The University of Tennessee at Martin
Institutional Review Board (IRB)
Policy and Procedures

THE UNIVERSITY OF
TENNESSEE
MARTIN

OFFICE OF RESEARCH, OUTREACH,
AND ECONOMIC DEVELOPMENT

124 Gooch Hall

Martin, TN 38238

(731) 881-7015

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Article I. THE INSTITUTIONAL REVIEW BOARD (IRB)

Section 1.01 Introduction

The University of Tennessee at Martin (UTM) Institutional Review Board (IRB) operates under the US Department of Health and Human Services regulations for the Protection of Human Research Subjects: Title 45 of the Code of Federal Regulations, Part 46 (45 CFR 46). The IRB also is guided by the ethical principles regarding all research involving humans as subjects as set forth in the April 18, 1979, report of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, entitled: "Ethical Principles and Guidelines for the Protection of Human Subjects of Research," commonly referred to as The Belmont Report.

Section 1.02 Regulatory Compliance

UTM has filed an Institutional Assurance of Compliance with DHHS Regulations with the Office of Human Research Protection (OHRP). The assurance includes a statement of ethical principles and institutional policy, a detailed identification of UTM's responsibilities, ORI's general procedures, the Institutional Review Board's policies and procedures, and the general responsibilities of the research investigator. As part of its assurance, the UTM IRB reviews all research involving human subjects regardless of sponsorship. The Institutional Assurance of Compliance at UTM is under assigned assurance number FWA00004149 and the IRB Registration Number is 0004048. The Executive Director of Research, Outreach, and Economic Development serves as the Institutional Official.

Section 1.03 Jurisdiction

The IRB is an administrative body established to protect the rights and welfare of human research subjects recruited to participate in research activities conducted under the auspices of the institution with which it is affiliated. All faculty and staff using human subjects or identifiable, private information about human subjects to conduct research within the course and scope of their duties are required to have prior approval from the IRB before research is initiated. All students whose research involved human subjects and is conducted under the advisement of a faculty member are required to obtain IRB approval prior to research beginning. Projects must be approved prior to data collection regardless of funding status and regardless of the source of funds. All research proposals must be reviewed by the IRB and no individual other than the IRB Chair or their designee may exempt a proposal from review.

Research is defined as: "...A systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge." Activities that meet this definition constitute research for purposes of this policy, whether

or not they are conducted or supported under a program that is considered research for other purposes. For example, some demonstration and service programs may include research activities. For purposes of this part, the following activities are deemed not to be research: (1) Scholarly and journalistic activities (e.g., oral history, journalism, biography, literary criticism, legal research, and historical scholarship), including the collection and use of information that focus directly on the specific individuals about whom the information is collected. (2) Public health surveillance activities, including the collection and testing of information or biospecimens, conducted, supported, requested, ordered, required, or authorized by a public health authority. Such activities are limited to those necessary to allow a public health authority to identify, monitor, assess, or investigate potential public health signals, onsets of disease outbreaks, or conditions of public health importance (including trends, signals, risk factors, patterns in diseases, or increases in injuries from using consumer products). Such activities include those associated with providing timely situational awareness and priority setting during an event or crisis that threatens public health (including natural or man-made disasters). (3) Collection and analysis of information, biospecimens, or records by or for a criminal justice agency for activities authorized by law or court order solely for criminal justice or criminal investigative purposes. (4) Authorized operational activities (as determined by each agency) in support of intelligence, homeland security, defense, or other national security missions.

A *Human Subject* means: "A living individual about whom an investigator (whether professional or student) conducting research: (i) Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or (ii) Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens."

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

Section 1.04 Composition of the Institutional Review Board

The UTM IRB shall be composed of the following:

1. At least five (5) members of sufficiently diverse backgrounds, including consideration of race/ethnicity, gender, age, professional expertise, and cultural backgrounds, to promote complete and adequate review of research activities commonly conducted by the university.
2. Persons who can ascertain the acceptability of research applications in terms of institutional commitments, applicable law, and professional standards.
3. At least one member whose primary concern is in a scientific area.
4. At least one member whose primary concern is in a nonscientific area.

