

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

TABLE OF CONTENTS

Policies

<u>Responsibility and Scope of the UT Tyler IRB</u>	3
<u>Responsibilities of the Principal Investigator</u>	4
<u>Types of Reviews by the UT Tyler IRB</u>	6
<u>Decisions of IRB Reviews</u>	12
<u>Submissions of Proposals</u>	14
<u>Procedures for Investigating and Reporting Incidents of Research Misconduct and Non-Compliance</u>	16
<u>Suspension/Termination of Investigations</u>	19
<u>Unanticipated Problems or Adverse Event/Death</u>	20
<u>Policy on Management of Human Subject Complaints and Assurance of Confidentiality</u>	22
<u>Informed Consent</u>	23
<u>HIPPA Privacy Rule Policy in Research</u>	28
<u>UT Tyler HIPAA Requirements</u>	31
<u>Policy on Protection of Pregnant Women, Human Fetuses and Neonates in Research</u>	37
<u>Protection of Prisoners in Research</u>	43
<u>Policy on Informed Consent of Children</u>	47
<u>Protection of Children involved in Research</u>	48
<u>Compliance and Monitoring</u>	55

<u>Unaffiliated Investigator Agreement</u>	57
<u>External Reviews Conducted by the University of Texas at Tyler Institutional Review Board</u>	58
<u>The University of Texas at Tyler Institutional Review Board Review of IRB Policies, procedures and Forms</u>	59
<u>Policy on Student Course-Related Research Projects</u>	60
<u>Information for IRB Members</u>	
<u>General Information for IRB Members</u>	66
<u>IRB Member Agreement</u>	67
<u>Streamlining IRB Meetings: What You Can Do?</u>	69
<u>IRB Links to Forms</u>	70

THE UNIVERSITY OF TEXAS AT TYLER INSTITUTIONAL REVIEW BOARD

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. Arlene Horne, Associate Vice-President for Research and Federal Relations (AVPRFR)

Reporting Structure: The Institutional Review Board (IRB) reports directly to the Research Council, who reports to the Associate Vice-President for Research. The VP for Research reports directly to the President of the University.

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 Sponsored Research before a proposal can be processed.

In addition, the PI shall:

- Ensure the PI, co-investigators, research assistants are all 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.

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 undergoes an administrative review to determine it exempt.

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):

The following categories for Expedited Research is in compliance with 45 CFR 46.110 and 21 CFR 56.110 of the Federal Policy for the Protection of Human Subjects, located at:
<http://www.hhs.gov/ohrp/humansubjects/guidance/expedited98.htm>

RESEARCH CATEGORIES

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

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

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

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

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

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

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

Examples: (a) hair and nail clippings in a nondisfiguring manner; (b) deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction; (c) permanent teeth if routine patient care indicates a need for extraction; (d) excreta and external secretions (including sweat); (e) uncannulated saliva collected

either in an unstimulated fashion or stimulated by chewing gumbase or wax or by applying a dilute citric solution to the tongue; (f) placenta removed at delivery; (g) amniotic fluid obtained at the time of rupture of the membrane prior to or during labor; (h) supra- and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques; (i) mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings; (j) sputum collected after saline mist nebulization.

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

Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.)

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

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

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

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

CATEGORY #7 Research on individual or group characteristics or behavior (including, but not limited to, research on perception,

cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.

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

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

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

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

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

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

C. Exempt Research

1. Exempt research at UT Tyler shall be reviewed for compliance with 45 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.

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.

SUBMISSION OF PROPOSALS

I. Required Education:

- A. All PIs and co-investigators must have on file with the UT Tyler IRB a current certificate (initial certifications good for 3 years) from the UT Tyler IRB Training Post. The course may be accessed by contacting the IRB Chair or the Office of Sponsored Research.
- 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 Sponsored Research 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. Submit proposals to the IRB Chair two weeks prior to scheduled 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 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):

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

Any allegation of research misconduct or non-compliance must be reported to either the Associate Vice President for Research and Federal Relations, or to the IRB Chair. Upon receipt of the reported allegation, the IRB Chair will form an *ad hoc* subcommittee composed of the IRB Chair and any other IRB member whose presence is deemed as essential by the Chair. The *ad hoc* subcommittee will be responsible for conducting a formal inquiry into the allegation(s). In the event that the subcommittee finds reasonable evidence of non-compliance or research misconduct, the Chair shall 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 then determine what restrictions, conditions, or other actions are necessary to resolve the misconduct or non-compliance and what procedures will be required to prevent future occurrences. Documentation

of the non-compliance issue will be completed by the IRB Chair in collaboration with the ad hoc committee and the IRB on the IRB Research Misconduct and Non-Compliance Form.

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).

B. Reporting of Investigations

Upon completion of the investigative process, the completed IRB Research Misconduct and Non-Compliance Form must be submitted to the Institutional Official (IO) at UT Tyler (Associate Vice President for Research). The IO will submit a report to the Office for Human Research Protections (OHRP), and the FDA if the incident(s) were associated with an FDA regulated investigational drug or device study. 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 should also include the date(s) the investigation was accomplished, the identity of the members of the ad hoc subcommittee, the results of the investigation in detail, and the restrictions, conditions, or other actions deemed by the IRB to be necessary to resolve the non-compliance. Finally, the report should also delineate the actions taken by the IRB and/or PI to prevent future occurrences.

C. 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.

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 Associate Vice-President for Research at UT Tyler
- FDA if the PI holds the Investigational New Drug (IND) or New Device Exemption (IDE)
- Funding agency
- Department chair/administration

The IRB Chair and IO ensure that the event is reported promptly to the Office of Human Research Protections (OHRP).

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
- Associate VP for Research
- 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 Associate VP for Research 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

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.

II. ONGOING INFORMED CONSENT

Informed consent is communication process that continues during the entire study. Many of the elements of informed consent previously discussed apply throughout the study. The 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.
2. The UT Tyler IRB requires that all consent forms be written in the second person, e.g., “you should understand that...”
3. The signature page may be written in the first person, e.g., “I understand that...” The following are the required elements (extracted from 45 CFR Part 46.116 and 21 CFR 50.25):
4. Basic Elements of Informed Consent:
 - a. A statement that the study involves research, an explanation of the purposes of the research, the duration of the subject’s participation, a description of the procedures to be followed, and identification of any procedures which are experimental;
 - b. A description of any reasonably foreseeable risks or discomforts that the subjects may encounter, and, if appropriate, a statement that some risks are currently unforeseeable;
 - c. A description of possible benefits, if any, to the subject and others which may be reasonably expected. It should be stated that since it is an experimental treatment or procedure, no benefits can be guaranteed;
 - d. A discussion of possible alternative procedures or treatments, if any, that might be advantageous to the subject. One alternative might be to choose not to participate in the research;
 - e. A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained and that notes the possibility that the FDA, the sponsor, the UT Tyler IRB, or others may inspect the records;

- f. For research involving more than minimal risk, an explanation as to whether any compensation and/or any medical treatments are available if a research-related injury occurs and, if so, what they consist of, or where further information may be obtained;
- g. An explanation of whom to contact for answers to pertinent questions about (i) the research (generally the PI or another staff member closely associated with the study), (ii) the rights of the research subject (usually the IRB chairperson), and (iii) any research-related injury to the subject (generally the PI or another staff member closely associated with the study). For item (iii), this should be a telephone number or numbers whereby the research subject can reach an appropriate person 24 hours a day, not just during normal working hours; and
- h. A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.
- i. A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is becomes pregnant), which are currently unforeseeable;
- j. Anticipated circumstances under which the subject's participation may be terminated by the PI without regard to the subject's consent;
- k. A description of any additional costs for which the subject will be responsible, that may result from participation in the research study;
- l. The consequences of a subject's decision to withdraw from the research and the procedures for orderly termination of participation by the subject;
- m. A statement that significant new findings developed during the course of the research, which may relate to the subject's willingness to continue participation, will be provided to the subject;
- n. A description of any compensation or reimbursement for time, inconvenience, travel, and other similar costs to the subject; and
- o. The anticipated number of subjects that will be involved with the study, both totally and at UT Tyler.

