverse event occur. All data and safety monitoring plans must include, at a minimum, a description of the reporting mechanism of adverse events to the IRB (see UT Tyler IRB Handbook
the UT Tyler Policy On Unanticipated Problems Or Adverse Event/Death). In addition, the study sponsor, the FDA (if the researcher sponsors the IND or IDE for the agent or device), and the NIH must be notified according to their policies and procedures. For NIH-supported multi-center clinical trials, see http://grants.nih.gov/grants/guide/notice-files/not99-107.html.

NIH policy and guidance for data and safety monitoring can be found at: http://grants.nih.gov/grants/guide/notice-files/not98-084.html

Researchers must ensure that the NIH is informed of any actions taken by the IRB as a result of safety monitoring reviews.
**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 and Technology Transfer 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.
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.
UNDERGRADUATE AND GRADUATE STUDENT COURSE-RELATED RESEARCH PROJECTS

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

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). In some courses, students collect data involving human subjects by using professional research methods, even though the student’s work is not expected to contribute to generalizable knowledge.

Faculty and students are to adhere to the following criteria for determining when IRB 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:

1. Involve no more than minimal risk; AND
2. 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
3. The data will not be used beyond the classroom environment (i.e. will not be published or orally presented at a major conference) AND
4. The research review category would normally fall under the exempt or expedited review categories (defined by CFR 45 Part 46 available at the following website):

   45 CFR Part 46 HHS Regulations for Human Research

If the instructor is not certain that all of the criteria above have been met, the UT Tyler IRB Chair should be contacted.

Further, any “study” that involves any of the following must be approved by IRB before sample recruitment and data collection:

1. When data involves a sensitive subject matter, for example (list not all inclusive)
   a. Domestic abuse
   b. AIDS/HIV
   c. Mental health issues
d. Psychological issues
  e. Substance abuse
  f. Human trafficking

2. When the sample includes a vulnerable population group, for example (list not all inclusive)

  a. Prisoners
  b. Children under the age of 18
  c. Students in any academic setting and any age
  d. Persons with impaired decisional capacity
  e. Persons at risk for suicide
  f. Pregnant women

3. Any research involving more than minimal risk to human subjects

COURSE FACULTY RESPONSIBILITIES

The primary responsibility for assuring that the rights and welfare of human subjects are protected is delegated to the faculty member/instructor. These rights are explained in Attachment A. In addition, the course faculty member is accountable and responsible for:

- completing the UT Tyler IRB training (CITI); student completion of training is at the discretion of the course faculty.
- effectively communicating to students ethical principles of research
- reviewing and approving student research protocols prior to initiation of the research project
- monitoring students’ research activities and reports of findings
- assuring that the students’ work does not violate human subjects’ protection
- assuring that for any interventional research, that
  - it is minimal risk
  - that participants sign a written informed consent that reflects the UT Tyler procedures for written informed consent
- reviewing and approving the instruments, methods and procedures of the research protocol in their final form prior to their use by student researchers
- maintaining a record for at least one calendar year of research protocols which includes the research project title, the student researchers’ names and the date of the instructors’ review and approval

DEFINITIONS
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.

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.

2. "Human Subject" means an individual about whom an investigator conducting research obtains data through some type of observation or interaction with the person.

3. "Student Researcher" means any student enrolled in a course at UT 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).

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.

5. Categories for exempt and expedited research to which this policy applies:

   a. research conducted in established or commonly accepted educational settings involving normal educational practices;

   b. 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;

   c. 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;
d. 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;
e. moderate exercise by health volunteers;
f. recording of data from subjects 18 years or older using noninvasive procedures routinely employed in clinical practices.
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.
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 and Technology Transfer, 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 and Technology Transfer 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 researcher 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

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.
IRB LINKS TO FORM EXAMPLES

Use the links below to review examples of the various IRB forms. These are examples only and are not to be completed for IRB submissions. Use the forms posted on the ORTT Website at [http://www.uttyler.edu/research/forms.htm](http://www.uttyler.edu/research/forms.htm).