5. A member who is not affiliated with the institution or does not have an immediate family member affiliated with the institution.

No one (1) department may have more than one (1) member on the Board. The Vice Chancellor for Academic Affairs at UTM is the appointing authority for the UTM IRB. Board members serve three-year terms. There is no maximum time limit that a board member may serve. Reappointments to additional three-year terms are made at the discretion of the Vice Chancellor for Academic Affairs and the Institutional Official. Ideally, the Chair of the IRB and at least two people on the Board have prior service with an IRB.

The IRB will elect its own Chair for a two-year term. The IRB Chair may be reappointed to additional terms at the discretion of the Institutional Official. The IRB Chair may resign at any time by submitting a letter of resignation to the Institutional Official. The Institutional Official may remove the IRB Chair from the committee if the Chair is unable to meet his/her responsibilities.

The nonaffiliated member(s) should not be vulnerable to intimidation by the professionals on the IRB, and their services should be fully utilized by the IRB. The members of the university IRB shall compile a list of nominees for the nonaffiliated member position and submit same to the Executive Director of Research, Outreach, & Economic Development and the IRB Chair who shall select the community representative from the list in consultation with the Vice Chancellor for Academic Affairs. No member of the UTM IRB will participate in the IRB's initial or continuing review of any project in which that member has a conflicting interest, except to provide information requested by the IRB. An investigator can be a member of the IRB; however, there is a stipulation that must be adhered to without exception: The investigator-as-member cannot participate in the review and approval process for any project in which he or she has a present or potential conflict of interest. Where the investigator-member has a conflicting interest, he or she should be present only to provide information requested by the IRB. He or she should be absent from the meeting room during the discussion and voting phases of the review and approval process; IRB minutes should reflect whether these requirements have been met.

The UTM IRB shall meet at a regularly scheduled time and place. This time and place will be published in the UTM Addenda and on the Office of Research and Sponsored Programs SharePoint site each semester, and Board members will be notified in writing and through email of the schedule. If no IRB application is submitted for full review within 10 working days of the regularly scheduled meeting, the Institutional Official shall cancel the meeting and notify the IRB accordingly.

The UTM IRB is empowered to call in outside consultants and/or UTM faculty consultants and may utilize review subcommittees where it deems appropriate.

Section 1.05 Responsibilities of the Institutional Review Board

The UTM IRB is an administrative body established to protect the rights and welfare of human subjects recruited to participate in research activities conducted under the auspices of the institution with which it is affiliated. The IRB has the authority to approve, require modifications in, or disapprove all research activities that fall within its jurisdiction as specified by both the federal regulations and local institutional policy. The IRB is not concerned with a researcher's choice of topic, research design, methodology, and controls except as they have a bearing on (1) the rights or welfare of the subjects involved or (2) on an assessment of the potential benefits to society in studies posing a definite risk to the subjects. The review responsibilities of the IRB are as follows:

1. To meet as a Board with a quorum present and to approve or disapprove with or without specified modifications the applications brought to it. A quorum of the Board shall be defined as a majority of the total membership duly convened to carry out the Board's responsibilities under the terms of the Assurance. As necessary, the Board will arrange to have qualified consultants with special competencies relevant to the proposal participate in the review. Approval shall be contingent upon assurance that the risks are kept to an absolute minimum and that any risks are clearly outweighed by the potential benefits. The Board, at its discretion, may invite the principal investigator to be present at the meeting so that any modifications in procedure to protect subjects can be worked out directly between the Board and the investigator.
2. To offer consultation and advice on safeguarding the rights and welfare of human subjects.
3. Thoroughly review all IRB application materials to ensure responsible, ethical research will be conducted with minimal risk. The IRB has the authority to request additional information in all areas if necessary to ensure an informed review of the proposed research project.
4. Review and have authority to approve, exempt, require modifications, or disapprove all research activities covered by this policy.
5. Conduct continuing review of research covered by this policy at intervals appropriate to the degree of risk, but not less than once per year.
6. Have authority to observe or have a third party observe the consent process and research.
7. Review proposed changes in research activities to ensure that changes in approved research during the period for which IRB approval has been given have not been initiated without IRB review and approval.
8. Require that information given to subjects as part of informed consent is in accordance with policy and make a decision on whether to waive documentation of informed consent.
9. Notify, in writing, investigators and the institution of its decision to approve or disapprove the proposed research activity, or of modifications required to secure