IV. WAIVER OF INFORMED CONSENT

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

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

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

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

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

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>

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

- 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

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

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

I. Background

- A. The Health Information Portability Accountability Act (HIPAA) Privacy Rule establishes the conditions under which protected health information may be used or disclosed by covered entities for research purposes.
- B. Research is defined in the Privacy Rule as, “a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge.” See 45 CFR 164.501.
- C. A 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:

1. Documented Institutional Review Board (IRB) Approval.

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

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

- b. **A covered entity (e.g., a health care facility that houses the protected health information) may use or disclose protected health information for research purposes following an approved waiver of authorization by the UT Tyler IRB, provided it has obtained documentation of *all* of the following:**

> Identification of the IRB approval and the date on which the waiver of authorization was approved;

> A statement that the IRB has determined that the waiver of authorization, in whole or in part, satisfies the three criteria in the Privacy Rule;

>A brief description of the protected health information for which use or access has been determined to be necessary by the IRB;

> A statement that the alteration or waiver of authorization has been reviewed and approved under either normal or expedited review procedures; and

> The signature of the chair or other member, as designated by the chair, of the IRB or the Privacy Board, as applicable.

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

> The use or disclosure of protected health information involves no more than a minimal risk to the privacy of individuals, based on, at least, the presence of the following elements:

*an adequate plan to protect the identifiers from improper use and disclosure;

* an adequate plan to destroy the identifiers at the earliest opportunity consistent with conduct of the research, unless there is a health or research justification for retaining the identifiers or such retention is otherwise required by law;

*adequate written assurances that the protected health information will not be reused or disclosed to any other person or entity, except as required by law--for example, authorized oversight of the research project by the IRB may necessitate review of the health information or for other research for which the use or disclosure of protected health information would be permitted by the Privacy Rule.

>The research could not practicably be conducted without the waiver; and

>The research could not practicably be conducted without access to and use of the protected health information.

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

2. Access to PHI as Preparatory to Research

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

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

The following is needed from the PI:

- b. HIPAA Disclosures from the 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) (<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 Sponsored Research or the IRB Chair.

POLICY ON INFORMED CONSENT OF CHILDREN

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

I. Definitions

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

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

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

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

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

II. Age Requirements for Assent

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

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

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

PROTECTION OF CHILDREN INVOLVED IN RESEARCH

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

I. To What Do These Regulations Apply?

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

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

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

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

II. Definitions

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

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

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

III. UT Tyler IRB Duties

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

a. Research not involving greater than minimal risk:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

IV. Requirements For Permission By Parents Or Guardians And For Assent By Children

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

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

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

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

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

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

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

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

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

V. Wards

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

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

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

COMPLIANCE AND MONITORING OF PROTOCOLS

The UT Tyler IRB is responsible for conducting the safety and monitoring process for all approved protocols. Methods for conducting reviews are established at the first meeting of the academic year.

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 OSR 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 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 Sponsored Research and the PI must first be completed.

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

THE UNIVERSITY OF TEXAS AT TYLER
Institutional Review Board

Review of IRB Policies, Procedures and Forms

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

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

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

The University of Texas at Tyler

Undergraduate and Graduate Student Course-Related Research Projects*

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

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

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

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

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

following website:

<http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm#46.101>).

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

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

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

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

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

ATTACHMENT A

1. Ethical Principles for the Protection of Human Subjects of Research
 - 1.1. Every person has the right to determine what shall be done to him or her, what activities he or she shall engage in and what risks he or she will take. Consequently, research on human subjects cannot be carried out without the subjects' competent, voluntary and informed consent.
 - 1.2. No person should be placed at risk as a subject of research unless the risks are reasonable in relation to the anticipated benefits of the research.
 - 1.3. The risks and burdens to subjects should not be unjustly distributed. The recruitment and selection of subjects should be reasonably related to the research and should not impose inequitable risks and burdens on any segment of society.
 - 1.4. Special consideration and protection should be given in research to persons who may lack full capacity to secure their own rights and interests, due to age, mental capacity, involuntary custody, cultural barriers or other special circumstances.
2. Definitions
 - 2.1. "Student Research" means any observation or intervention by a student as part of a course which is designed to develop or contribute to student learning or to general knowledge, and for which publication of findings outside class will not take place.
 - 2.2. "Human Subject" means an individual about whom an investigator conducting research obtains: (1) data through intervention or interaction with the person, or (2) personally identifiable information.
 - 2.3. "Student Researcher" means any student enrolled in a course at The University of Texas at Tyler who conducts research on human subjects as an assignment or project in the course (excluding master's or doctoral theses research which are not designated as classroom projects).
 - 2.4. "Minimal risk" is the probability and magnitude of harm that is normally encountered in the daily lives of healthy individuals, or in the routine medical, dental or psychological examination of healthy individuals. Minimal risk does not involve data that, if made public, could place the subject at risk of criminal or civil liability, be damaging to the subject's

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

3. Responsibility of Instructors

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

4. Instructor Review of Student Research

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

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

5. IRB Review of Student Research

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

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 Associate VP for Research, 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 Sponsored Research 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 OSR Website at <http://www.uttyler.edu/research/forms.htm>.

IRB Informed Consent Template Form	71
IRB Continuing Review Form	78
IRB Discontinuance Form	83
IRB Exempt Form	85
IRB Expedited Form	90
IRB Full Board Form	100
IRB Modification Form	124
IRB Research Misconduct And Non-Compliance Review Form	127
IRB Unanticipated-Adverse Event Form	129

INFORMED CONSENT FORM TEMPLATE (ICF)

Please be aware of the following:

This ICF is a ***template***, and as such, it has instructions, notes and examples in **blue text** that must be removed prior to submitting the ICF to the IRB for approval.

Select or modify the sample items in brackets and/or in **blue text** as appropriate.

Item numbers 9 and 10 on this template include alternate wording suggestions in **red text**. Please choose wording that participants can read and understand.

Please be sure to modify other items as appropriate for intellectual levels of those signing the consent form.

BEFORE SUBMITTING the ICF the IRB FOR APPROVAL, PLEASE BE SURE ALL TEXT IS BLACK AND THAT YOU HAVE ADDRESSED ALL ITEMS

For any questions about this form, please contact Dr. Gloria Duke
903-566-7023
gduke@uttyler.edu

THE UNIVERSITY OF TEXAS AT TYLER
Informed Consent to Participate in Research

1. Project Title: _____
2. Principal Investigator's Name: _____
3. Participant's Name: _____

To the Participant: [Ensure the following is written at the intellectual level of the participant.](#)

You are being asked to take part in this study at The University of Texas at Tyler (UT Tyler). This consent form explains why this research study is being performed and what your role will be if you choose to participate. This form also describes the possible risks connected with being in this study. After reviewing this information with the person responsible for your enrollment, you should be able to understand and make an informed decision on whether you want to take part in this study.

DESCRIPTION OF PROJECT: [Word the information as if you were speaking to the potential participant.](#)

4. Purpose of the Study [\(Explain all purposes of the study and if appropriate, include a statement that the study is experimental; make it clear that the project *is for* research purposes only; be sure all language is at the intellectual level of the participants; **be sure all information is presented in the language and reading level understandable to the potential participant; average reading levels for consent forms are at 5th-8th grade unless you are assured it is higher than this, e.g., college students, etc.** The IRB will return consent forms that are not written at this level if any potential subject or person signing for a subject is perceived to be 8th grade or less\). Remember that some persons appear to understand more than they actually do! Be sure that the person who signs the form can explain the study/risks/procedures back to you or to the person after they read the consent form.](#)

[Example: We invite you to participate in a research study \(that is experimental\) that will measure how well physical activity helps you to feel less fatigued or tired. We also want to see how the physical activity improves your quality of life.](#)

5. **Research Procedures** [Describe all procedures, identifying any that are experimental; make clear the participant's involvement, including the duration of their involvement and exactly what will be expected of them]

Example: You will be asked to walk at your own pace 5 days a week for 30 minutes. You will also be asked to keep a written record of this activity. There are 2 types of questionnaires we will ask you to fill out at the beginning and at the end of the study. These questionnaires take about 45 minutes to finish.

6. **Side Effects/Risks** [Describe any reasonably foreseeable risks or discomforts to the participant, again, using language easily understood by the participant. Even if there are no foreseeable risks, let them know that there may be uneasiness or anxiety through mere participation in the study.]

Example: Possible side effects from participating in this study may be those similar to how you feel when you exercise too hard when you are not used to it. For example, you may have some shortness of breath and feel tired when you first begin. It will be very important that you follow the directions that we give you about how to pace yourself and what to do if you have certain signs and symptoms. Because your doctor has given permission for you to be a part of this study, your risks of having heart problems, such as a heart attack, stroke, or other problems, are very low. The other risk may be related to the amount of time it will take for you to fill out the questionnaires. This may make you tired, or even a little anxious as you answer some of the items about your health problems.

Example for participants completing questionnaires: Questionnaires may contain questions that are sensitive in nature. You may refuse to answer any question that makes you feel uncomfortable. If you have concerns after completing the questionnaires, we encourage you to contact the principal investigator (contact information will be at the end of this consent form).

Any possible risks have been listed above, but please keep in mind that unpredicted risks may exist.

7. **Potential Benefits** [Describe any benefits to the participant or to the person signing for the participant which may reasonably be expected from the research. State if there are no potential benefits. Honorariums or other incentives are not considered to be "benefits". A benefit may include tangible or intangible benefits.]

Example: Your participation in this study may help researchers discover information that can help other people. There are no direct benefits to you by participating in this study.

UNDERSTANDING OF PARTICIPANTS

8. I have been given an opportunity to ask any questions concerning the [procedure/survey/treatment/or the like] involved and the investigator has been willing to answer my questions. This [procedure/survey/treatment/or the like] will be [administered/conducted/or the like] at [The University of Texas at Tyler] as part of the project titled, numbered, and described above. I hereby authorize _____, the principal investigator, and/or the investigator she/he may designate, to (administer/conduct/or the like) the [procedure/survey/treatment/Or the like].
9. I have been told and I understand that my participation in this study is strictly voluntary and that I may refuse to participate without penalty or loss of benefit to which I am otherwise entitled.

(NOTE: The following is an alternate wording for those 8th grade and under; it may still need to further modified depending on the intellectual level of the signer):

I am taking part in this study because I want to. I chose to take part in this study after having been told about the study and how it will affect me. I know that at anytime I can decide I do not want to do the study any more. I know that if I decide I do not want to do the study any more nothing will happen to me and it is OK to stop doing the study).

10. I have been told and I understand that I may withdraw my consent and stop my participation in this study at any time, and that such withdrawal of consent or discontinuation will involve no penalty or loss of benefits to which I am otherwise entitled.

NOTE: The following are alternate wordings for those 8th grade and under—it may still need to further modified depending on the intellectual level of the signer.

I know I can stop being a part of the study whenever I want to. If I do stop I know this means that nothing will happen to me and I will not lose anything I am supposed to receive, like benefits, or have any costs or other types of penalties.

A lower level version of this: If I sign this consent form I know it means that I am saying that I have been told that I can stop being a part of this study at anytime. I know that if I do stop being a part of the study nothing will happen to me.

In addition, I understand the following:

- I will be informed of any new information or findings that may affect my willingness to continue participating in this study.

- The study may be changed or stopped at any time by the principal investigator or by The University of Texas at Tyler.
- The principal investigator will gain my written consent for any changes that may affect me

11. I have been assured that confidentiality will be preserved and that my name will not be revealed in any reports or publications resulting from this study without my expressed written consent, except that qualified investigators from the Department of Health and Human Services may review my records where appropriate and necessary.

I also understand that any personal health information or other information collected during this study may be shared with the following as long as no identifying information as to my name, address or other contact information is provided:

- Organization contributing money to be able to conduct this study
- Other researchers interested in combining your information with information from other studies
- Information shared through presentations or publications

I understand The UT Tyler Institutional Review Board (the group that ensures that research is done correctly and that measures are in place to protect the safety of research participants) may review documents that have my identifying information on them as part of their compliance and monitoring process. I also understand that any personal information revealed during this process will be kept strictly confidential.

I also understand that any information regarding safety of drugs must be shared, but in regards to any other information, I may cancel my permission at any time to share information collected from me by contacting the researcher named in this consent at the following address:

[Name of PI and contact information](#)

The University of Texas at Tyler
 Institutional Review Board
 c/o Office of Sponsored Research
 3900 University Blvd
 Tyler, TX 75799

12. I have been informed of the reasonably foreseeable risks associated with participation in this research project. I have been informed that should I suffer any injury as a result of participation in this project, [\[the following medical services will be available: _____\]](#). I understand, however, that in the absence of negligence on the part of The University of Texas at Tyler personnel, I cannot expect to receive any payment for medical expenses or any financial compensation for such injury.

13. I understand that I [will/will not] be charged for [any] costs involved in this project. For example, The costs will be approximately \$_____, specifically for _____. For example, For undergoing this procedure, I will be paid \$_____.

My insurer and/or I will be responsible for the cost of any supportive or treatment of any research-related complications or injuries.

I also understand that I will not be compensated for any patents or discoveries that may result from my participation in this research.

14. If I have any questions concerning my participation in this project, I shall contact Name of PI or other contact person at telephone #1. If I have any questions concerning my rights as a research subject, I shall contact Dr. Gloria Duke, Chair of the IRB, at (903) 566-7023. I understand that I may contact Dr. Duke with questions about research-related injuries.

15. CONSENT/PERMISSION FOR PARTICIPATION IN THIS RESEARCH STUDY

Based upon the above, I consent to [participate in the research/undergo the described procedure/participate in the described survey/or the like]. I give the principal investigator or study researcher permission to enroll me in this study. I have received a signed copy of this consent form.

_____ Signature of Participant	_____ Date
_____ Signature of Person Responsible	_____ Relationship to Participant
_____ Signature of Child (ages 13-17 years)	_____
_____ Witness	_____ Witness

16. I have discussed this project with the participant and/or her/his authorized representative, using language that is understandable and appropriate. I believe that I have fully informed this participant of the nature of this study and its possible benefits and risks, and I believe the participant understood this explanation

_____ Investigator	_____ Date
-----------------------	---------------

TRANSLATOR

I have translated this consent form into (specify language) and I assisted the investigator in the consenting process for this participant.

Translator Printed Name

Translator Signature

Date

**THE UNIVERSITY OF TEXAS AT TYLER
INSTITUTIONAL REVIEW BOARD**

CONTINUING REVIEW OF PROTOCOLS INVOLVING HUMAN SUBJECTS

The UT Tyler Policy on the protection of human subjects provides for the continuing review of all activities involving the use of human subjects. The information requested below will provide the basis for the continuing review of your study, which is now subject to this periodic review.

Date:

Please Answer All Questions. If a Question Does Not Apply to Your Study Answer "N/A."

Original Date of Approval:

1. IRB#
2. Title of Project
3. Principal Investigator:
4. Department:
5. Telephone Ext:
6. For this protocol, approval is requested for:

(For This And All Other Boxes, Highlight Box And Type "X")

Continuance

Discontinuance

Reason for Request:

7. Check the one(s) which most accurately describes the current status of the above protocol:

Study has not yet begun since the original date of approval (please explain):

- Study is currently active
- Study is on "hold" (please explain):
- Study has been terminated (please explain):
- Other (please explain):

8. Has the project protocol, procedures and/or the Informed Consent form changed in this last reporting period? (Consider changes in title, sample size, subject reimbursement, clinical procedures, drugs, etc.).

Yes No

(If yes, answer 8.a. through 8.b.)

8.a. Were changes in the project protocol, procedures and/or Informed Consent Form reported in writing (IRB Modification in Approved Protocol) to, and approved by, the IRB?

Yes No

8.b. Briefly describe the changes:

8.c. Please list the names of any investigators who have been added or deleted during this reporting period.

Added:

Deleted:

Please explain:

8.d. Has your assessment of the risks the benefits or risks changed during this reporting period (since initial, last modification or last continuing review)?

Yes No

If yes, please explain:

9. If this protocol is part of a study supported by a granting agency, were changes reported to the granting agency?

Yes No

9.a. If yes, please attach a copy of any protocol-related correspondence to the granting agency.

I. SUBJECT RECRUITMENT/PARTICIPATION

10. Number of subjects approved:
11. Total number of subjects enrolled to date:

If none, state "0" and explain:

If the answer to item 11 is "0," you may now proceed to Item #16. If one or more subjects have been enrolled, please continue to complete the form.