IRB approval of the research activity. If the IRB decides to disapprove a research activity, it shall include in its written notification a statement of the reasons for its decision and give the investigator an opportunity to respond in person or in writing.
    - Monitor additional safeguards when vulnerable subjects (minors, prisoners, individuals with impaired decision-making capacity and economically or educationally disadvantaged persons) are involved in the research to protect against coercion or undue influence.
10. Report to the institution and OHRP any continuing or serious matters of non-compliance by investigators with the requirements and determination by the IRB.
11. Have authority to suspend or terminate approval of research that is not in compliance with the IRB's determinations or has been associated with unexpected serious harm to subjects.
    - To periodically review certain projects, when the Board deems review appropriate, with the principal investigator and collect annually a Review Statement for all projects involving human subjects to assure procedural compliance. With respect to the latter, each investigator must submit a Change and/or Termination Form on an annual basis and at the completion or termination of the project. This form can be obtained from the Office of Research and Sponsored Projects or may be accessed online at the ORSP web site. If in the judgment of the IRB Chair some problem may exist, the responsible investigator will be asked to appear before the Board for a comprehensive review; and
12. To keep records and maintain a file of all projects reviewed for a period of at least three (3) years following completion of the project. All records shall be accessible for inspection and copying by authorized representatives of the federal government, or the IRB or ORSP, at reasonable times and in a reasonable manner.

Section 1.06 Recordkeeping for the Institutional Review Board

The UTM Office of Research and Sponsored Programs (ORSP) will maintain the following:

1. Files for each IRB application that contains the following: the original completed application with all required attachments, copies of all correspondence with the applicant including the authorization to conduct research and the IRB docket number, and originals of required forms.
2. Minutes of all UTM IRB meetings in sufficient detail to record the following information: attendance at each meeting; actions taken by the IRB; the vote on actions taken (including the number of members voting for, against, and abstaining); the basis for requiring changes in or disapproving research; and a written summary of the discussion of controverted issues and their resolution. Records of continuing review activities.
3. Copies of all correspondence between the IRB and investigators.

4. A list of all IRB members identified by name; earned degrees; representative capacity; indications of experience such as board certifications, licenses, etc., sufficient to describe each member's chief anticipated contributions to IRB deliberations; and any employment or other relationship between each member and the institution (i.e., full-time employee, part-time employee, member of governing panel or board, stockholder, paid or unpaid consultant).
5. A compendium of written procedures; and
6. Statements of significant new findings provided to subjects.

The ORSP is responsible for determining if the research protocols qualify for exemption from continuing review under the Common Rule regulations. If exempt, the researcher will be notified in writing and no further reports are required except where changes in procedure arise. All nonexempt research protocols will be forwarded to the Expedited Review Committee of the IRB if they qualify for Expedited review under the regulations, or to the full IRB if they do not qualify.

The ORSP will report information, as appropriate, to the IRB; the Office of Protection from Research Risks (OPRR); and the Department of Health and Human Services (DHHS); research investigators; and department chairs. IRB records will be retained for at least three (3) years; records pertaining to research that is conducted will be retained for three (3) years after completion of the research. All records will be accessible for inspection and copying by authorized representatives of the department or agency supporting or conducting the research at reasonable times and in a reasonable manner.

Section 1.07 Responsibilities of the Investigator/Researcher

The qualifications of the principal investigator should be considered when reviewing proposals. IRBs may require less experienced research investigators to be sponsored by seasoned researchers. Proposals that require skills beyond those held by the principal investigator should be modified to meet the investigator's skills, have additional qualified personnel added, or be disapproved. While the Institutional Review Board (IRB) acts as the official review board, the investigator is not relieved of personal and ethical responsibility for the design and conduct of the research as it may affect the welfare of subjects involved. In addition to complying with the formal procedures for obtaining approval of a project by IRB, each investigator must:

1. be thoroughly familiar with ethical guidelines for conduct or research utilizing human subjects and comply with these guidelines both in fact and spirit.
2. complete CITI training on the Responsible Conduct of Research as appropriate.
3. be sensitive to ethical considerations related to his/her research which may not be specifically covered by the guidelines.

4. follow the established University procedures, along with those recommendations for alterations in procedure by the IRB which were given as part of the conditions of acceptance of the proposed project.
5. bring to the attention of the IRB any alterations in procedure which might conceivably have some relation to the rights or welfare of human subjects.
6. bring to the attention of the IRB during any phase of any project problems (e. g., adverse reactions to drugs or medical devices) for further disposition by the IRB and for reporting to the Department of Health and Human Services; and
7. submit a Change and/or Termination Form, as required by the IRB.

Research investigators shall prepare protocols giving complete descriptions of the proposed research. The research plan must include provisions for the adequate protection of the rights and welfare of prospective subjects and ensure those pertinent laws and regulations are observed. Samples of informed consent documents must be included with protocols. Research investigators are responsible for obtaining informed consent and ensuring that no human subject will be involved in the research before obtaining the consent.

The research plan must address quality assurance standards set by the institution. In addition, applicable external standards for quality assurance must be met. External standards are of particular concern for research conducted in clinical facilities. Appropriate reviews for scientific merit must be conducted before the research is approved. Mechanisms for monitoring the progress of the research must be in place. Research investigators, through their research design, determine whether the proposed research will involve human subjects. When it is not clear whether the research will involve human subjects, investigators should seek assistance from the IRB in making this determination.

Researchers are responsible for complying with all IRB decisions, conditions, and requirements. Research investigators are responsible for reporting the progress of the research to the IRB and/or appropriate institutional officials as often as and in the manner prescribed by the IRB but no less than once per year.

The PI for human subjects research under the auspices of the University of Tennesse at Martin must be faculty, staff, or student at the institution. When a student is conducting research utilizing human subjects under the auspices of the university, it is the responsibility of the graduate coordinators in each college or the faculty supervisor in cases of independent class or other study to review the proposal and ensure compliance with the IRB guidelines. Students may not serve as PI for research classified as full review. Student-led research is subject to an expedited review, even if it would otherwise fall into an exempt category.

Individuals who are debarred, disqualified, or otherwise restricted from participation in research or as a recipient of grant funds for research by a federal, state, or other agency may not serve as PI.

Article II. Categories of Review and the Application/Approval Process

Specific criteria for IRB approval of research are discussed in more detail in the following sections; however, the following elements are central to IRB decisions. The IRB will consider whether:

1. Risks to subjects are minimized.
2. Risks are reasonable in relation to anticipated benefits.
3. Selection of subjects is equitable.
4. Informed consent is sought from each subject; and
5. Informed consent is appropriately documented.

There are five (5) categories of review for projects involving human subjects in research settings:

1. Exempt
2. Expedited
3. Full Board Review
4. Continuing or annual renewal
5. Classroom assignments

The Office for Human Research Protections (OHRP) provides graphic aids as a guide for institutional review boards (IRBs), investigators, and others who decide if an activity is research involving human subjects that must be reviewed by an IRB under the requirements of the U.S. Department of Health and Human Services (HHS) regulations at 45 CFR part 46. The charts are intended to assist IRBs, institutions, and investigators in their decision-making process and should not be used as substitutes for consulting the regulations. OHRP cautions that the full text of applicable regulatory provisions should be considered in making final decisions. The charts do not address requirements that may be imposed by other organizations, such as the Food and Drug Administration, National Institutes of Health, other sponsors, or state or local governments.