12. Total number of subjects enrolled during this reporting period:
13. Number of additional subjects you intend to enroll:

If none, state "0" and explain:

14. Number of subjects actively involved in the study at this time:

(Be sure consent forms are readily available for IRB compliance reviews)

15. Number of subjects enrolled during this reporting period who were (if none, state "0" for each category):

Children:

Pregnant:

Mentally Disabled:

Prisoners:

Fetuses ex utero:

16. If your investigation required written subject consent:
- 16.a. Was this consent obtained from each subject? YES NO
- 16.b. Did subjects receive a copy of the Informed Consent Form? YES NO
17. If your investigation was approved for non-written consent:
- 17.a. Was this consent obtained from each subject? YES NO
- 17.b. Where is evidence recorded that consent was obtained? YES NO
- 17.c. Briefly describe any problems encountered in obtaining subject consent:

UNANTICIPATED PROBLEMS/ADVERSE EVENTS:

18. Did any unusual and/or unanticipated side effects or serious problems arise during this during this reporting period (includes medication errors)? YES NO
- If yes, please answer 18.a. and 18.b.
- 18.a. Were these problems reported in writing (IRB Unanticipated Problem or Adverse Event/Death form) to, and acknowledged by, the IRB?
 YES NO
- 18.b. Please describe these problems briefly with number of occurrences and/or number of subjects involved:
19. List publications, if any, resulting from the study, and attach copy:

INSTRUCTIONS:

- Complete and electronically return IRB Continuing Review form to the IRB Chair
- If project has been completed or terminated, complete and return IRB Continuing Review form and be prepared to submit copies of signature pages of informed consent forms upon request of IRB

My signature indicates that I am taking every precaution to minimize risks to subjects:

"SIGNATURE" OF PRINCIPAL INVESTIGATOR

PI Name: _____

(Electronic submission of this form by PI indicates signature)

Date: _____

IRB:

Approved by:

Date:

**THE UNIVERSITY OF TEXAS AT TYLER
INSTITUTIONAL REVIEW BOARD**

REQUEST FOR DISCONTINUANCE OF STUDY

Date:

Title Of Protocol:

IRB#:

Principal Investigator:

Department:

Telephone Extension:

Last Submission/Review Date:

Original Date of Approval:

REASON FOR REQUEST: (Highlight Box And Type "X")

- PI does not wish to pursue Sponsor cancelled the study
- Enrollment ended (closed) No contract
- New data became available which negates the need for this study.
- Other: _____
- Not enough assistance to perform the study
- Adverse events profile indicates need for discontinuation. (Attach IRB Adverse Event/Death form)
- Efficacy of therapeutic agent is insufficient to pursue further investigation.

SUBJECT RECRUITMENT/PARTICIPATION

Number of participants approved:

Total number of consents signed:

Total number of participants entered into study:

Number of:

Males:

Females:

Children:

Blacks:

Asians:

Hispanics:

Other Minorities:

Pregnant Women:

Prisoners:

Mentally Disabled:

Fetuses in utero:

Fetuses ex utero:

Total number of discontinued participants for any reason:

Total number of completed participants:

Total number of participants enrolled since last submission/review date:

Completed:

Discontinued:

If none, state "0" and explain:

Outcome of study if known:

Attach any publications or abstracts from UT Tyler that have been completed as of this date.

Number of abstracts:

Number of papers:

Please attach a complete list of participants by initials or by study code number. Also be prepared to submit copies of all informed consent form signature pages.

SIGNATURE OF PRINCIPAL INVESTIGATOR

Principal Investigator Signature
(Electronic submission of this form by PI indicates signature)

Date

<p>Received: _____</p> <p>By: _____</p> <p>Approval Date: _____</p>

THE UNIVERSITY OF TEXAS AT TYLER
INSTITUTIONAL REVIEW BOARD

EXEMPT RESEARCH APPLICATION

IRB: _____
Approved by: _____
Date: _____

A complete listing of the six categories of research with human subjects that are exempt is given in Subpart **46.101(b)** of the Federal Policy for the Protection of Human Subjects at <http://www.med.umich.edu/irbmed/FederalDocuments/hhs/HHS45CFR46.html#46.101>, and on Page 4 of this form.

Attach (electronically) with this application:

- Written consent form unless a waiver of written informed consent is requested
- Dean/Department Chair Approval form (to be sent by Dean or Department Chair electronically)
- Brief research proposal that outlines background and significance, research design, research questions/hypotheses, data collection instruments and related information, data collection procedures, data analysis procedures.
- Human Subject Education Certification for PI, co-investigators, and research assistants participating in recruitment, data collection, data analysis, or, if they have any exposure to identifiable data (if training has not been completed at UT Tyler within a 3 year period of time)
- Tool/instrument/survey; if copyright or other issues prohibit electronic form, submit one hard copy

Date:

Title Of Study:

Principal Investigator:

Faculty Sponsor And Email If PI Is Student:

Purpose Of Study:

Research Questions:

Reason Research Is Exempt (specify which exempt category, last page of this document):

Population To Be Studied: **Ages:** **Gender:**

Number of Subjects:

Significance of Study:

Source of Data to be Collected (Specific population inclusion/exclusion criteria, medical records, existing specimens, discarded tissue, etc):

Method of Sampling (convenience, etc.):

Methods of Sample Recruitment (attach any verbal/phone/written scripts, flyer, ads, etc.)

Person(s) Responsible for Recruitment:

Methods of Data Collection

Methods of Data Analysis:

Approximate Duration of Time Over Which the Study Will Be Conducted:

Procedures That Will Be Used To Maintain Confidentiality of Information:

Method of Obtaining Consent (if applicable, attach copy of consent form):

(For sample participants under the age of 18 years, the PI is responsible for abiding by the UT Tyler Policy on Informed Consent for Children).

Source of Funding (If applicable, please attach copy of Grant Application):

SIGNATURE OF PRINCIPAL INVESTIGATOR: Signature indicates agreement by the PI to abide by

IRB policies and procedures and the Assurance, and to the obligations as stated in the “Responsibilities of the Principal Investigator”, and to use universal precautions with potential exposure to specimens.

Principal Investigator Signature
(Electronic submission of this
form by PI indicates signature)

Date

Categories for Exempt Research

The following categories for Exempt Research is in compliance with Subpart **46.101(b)** of the Federal Policy for the Protection of Human Subjects, located at:
<http://www.med.umich.edu/irbmed/FederalDocuments/hhs/HHS45CFR46.html#46.101>

1. 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.

2. 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.

3. 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.

4. 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.

5. 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.

6. 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 UNIVERSITY OF TEXAS AT TYLER
INSTITUTIONAL REVIEW BOARD

EXPEDITED RESEARCH APPLICATION

IRB:

Approved by:

Date:

To qualify for expedited review research must present no more than minimal risk to human subjects and cannot explore sensitive topics. In addition the research must fit the categories of expedited research, per OHRP regulations.

Attach (electronically) with this application:

- Written consent form unless a waiver of written informed consent is requested
- Dean/Department Chair Approval (to be sent by Dean or Department Chair electronically)
- Brief research proposal that outlines background and significance, research design, research questions/hypotheses, data collection instruments and related information, data collection procedures, data analysis procedures.
- Human Subject Education Certification for PI, co-investigators, and research assistants participating in recruitment, data collection, data analysis, or, if they have any exposure to identifiable data (if training has not been completed at UT Tyler within a 3 year period of time)
- Tool/instrument/survey; if copyright or other issues prohibit electronic form, submit one hard copy

COMPLETE ALL ITEMS TO AVOID DELAY IN IRB APPROVAL

DATE:

Principal Investigator	(Last) (First) (MI)
<i>PI Title and Credentials</i>	<input type="checkbox"/> Assistant Professor <input type="checkbox"/> Associate Professor <input type="checkbox"/> Professor <input type="checkbox"/> Other
<i>Faculty Sponsor/Telephone</i> <i>(if PI is student)</i>	
PI's Department	
PI's Telephone Number	
<i>Contact Person in Absence of PI</i>	
<i>Telephone #s</i>	
Title of Proposed Research (must match the NIH/Sponsor title if applicable)	
Start Date/Finish Date	
<i>Source of Funding</i>	<input type="checkbox"/> NIH <input type="checkbox"/> Local <input type="checkbox"/> Industry <input type="checkbox"/> Other Federal (Specify) <input type="checkbox"/> Other (Specify)

1. Designate the category that qualifies this proposal for expedited review (see UT Tyler Expedited Categories at the end of this application) and justify this designation by responding to the statements below each category

<p>Category # Information Required for Justification (See specific information under each category)</p>

2. If this is a retrospective chart review (Category 5)(health records research), refer to the IRB's HIPAA policies and procedures and complete any appropriate forms. In addition, all of the following **must be addressed**: 1) describe specifically what data will be collected, whether or not subject identifiers will be present, and at what point in time identifiers will be destroyed. 2) state why the research could not practicably be carried out without access to and use of the protected health information.