- Chart 1: Is an Activity Human Subjects Research Covered by 45 CFR Part 46?
- Chart 2: Is the Human Subjects Research Eligible for Exemption Under 45 CFR 46.104(d)?
- Chart 3: Does Exemption 45 CFR 46.101(b)(1) for Educational Settings Apply?
- Chart 4: Does Exemption 45 CFR 46.101(b)(2) or (b)(3) for Educational Tests, Surveys, Interviews, or Observation of Public Behavior Apply?
- Chart 5: Does Exemption 45 CFR 46.104(d)(3) for Benign Behavioral Interventions Apply?

- Chart 6: Does Exemption 45 CFR 46.104(d)(4) for Secondary Research That Does Not Require Consent Apply?
- Chart 7: Does Exemption 45 CFR 46.104(d)(5) for Public Benefit or Service Programs Apply?
- Chart 8: Does Exemption 45 CFR 46.104(d)(6) for Food Taste and Acceptance Studies Apply?
- Chart 9: Does Exemption 45 CFR 46.104(d)(7) Storage for Secondary Research for Which Broad Consent is Required Apply?
- Chart 10: Does Exemption 45 CFR 46.104(d)(8) for Secondary Research for which Broad Consent is Required Apply?
- Chart 11: Is Continuing Review Required Under 45 CFR 46.109(f)?
- Waiver or Alteration of Informed Consent in Research Involving Public Benefit and Service Programs Conducted by or Subject to the Approval of State or Local Government Officials (45 CFR 46.116(e))
- When Can Informed Consent Be Waived or Altered Under 45 CFR 46.116(f)?
- Chart 14: Can Documentation of Informed Consent Be Waived Under 45 CFR 46.117(c)?

Section 2.01 Exempt Designation Review

The exempt designation refers to various types of research that do not require continued monitoring by the IRB. Research activities exempt from formal review must present no greater than minimal risk to participants and meet the definition of one or more of the eight (8) categories defined by the Department of Health and Human Services regulation 45 CFR 46.104:

1. **Exempt Category 1:** Research, conducted in established or commonly accepted educational settings, that specifically involves normal educational practices that are not likely to adversely impact students' opportunity to learn required educational content or the assessment of educators who provide instruction. This includes most research on regular and special education instructional strategies, and research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.
2. **Exempt Category 2**: Research that only includes interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording) if *at least one* of the following criteria is met:
    i. The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects.
    ii. Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be

damaging to the subjects' financial standing, employability, educational advancement, or reputation; or

iii. The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review.

3. **Exempt Category 3:** Research involving benign behavioral interventions in conjunction with the collection of information from an adult subject through verbal or written responses (including data entry) or audiovisual recording if the subject prospectively agrees to the intervention and information collection and at least one of the following criteria is met:
   i. The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects.
   ii. Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or
   iii. The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review.
      - For the purpose of this provision, benign behavioral interventions are brief in duration, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the subjects, and the investigator has no reason to think the subjects will find the interventions offensive or embarrassing. Provided all such criteria are met, examples of such benign behavioral interventions would include having the subjects play an online game, having them solve puzzles under various noise conditions, or having them decide how to allocate a nominal amount of received cash between themselves and someone else.
      - If the research involves deceiving the subjects regarding the nature or purposes of the research, this exemption is not applicable unless the subject authorizes the deception through a prospective agreement to participate in research in circumstances in which the subject is informed that he or she will be unaware of or misled regarding the nature or purposes of the research.
4. **Exempt Category 4**: Secondary research for which consent is not required: Secondary research uses of identifiable private information or identifiable biospecimens, if at least one of the following criteria is met:
   i. The identifiable private information or identifiable biospecimens are publicly available.

ii. Information, which may include information about biospecimens, is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained directly or through identifiers linked to the subjects, the investigator does not contact the subjects, and the investigator will not re-identify subjects;

iii. (*Note: This exemption applies only to research conducted at HIPAA covered entities and is not available to UTM researchers.*) The research involves only information collection and analysis involving the investigator's use of identifiable health information when that use is regulated under 45 CFR parts 160 and 164, subparts A and E, for the purposes of "health care operations" or "research" as those terms are defined at 45 CFR 164.501 or for "public health activities and purposes" as described under 45 CFR 164.512(b); or

iv. The research is conducted by, or on behalf of, a Federal department or agency using government-generated or government-collected information obtained for non-research activities, if the research generates identifiable private information that is or will be maintained on information technology that is subject to and in compliance with section 208(b) of the E-Government Act of 2002, 44 U.S.C. 3501 note, if all of the identifiable private information collected, used, or generated as part of the activity will be maintained in systems of records subject to the Privacy Act of 1974, 5 U.S.C. 552a, and, if applicable, the information used in the research was collected subject to the Paperwork Reduction Act of 1995, 44 U.S.C. 3501 et seq.

5. **Exempt Category 5:** Research and demonstration projects that are conducted or supported by a Federal department or agency, or otherwise subject to the approval of department or agency heads (or the approval of the heads of bureaus or other subordinate agencies that have been delegated authority to conduct the research and demonstration projects), and that are designed to study, evaluate, improve, or otherwise examine public benefit or service programs, including procedures for obtaining benefits or services under those programs, possible changes in or alternatives to those programs or procedures, or possible changes in methods or levels of payment for benefits or services under those programs. Such projects include, but are not limited to, internal studies by Federal employees, and studies under contracts or consulting arrangements, cooperative agreements, or grants. Exempt projects also include waivers of otherwise mandatory requirements using authorities such as sections 1115 and 1115A of the Social Security Act, as amended. Each Federal department or agency conducting or supporting the research and demonstration projects must establish, on a publicly accessible Federal Web site or in such other manner as the department or agency head may determine, a list of the research and demonstration projects that the Federal department or agency conducts or supports under this provision. The research or demonstration project must be published on this list prior to commencing the research involving human subjects.

6. **Exempt Category 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.
7. (*Note: This category is not applicable to UTM researchers as broad consent is not implemented at UTM*). **Exempt Category 7:** Storage or maintenance for secondary research for which broad consent is required: Storage or maintenance of identifiable private information or identifiable biospecimens for potential secondary research use if an IRB conducts a limited IRB review and makes the determinations required by § 46.111(a)(8).
8. (*Note: This category is not applicable to UTM researchers as broad consent is not implemented at UTM*). **Exempt Category 8:** Secondary research for which broad consent is required: Research involving the use of identifiable private information or identifiable biospecimens for secondary research use, if the following criteria are met:
    i. Broad consent for the storage, maintenance, and secondary research use of the identifiable private information or identifiable biospecimens was obtained in accordance with § 46.116(a)(1) through (4), (a)(6), and (d);
    ii. Documentation of informed consent or waiver of documentation of consent was obtained in accordance with § 46.117;
    iii. An IRB conducts a limited IRB review and makes the determination required by § 46.111(a)(7) and makes the determination that the research to be conducted is within the scope of the broad consent referenced in paragraph (d)(8)(i) of this section; and
    iv. The investigator does not include returning individual research results to subjects as part of the study plan. This provision does not prevent an investigator from abiding by any legal requirements to return individual research results.

Section 2.02 Expedited Designation Review

Research activities may be eligible for expedited review if they present no more than minimal risk to human subjects and involve only procedures listed in one or more of the nine categories listed below. The nine categories of activities listed should not be considered minimal risk simply because they are listed. Inclusion on this list 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. Both the Applicability and the Research Categories sections of the

regulations need to be considered to qualify for expedited review; however, if subjects will be randomized to treatment and control groups, then the study does not qualify for expedited review.

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

<u>Research Categories</u>

1. **Expedited Category 1:** Clinical studies of drugs and medical devices only when condition (a) or (b) is met.
    a. (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.

    (*Note: The drug or device must be approved and use exactly according to its labeling. All study procedures other than use of the drug or device must be of minimal risk for the study to qualify for expedited review.*)
2. **Expedited 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 [2], 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.