3. **Purpose Of Study:**
4. **Research Questions:**
5. **Background and Significance of Study (may copy/paste from proposal but please include just enough to demonstrate significance):**

6. **POPULATION AND SAMPLE**

6a. Inclusion and exclusion criteria:

<u>General Inclusion:</u>	
• Approximate number of subjects	<input type="checkbox"/> NA
• Age Range	
• Gender: Males	<input type="checkbox"/> Yes <input type="checkbox"/> No
Females	<input type="checkbox"/> Yes <input type="checkbox"/> No
Explain below if either gender is excluded.	
• Will all racial/ethnic groups be included?	<input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> NA
Explain any exclusion.	
<u>Protocol Sample Inclusion Criteria:</u>	
<u>Protocol Sample Exclusion Criteria:</u>	

- 6b. Special classes possibly eligible to participate in the research: Mentally Impaired
 Children Pregnant Women

Note: Studies with the following class cannot be Expedited: **Prisoners**

- 6c. **Recruitment procedures** (attach any recruitment materials, e.g., flyers, advertisements, telephone script, letters, etc.)

6d. **Method of Sampling (convenience, etc.):**

6e. **Method of Sample Recruitment and Persons Responsible for**

Recruitment:

7. **Informed Consent**

Describe the method to be used to obtain informed consent. Prospective research ordinarily requires written informed consent. If any special classes are eligible to participate, discuss how the consent process will differ. **Inclusion of children (under 18 years) requires permission of at least one parent AND the assent of the child (refer to UT Tyler's Policy on Informed Consent of Children).**

For sample participants under the age of 18 years, the PI is responsible for abiding by the UT Tyler Policy on Informed Consent for Children.

7a. **This section only for those requesting a waiver or alteration of informed consent**

Justify the waiver or alteration in accordance with the following four criteria established under 45CFR46.116(d)(1-4). All four criteria must be met.

1. The research involves no more than minimal risk* to the subjects Yes No

2. The waiver or alteration will not adversely affect the rights and welfare of the subjects
 Yes No

3. The research could not practicably be carried out without the waiver or alteration,
 Yes No AND

4. Whenever appropriate, the subjects will be provided with additional pertinent information after participation Yes No.

8. **Data Collection Procedures** (specify who, what, when, where, how, duration type of information)

9. **Confidentiality of Data:** Specify how confidentiality will be maintained for research data and/or specimens.

10. **Identifiability of data or specimens:** Will the specimens or data be identifiable?

Yes No If yes, complete item 9a

9a. State the type of identification, direct or indirect, on any specimens or data when they are made available to your study team:

Direct Identifiers include subject name, address, social security, etc.

Indirect Identifiers include any number that could be used by the investigator or the source providing the data/specimens to identify a subject, e.g., pathology tracking number, medical record number, sequential or random code number)

11. **Access to Data:** Specify faculty and staff (members of the study team) permitted to have access to the study data.
12. **Protection of Data:** **State** how data will be protected, e.g., located filing cabinet in investigator's office, on password protected computer, location(s) of computer, etc.
13. **Risks and benefits to the subjects and/or society**

Risks:

Benefits:

SIGNATURE OF PRINCIPAL INVESTIGATOR: Signature indicates agreement by the PI to abide by UT Tyler IRB policies and procedures in the UT Tyler Handbook and the Federal Wide Assurance, to the obligations as stated in the "Responsibilities of the Principal Investigator" and to use universal precautions with potential exposure to specimens.

Principal Investigator Signature
(Electronic submission of this
form by PI indicates signature)

Date

**The University of Texas at Tyler
Institutional Review Board
Categories for Expedited Research**

The following describes research activities and categories for expedited reviews:

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

(B) The categories in this list apply regardless of the age of subjects, except as noted.

(C) The expedited review procedure may not be used where identification of the subjects and/or their responses would reasonably place them at risk of criminal or civil liability or be damaging to the subjects in terms of financial standing, employability, insurability, reputation, or be stigmatizing, unless reasonable and appropriate protections will be implemented so that risks related to invasion of privacy and breach of confidentiality are no greater than minimal.

(D) The expedited review procedure may not be used for classified research involving human subjects.

(E) The standard requirements for informed consent (or its waiver, alteration, or exception) apply regardless of the type of review--expedited or convened--utilized by the IRB.

(F) Categories one (1) through seven (7) pertain to both initial and continuing IRB review.

The following categories for Expedited Research is in compliance with 45 CFR 46.110 and 21 CFR 56.110 of the Federal Policy for the Protection of Human Subjects, located at: <http://www.hhs.gov/ohrp/humansubjects/guidance/expedited98.htm>

RESEARCH CATEGORIES

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

(a) Research on drugs for which an investigational new drug application (21 CFR Part 312) is not required. (Note: Research on

marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review.)

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

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

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

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

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

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

collected by buccal scraping or swab, skin swab, or mouth washings; (j) sputum collected after saline mist nebulization.

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

Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.)

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

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

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

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

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

(NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. [45 CFR](#)

46.101(b)(2) and (b)(3). This listing refers only to research that is not exempt.)

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

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

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

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

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

**THE UNIVERSITY OF TEXAS AT TYLER
INSTITUTIONAL REVIEW BOARD
FULL BOARD REVIEW APPLICATION**

IRB: Approved by: Date:

The University of Texas at Tyler faculty, staff, students, or employees who propose to engage in any research, demonstration, development, or other activity involving the use of human subjects must have review and approval of that activity by the IRB, prior to initiation of the project. The Committee is responsible for safeguarding the rights and welfare of subjects who participate in the proposed research activity.

The purpose of this form is to review proposals which may not be eligible for exempt or expedited review.

Attach (electronically) with this application:

- Written consent form unless a waiver of written informed consent is requested
- Dean/Department Chair Approval (to be sent by Dean or Department Chair electronically)
- Brief research proposal that outlines background and significance, research design, research questions/hypotheses, data collection instruments and related information, data collection procedures, data analysis procedures.
- Human Subject Education Certification for PI, co-investigators, and research assistants participating in recruitment, data collection, data analysis, or, if they have any exposure to identifiable data (if training has not been completed at UT Tyler within a 3 year period of time)
- Tool/instrument/survey; if copyright or other issues prohibit electronic form, submit one hard copy

PLEASE ANSWER ALL QUESTIONS IN ORDER TO AVOID IRB APPROVAL. IF A QUESTION DOES NOT APPLY, ANSWER "N/A."

(For This And All Other Boxes, Highlight Box And Type "X" or Content)

Initial Submission Resubmission Other

1. Project Title:
2. Principal Investigator:
 - 2a. Title:
 - 2b. Department:
 - 2c. Telephone:
3. In the absence of the Principal Investigator, identify contact person:

Telephone:
4. For non-faculty submitting a protocol, please identify the faculty member responsible for conduct of the research.

Name: Telephone:

Title: Department:
5. Expected Starting Date:
6. Expected Completion Date:
7. Possible support from Extramural Sponsor? Yes No

If "Yes," name of Sponsor:

Summary of the Research Protocol

8. List research questions, numerically:
9. List potential benefits that may accrue to the study subjects as a result of their participation.

10. List potential benefits that may accrue to society as a result of this study.

11. Will the study require the use of human organs, tissue, or body fluids other than urine or blood? Yes No

If "Yes," check the appropriate box:

11a. The specimens will be collected specifically for this project. Yes No

11b. The specimens will be obtained from discarded material collected for clinical purposes. Yes No

11c. Describe the nature of the specimens and indicate from whom or where they will be obtained.

11d. Will the donors be identified? Yes No

Study Population

12. Please indicate which, if any, of the following are involved:

Normal Subjects	<input type="checkbox"/>	Fetuses	<input type="checkbox"/>
Students	<input type="checkbox"/>	Children	<input type="checkbox"/>
Faculty/Staff	<input type="checkbox"/>	Prisoners	<input type="checkbox"/>
Other Patients	<input type="checkbox"/>	Mentally Disabled	<input type="checkbox"/>
Pregnant Women	<input type="checkbox"/>	Nonconsenting Subjects	<input type="checkbox"/>

13. Needed number of subjects:

14. Age range of subjects:

15. What is your justification for this number of subjects (e.g., power analysis, data saturation)?

16. Source of subjects:

17. List all criteria for including subjects:
18. List all criteria for excluding subjects:
19. To your knowledge, will any subjects also be participating in other research protocols? Yes No
- 19.a. If so, which studies?
20. What rewards, remuneration, or other incentives will be used to recruit subjects?
21. Describe in detail how you will recruit subjects.*
- | | | |
|----|--------------------------------------|--------------------------|
| A. | Direct person-to-person solicitation | <input type="checkbox"/> |
| B. | Telephone | <input type="checkbox"/> |
| C. | Letter | <input type="checkbox"/> |
| D. | Notices | <input type="checkbox"/> |
| E. | Other (explain) | <input type="checkbox"/> |

****If the subjects are to be recruited under A & B, please include an outline of the oral presentation.***

For items C, D, and E please submit verbatim copies, e.g., letter, notices, advertisements.

Interventions/Measurements/Data Collection Procedures

22. Will blood samples be required? (If so, answer a through f)

Yes No

- | | | | | |
|------|-------------------|--------------------------|-------------------|--------------------------|
| 22a. | Venipuncture | <input type="checkbox"/> | Venous catheter | <input type="checkbox"/> |
| | Arterial puncture | <input type="checkbox"/> | Arterial catheter | <input type="checkbox"/> |

Cutaneous

(e.g., finger, heel)

22b. Will the collection procedure consist only of drawing an extra volume of blood at the time blood is drawn for clinical purposes?

Yes No

22c. Specify the important features of the blood collection, including the volume of research blood obtained in each collection, along with the frequency and duration of the collection (e.g., 10 ml at noon and 8 p.m., one day every two weeks for a six-month period).

22d. Will >50 ml of blood be drawn from the same subject more than once?

Yes No

22e. If "Yes," what procedures will be in place to assure that the frequency and amounts will not exceed the specifications?

22f. Is it known or anticipated that any subjects will also be having blood drawn for other purposes during the study period?

Yes No

23. Please indicate any of the following you propose to use and provide copies (if copies are not available electronically, send hard copies via mail to IRB Chair):

- | | | | |
|--------------------------|--------------------------|-----------------------------|--------------------------|
| a. Educational Tests | <input type="checkbox"/> | e. Interview | <input type="checkbox"/> |
| b. Questionnaires | <input type="checkbox"/> | f. Previously recorded data | |
| c. Psychological Tests | <input type="checkbox"/> | including clinical records | <input type="checkbox"/> |
| d. Educational Materials | | | |
| (curricula, books, etc.) | <input type="checkbox"/> | | |

24. Will the study involve the use of drugs?

Yes No

- a. A placebo yes no Name: _____
- b. A standard FDA-approved agent Name: _____
- c. A non-therapeutic approved agent
(e.g., to modify a physiologic response) Name: _____
- d. A new investigational therapeutic agent Name: _____
- e. A new use for an agent approved for another
purpose Name: _____

For (d) or (e) give IND # _____

25. Will the study involve the use of a new device?

Yes No

If so,

- a. The device has an IDE number Number: _____
- b. It is for therapeutic use
- c. It is for diagnostic use

26. Identify any additional procedures/interventions (invasive or otherwise) drugs, documents, or tests involved in this activity that are used **solely for research purposes**.

27. Describe, in detail, **data collection procedures**: specify who, what, when, where, how, etc.

28. List potential risks (physiological/psychological risks, injury) to subjects that may be incurred during the study

28a. If risks or injury are associated with this project, what is the likelihood of their occurrence?

29. Describe actions to minimize risks to subjects.

Confidentiality-Privacy-Coercion

30. Since all data collected on individual subjects in a research study is generally considered confidential, how will you maintain confidentiality and anonymity of your data? (e.g., by coding, especially if shared with another researcher)

30.a. Where will data be stored (e.g., in a locked file cabinet, pass-word protected computer)?

31. Does this research involve medical chart reviews? Yes No

If “yes”, please answer Items 31a-31d

31a. Please explain what type of information will be obtained:

31b. Will the records be reviewed without the patient's permission?

Yes No

31c. If “Yes,” please explain why a verbal or written informed consent will not be requested:

31d. Have HIPAA forms been completed and submitted to the IRB?

Yes No

32. Could any part of this activity result in the potential identification of child abuse, communicable diseases, or criminal activities?

Yes

No

32a. If "Yes," estimate the likelihood of disclosure:

33. Aside from possible loss of confidentiality, could any part of this activity be seen as invading the privacy of the participants of this study?

Yes

No

33a. If "Yes," explain and describe proposed safeguards:

34. Does any part of this activity have the potential for coercion of the subject?

Yes

No

34a. If "Yes," explain and describe proposed safeguards:

35. Is there a potential **Conflict of Interest** pertaining to this protocol as defined in the UT Tyler *Conflict of Interest* policy on the part of any individual at UT Tyler who is associated with this protocol?

Yes

No

35a. If "Yes," please explain.

35b. If you answered "yes" to the above question, or, if this research is either federally funded, or federal funding has been applied for, a UT

Tyler Conflict of Interest form must be completed by accessing the Office of Sponsored Research (OSR) website before final approval.

35c. Is this research protocol either federally funded, or is in the process of applying for federal funds? Yes No

3d. Has a **COI** form been completed and submitted to the OSR? Yes No

36. Could the desired information be obtained from animals or other laboratory models? Explain:
Yes
No

Cost of Research

37. Will the subjects incur any additional expenses for experimental (or otherwise unnecessary diagnostic) tests or procedures?
Yes
No
If "Yes," explain:

Informed Consent

38. **Written informed consent** from the subject or from a legally responsible representative of the subject **is normally required** from human research participants. The proposed consent form should follow the guidelines of the UT Tyler Informed Consent Template and should be included with the materials submitted to the IRB.

For sample participants under the age of 18 years, the PI is responsible for abiding by the UT Tyler Policy on Informed Consent for Children.

- 38a. Will you be obtaining consent other than written consent?

Yes No

- 38b. If you do not propose to obtain consent please provide your rationale for obtaining **oral** consent or assent (assent applies to subjects under 18 years old. See UT Tyler's Policy on Protection of Children Involved in Research)

- 38c. If written consent is being obtained and confidentiality is assured in the informed consent form, where do you plan to keep the signed informed consent forms?

Cooperative Agreements with Other Institutions

39. If any part of this study will be conducted in an institution or location administratively separate from UT Tyler, please indicate at which institution (attach IRB approval letter from the other institution).

40. Does this activity utilize recorded data to be sent to cooperating institutions not under your control?

Yes

No

- 40a. If so, could the data contain personal or sensitive information?

Yes

No

40b. If “Yes,” how do you propose to maintain confidentiality of the data?

Consultation and Collaboration

41. Subject Recruitment and Management: If approval is required from other professionals for the recruitment or management of the subjects, please identify and provide contact information from the individual(s) responsible for the subjects. Electronic letter of approval must be submitted by the PI.

Name of Professional:

Institution/Agency:

Contact Information:

Name of Professional:

Institution/Agency:

Contact Information:

Name of Professional:

Institution/Agency:

Contact Information:

42. Consultation

It is highly recommended that in areas of uncertainty, consultation be obtained and that evidence of such be submitted with the protocol. The IRB, on an individual basis, shall, where appropriate, request that investigators obtain consultation. If applicable, state how and where you will obtain consultation.

43. Research Collaboration:

Research collaborators are other non-UT Tyler-affiliated researchers whose participation enhances the scientific merit of a research project. List collaborators below and have each verify that they have read the research protocol and agree to participate by emailing the PI, and PI is to forward these emails of agreement to IRB Chair with this application.

Collaborator Name:

Collaborator Institution:

Collaborator Contact Information:

44. IRB Access to Records

The IRB is accountable to the FDA/DHHS for the continuing review of research protocols that involve human subjects and therefore must have access to the records associated with investigational protocols involving human subjects. Where do you plan to keep your records?

SIGNATURE OF PRINCIPAL INVESTIGATOR: Signature indicates agreement by the PI to abide by UT Tyler IRB policies and procedures and the Federal Wide Assurance, and to the obligations as stated in the “Responsibilities of the Principal Investigator” and any other related policies and procedures described in the UT Tyler IRB Handbook (listed on the OSR website), and to use universal precautions with potential exposure to specimens.

Principal Investigator Signature
(Electronic submission of this
form by PI indicates signature)

Date

**THE UNIVERSITY OF TEXAS AT TYLER
INSTITUTIONAL REVIEW BOARD**

FULL BOARD REVIEW APPLICATION

IRB:

Approved by:

Date:

The University of Texas at Tyler faculty, staff, students, or employees who propose to engage in any research, demonstration, development, or other activity involving the use of human subjects must have review and approval of that activity by the IRB, prior to initiation of the project. The Committee is responsible for safeguarding the rights and welfare of subjects who participate in the proposed research activity.

The purpose of this form is to review proposals which may not be eligible for exempt or expedited review.

Attach (electronically) with this application:

- Written consent form unless a waiver of written informed consent is requested
- Dean/Department Chair Approval (to be sent by Dean or Department Chair electronically)
- Brief research proposal that outlines background and significance, research design, research questions/hypotheses, data collection instruments and related information, data collection procedures, data analysis procedures.
- Human Subject Education Certification for PI, co-investigators, and research assistants participating in recruitment, data collection, data analysis, or, if they have any exposure to identifiable data (if training has not been completed at UT Tyler within a 3 year period of time)
- Tool/instrument/survey; if copyright or other issues prohibit electronic form, submit one hard copy

PLEASE ANSWER ALL QUESTIONS IN ORDER TO AVOID IRB APPROVAL. IF A QUESTION DOES NOT APPLY, ANSWER "N/A."

(For This And All Other Boxes, Highlight Box And Type "X" or Content)

Initial Submission

Resubmission

Other

1. Project Title:

UT Tyler IRB Handbook

Approved 1-23-06; rev. 07/2007; 4/2008; 2/2/2009

2. Principal Investigator:

2a. Title:

2b. Department:

2c. Telephone:

3. In the absence of the Principal Investigator, identify contact person:

Telephone:

4. For non-faculty submitting a protocol, please identify the faculty member responsible for conduct of the research.

Name:

Telephone:

Title:

Department:

5. Expected Starting Date:

6. Expected Completion Date:

7. Possible support from Extramural Sponsor? Yes No

If "Yes," name of Sponsor:

Summary of the Research Protocol

8. List research questions, numerically:

9. List potential benefits that may accrue to the study subjects as a result of their participation.

11. List potential benefits that may accrue to society as a result of this study.

11. Will the study require the use of human organs, tissue, or body fluids other than urine or blood? Yes No

If "Yes," check the appropriate box:

11a. The specimens will be collected specifically for this project. Yes No

11b. The specimens will be obtained from discarded material collected for clinical purposes. Yes No

11c. Describe the nature of the specimens and indicate from whom or where they will be obtained.

11d. Will the donors be identified? Yes No

Study Population

12. Please indicate which, if any, of the following are involved:

Normal Subjects	<input type="checkbox"/>	Fetuses	<input type="checkbox"/>
Students	<input type="checkbox"/>	Children	<input type="checkbox"/>
Faculty/Staff	<input type="checkbox"/>	Prisoners	<input type="checkbox"/>
Other Patients	<input type="checkbox"/>	Mentally Disabled	<input type="checkbox"/>
Pregnant Women	<input type="checkbox"/>	Nonconsenting Subjects	<input type="checkbox"/>

13. Needed number of subjects:

14. Age range of subjects:

15. What is your justification for this number of subjects (e.g., power analysis, data saturation)?

16. Source of subjects:

17. List all criteria for including subjects:
18. List all criteria for excluding subjects:
19. To your knowledge, will any subjects also be participating in other research protocols? Yes No
- 19.a. If so, which studies?
20. What rewards, remuneration, or other incentives will be used to recruit subjects?
21. Describe in detail how you will recruit subjects.*
- | | | |
|----|--------------------------------------|--------------------------|
| A. | Direct person-to-person solicitation | <input type="checkbox"/> |
| B. | Telephone | <input type="checkbox"/> |
| C. | Letter | <input type="checkbox"/> |
| D. | Notices | <input type="checkbox"/> |
| E. | Other (explain) | <input type="checkbox"/> |

****If the subjects are to be recruited under A & B, please include an outline of the oral presentation.***

For items C, D, and E please submit verbatim copies, e.g., letter, notices, advertisements.

Interventions/Measurements/Data Collection Procedures

22. Will blood samples be required? (If so, answer a through f)

Yes No

- | | | | | |
|------|-------------------|--------------------------|-------------------|--------------------------|
| 22a. | Venipuncture | <input type="checkbox"/> | Venous catheter | <input type="checkbox"/> |
| | Arterial puncture | <input type="checkbox"/> | Arterial catheter | <input type="checkbox"/> |
| | Cutaneous | | | |

(e.g., finger, heel)

22b. Will the collection procedure consist only of drawing an extra volume of blood at the time blood is drawn for clinical purposes?

Yes No

22c. Specify the important features of the blood collection, including the volume of research blood obtained in each collection, along with the frequency and duration of the collection (e.g., 10 ml at noon and 8 p.m., one day every two weeks for a six-month period).

22d. Will >50 ml of blood be drawn from the same subject more than once?

Yes No

22e. If “Yes,” what procedures will be in place to assure that the frequency and amounts will not exceed the specifications?

22f. Is it known or anticipated that any subjects will also be having blood drawn for other purposes during the study period?

Yes No

23. Please indicate any of the following you propose to use and provide copies (if copies are not available electronically, send hard copies via mail to IRB Chair):

- | | | | |
|------------------------------------------------------|--------------------------|-----------------------------|--------------------------|
| a. Educational Tests | <input type="checkbox"/> | e. Interview | <input type="checkbox"/> |
| b. Questionnaires | <input type="checkbox"/> | f. Previously recorded data | |
| c. Psychological Tests | <input type="checkbox"/> | including clinical records | <input type="checkbox"/> |
| d. Educational Materials
(curricula, books, etc.) | <input type="checkbox"/> | | |

24. Will the study involve the use of drugs?

Yes No

- a. A placebo yes no Name: _____
- b. A standard FDA-approved agent Name: _____
- c. A non-therapeutic approved agent
(e.g., to modify a physiologic response) Name: _____
- d. A new investigational therapeutic agent Name: _____
- e. A new use for an agent approved for another
purpose Name: _____

For (d) or (e) give IND # _____

25. Will the study involve the use of a new device?

Yes No

If so,

- a. The device has an IDE number Number: _____
- b. It is for therapeutic use
- c. It is for diagnostic use

26. Identify any additional procedures/interventions (invasive or otherwise) drugs, documents, or tests involved in this activity that are used **solely for research purposes**.

27. Describe, in detail, **data collection procedures**: specify who, what, when, where, how, etc.

28. List potential risks (physiological/psychological risks, injury) to subjects that may be incurred during the study

28a. If risks or injury are associated with this project, what is the likelihood of their occurrence?

29. Describe actions to minimize risks to subjects.

Confidentiality-Privacy-Coercion

30. Since all data collected on individual subjects in a research study is generally considered confidential, how will you maintain confidentiality and anonymity of your data? (e.g., by coding, especially if shared with another researcher)

30.a. Where will data be stored (e.g., in a locked file cabinet, pass-word protected computer)?

31. Does this research involve medical chart reviews? Yes No

If “yes”, please answer Items 31a-31d

31a. Please explain what type of information will be obtained:

31b. Will the records be reviewed without the patient’s permission?

Yes No

31c. If “Yes,” please explain why a verbal or written informed consent will not be requested:

31d. Have HIPAA forms been completed and submitted to the IRB?

Yes No

32. Could any part of this activity result in the potential identification of child abuse, communicable diseases, or criminal activities?

Yes

No

32a. If "Yes," estimate the likelihood of disclosure:

33. Aside from possible loss of confidentiality, could any part of this activity be seen as invading the privacy of the participants of this study?

Yes

No

33a. If "Yes," explain and describe proposed safeguards:

34. Does any part of this activity have the potential for coercion of the subject?

Yes

No

34a. If "Yes," explain and describe proposed safeguards:

35. Is there a potential **Conflict of Interest** pertaining to this protocol as defined in the UT Tyler *Conflict of Interest* policy on the part of any individual at UT Tyler who is associated with this protocol?

Yes

No

35a. If "Yes," please explain.

35b. **If you answered "yes" to the above question, or, if this research is either federally funded, or federal funding has been applied for, a UT**

Tyler Conflict of Interest form must be completed by accessing the Office of Sponsored Research (OSR) website before final approval.

35c. Is this research protocol either federally funded, or is in the process of applying for federal funds? Yes No

3d. Has a **COI** form been completed and submitted to the OSR?
Yes No

36. Could the desired information be obtained from animals or other laboratory models? Explain:
Yes
No

Cost of Research

37. Will the subjects incur any additional expenses for experimental (or otherwise unnecessary diagnostic) tests or procedures?
Yes
No
If "Yes," explain:

Informed Consent

38. **Written informed consent** from the subject or from a legally responsible representative of the subject **is normally required** from human research participants. The proposed consent form should follow the guidelines of the UT Tyler Informed Consent Template and should be included with the materials submitted to the IRB.

For sample participants under the age of 18 years, the PI is responsible for abiding by the UT Tyler Policy on Informed Consent for Children.

- 38a. Will you be obtaining consent other than written consent?

Yes No

- 38b. If you do not propose to obtain consent please provide your rationale for obtaining **oral** consent or assent (assent applies to subjects under 18 years old. See UT Tyler's Policy on Protection of Children Involved in Research)

- 38c. If written consent is being obtained and confidentiality is assured in the informed consent form, where do you plan to keep the signed informed consent forms?

Cooperative Agreements with Other Institutions

39. If any part of this study will be conducted in an institution or location administratively separate from UT Tyler, please indicate at which institution (attach IRB approval letter from the other institution).

40. Does this activity utilize recorded data to be sent to cooperating institutions not under your control?

Yes

No

- 40a. If so, could the data contain personal or sensitive information?

Yes

No

40b. If “Yes,” how do you propose to maintain confidentiality of the data?

Consultation and Collaboration

41. Subject Recruitment and Management: If approval is required from other professionals for the recruitment or management of the subjects, please identify and provide contact information from the individual(s) responsible for the subjects. Electronic letter of approval must be submitted by the PI.

Name of Professional:

Institution/Agency:

Contact Information:

Name of Professional:

Institution/Agency:

Contact Information:

Name of Professional:

Institution/Agency:

Contact Information:

42. Consultation

It is highly recommended that in areas of uncertainty, consultation be obtained and that evidence of such be submitted with the protocol. The IRB, on an individual basis, shall, where appropriate, request that investigators obtain consultation. If applicable, state how and where you will obtain consultation.

43. Research Collaboration:

Research collaborators are other non-UT Tyler-affiliated researchers whose participation enhances the scientific merit of a research project. List collaborators below and have each verify that they have read the research protocol and agree to participate by emailing the PI, and PI is to forward these emails of agreement to IRB Chair with this application.

Collaborator Name:

Collaborator Institution:

Collaborator Contact Information:

44. IRB Access to Records

The IRB is accountable to the FDA/DHHS for the continuing review of research protocols that involve human subjects and therefore must have access to the records associated with investigational protocols involving human subjects. Where do you plan to keep your records?

SIGNATURE OF PRINCIPAL INVESTIGATOR: Signature indicates agreement by the PI to abide by UT Tyler IRB policies and procedures and the Federal Wide Assurance, and to the obligations as stated in the “Responsibilities of the Principal Investigator” and any other related policies and procedures described in the UT Tyler IRB Handbook (listed on the OSR website), and to use universal precautions with potential exposure to specimens.

Principal Investigator Signature
(Electronic submission of this
form by PI indicates signature)

Date

**THE UNIVERSITY OF TEXAS AT TYLER
INSTITUTIONAL REVIEW BOARD**

IRB MODIFICATION REQUEST

IRB:

Approved by:

Date:

Date:

Principal Investigator:

Department:

IRB #:

Project Title:

Original Approval Date

Please complete all sections as appropriate and submit to the UT Tyler IRB Chair.

IDENTIFICATION OF CHANGE(S)

A. GENERAL

- Change in Title of Protocol
- Resubmission to Grant/Contract Agency
- Change in Extramural Sponsor
- Change in Cooperating Institution

- Change in Status of Protocol (e.g., from "active" to "hold")

B. DESIGN

- Change in Study Design

C. PERSONNEL

- Change in investigators, faculty or staff:

Name:

Credentials:

Contact Information:

- Change in Consultant/Collaborator

D. RISK

- Change In Risk/Benefit Ratio (e.g., emergence of new side effects)

E. COST

- Change in Subject Expense
 Change in Subject Reimbursement

F. PROCEDURES INVOLVING SUBJECTS

- Change in collection of blood or other body fluids
 Change in subject evaluation (e.g., number of visits, etc.)
 Change in administration or dosage of drug
 Change in drug formulation
 Change/Deletion of any test
 Change/deletion of device

G. STUDY POPULATION

- Change in sample size
 Change in eligibility criteria
 Change in exclusion criteria
 Alteration of study groups
 Other:

H. SUBJECT RECRUITMENT

- Change in recruitment procedures
 Change in ads, flyers, etc.

I. OTHER

- Any other significant changes

EXPLANATION OF CHANGES**A. Modifications identified above require changes in:**

- Informed consent form (describe by highlighting or tracking of originally approved form)
 Change in previous IRB application (describe by item numbers)

Change in protocols (describe item number on application or on submitted proposal using highlighting or tracking of original document that was submitted to IRB)

B. Describe specifically by section, any changes identified above

C. Explain rationale for changes:

D. Will these changes result in a change of the risk/benefit ratio?

Yes No

If Yes, please explain:

ELECTRONIC ENCLOSURES AS NEEDED FOR CHANGES INDICATED:

- Revised Informed Consent Form(s)
- Letter from Sponsor
- Letter from Investigators indicating their removal or addition to study
- Revised Protocol (Date of Revised Protocol:))
- Revised IRB Full Board Review Application
- Revised Investigator's Brochure
- Other:

SIGNATURE OF PRINCIPAL INVESTIGATOR

Principal Investigator Signature
(Electronic submission of this
form by PI indicates signature)

Date

**THE UNIVERSITY OF TEXAS AT TYLER
INSTITUTIONAL REVIEW BOARD (IRB)**

IRB RESEARCH MISCONDUCT AND NON-COMPLIANCE REVIEW FORM

This form is to be completed by the IRB Chairperson and the ad hoc investigative committee in conjunction with the UT Tyler **Procedures for Investigating and Reporting Incidents of Research Misconduct and Non-Compliance** (refer to the University of Texas at Tyler Institutional Review Board (IRB) Handbook). Upon completion, this form is to be submitted to the UT Tyler Office of Sponsored Research, Vice President for Research and Federal Relations.

Date: _____ Reviewer: _____ Study: _____ Principal Investigator: _____

Level of Study Risk: Minimal Greater than Minimal

Category of Review: Exempt Expedited Full Board

Type of Misconduct: Fabrication Falsification Plagiarism

Type of Non-Compliance: General Serious Continuing

Summary/General Comments:

1. *Please indicate the nature of the non-compliance*

Deviated from approved IRB protocol

Failed to follow IRB procedures

Failed to protect participants' rights

Other _____

2. *Please list non-compliance history for PI, Co-PI, and faculty sponsors.*

3. *Please list PI, Co-PI, and faculty sponsor type and dates of human subjects training.*

4. How was this event reported to the IRB? _____

5. What steps if any did the investigator take to rectify the non-compliance?

6. Implications for risk to participants: _____

7. Implications for informed consent process: _____

8. Implications for the training of researchers: _____

9. Were there any injuries/adverse events/unanticipated events?

Yes _____ No _____

10. If so, please list:

11. Please list recommendations of ad hoc investigative committee for how to resolve this non-compliance case:

12. Please list final recommendations of IRB to be forwarded to the Office of Sponsored Research:

**THE UNIVERSITY OF TEXAS AT TYLER
INSTITUTIONAL REVIEW BOARD**

Report Of Unanticipated or Adverse Event/Death

This report must be submitted to the IRB Chair within 24 hours of the event. If serious injury or death is reported as the event, the IRB chair must be notified as soon as the event is noted. Please refer to the UT Tyler Policy on Unanticipated and Adverse Events for additional reporting responsibilities.

The following policy comes from:

<http://www.hhs.gov/ohrp/policy/AdvEvtGuid.htm#Q1>

The Office of Human Research Protection of the USDHHS considers ***unanticipated problems***, in general, to include any incident, experience, or outcome that meets **all** of the following criteria:

- (4) 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;
- (5) 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
- (6) 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 medical 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.

Indicate type of event: Unanticipated:

 Adverse:

Title of Protocol:

IRB Approval #:

Principal Investigator:

Subject initials:

Participant ID#:

Date enrolled in study:

Date and time of event:

Age or D.O.B at time of event:

Describe in detail the event:

Follow up action:

Referrals made:

In your opinion was the reported event a result of participation in the research?

 Probably Possibly Unlikely Unknown

 Not Related (Provide Explanation)

"SIGNATURE" OF PRINCIPAL INVESTIGATOR

PI Name:

(Electronic submission of this form by PI indicates signature)

Date:

Upon receipt of this report, the Institutional Review Board (IRB) will decide whether additional information is needed or whether further investigation of the incident is required. In some cases, an investigator may be required to suspend a study pending the outcome of the IRB review.

For IRB response to the above reported adverse event the IRB concludes:

- That no further follow-up is required**
- Additional materials are requested:**
- Continue to monitor and provide data when an end point is reached or by _____
MM DD YYYY
- Other:**

Institutional Review Board Representative

Date