3. **Expedited 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.
4. **Expedited 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.
5. **Expedited Category 5:** Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for non-research 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.)
   (*Note: (a) This category refers to materials collected for "non-research purposes," but can be used to cover research materials if the investigator's role is simply to analyze them. That is, if an investigator is receiving materials from colleagues who have separate approval to collect them, and the materials are handled with code numbers and other protections for confidentially, he or she may apply for expedited*

review for the analysis; (b) This type of research is exempt from review only if the data collected has no link whatsoever to identifiers (not even a code number).

6. **Expedited Category 6:** Collection of data from voice, video, digital, or image recordings made for research purposes.
7. **Expedited 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.)
8. **Expedited 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.
9. **Expedited 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.

<u>Additional Expedited Review Category Information</u>

- The Federal policy concerning expedited review categories is contained in the Federal Register (Volume 63, Number 216: pages 60634-60367).
- Sources of Categories: Department of Health and Human Services-Office for Protection from Research Risks (OPRP), National Institutes of Health, HHS. OPRR and the Food and Drug Administration (FDA) have identical lists of categories of research activities that may be reviewed by the IRB through the expedited review procedure.
- Historical Information: The Federal Policy (Common Rule) for the Protection of Human Subjects was published in the Federal Register on June 18, 1991 (56 FR 28003) and is employed by 17 Executive Branch agencies. This Federal Policy requires adherence to certain requirements by Federal agencies* and institutions receiving support from those agencies for research activities involving human subjects. The Federal Policy has three cornerstones: review of any research

involving human subjects by an IRB with limited exceptions, informed consent of all research subjects; and informal, written assurance of institutional compliance with the Policy. The Department of Health and Human Services' (DHHS) codification of the Federal Policy can be found at 45 CFR Part 46, Subpart A.

- Section 56-110 of the Federal Policy provides for expedited review procedures for certain categories of research involving no more than minimal risk, and for minor changes in approved research. This same section gives the Secretary, HHS, the authority to amend and republish the expedited review list as needed after consultation with the departments and agencies that are subject to the Federal Policy. The expedited review list that is referenced in the Federal Policy was originally published by the Secretary, HHS in 1981 (46FR 8392, 46FR 8980). It listed categories of research that could be reviewed by the IRB through an expedited review procedure. The FDA also references an expedited review list (21 CFR Part 56) for matters under FDA's jurisdiction. The HHS and FDA lists have differed slightly, in that item nine (9) on the 1981 HHS expedited review list regarding certain types of behavioral research is not included in the list referenced in 21 CFR 56.110. The following agencies adopted the Common Rule: Department of Agriculture; Department of Energy; National Aeronautics and Space Administration; Department of Commerce; Consumer Product Safety Commission; International Development Cooperation Agency-Agency for International Development, Department of Housing and Urban Development; Department of Justice, Department of Defense; Department of Health and Human Services; Department of Education; Department of Veterans Affairs; Environmental Protection Agency; National Science Foundation; Department of Transportation; Central Intelligence Agency; and the Social Security Administration. (OHRP)

Section 2.03 Full Board Review

Full board review is used for studies that involve more than minimal risk to the subjects. The full UTM IRB typically reviews research projects that involve participants selected from groups that are considered especially vulnerable to coercion or undue influence in research settings. These groups include children (including indirectly infants if their nursing mothers are research participants), fetuses, pregnant women, mentally disabled (i.e., cognitively impaired) persons, prisoners, and economically or educationally disadvantaged persons. The primary review concerns are (1) the use of persons from these groups is justified, (2) risks are minimized, and (3) additional safeguards are implemented to minimize risks unique to each group. If the research risks are greater than minimal risks (i.e., those ordinarily encountered in daily life during routine psychological or physical examinations), then the research must directly benefit participants, and those benefits must exceed the risks.

Categories of Full Board Review

1. Projects requiring the use of deception.
2. Use of prisoners, pregnant women, fetuses, the seriously ill, or persons with mental disabilities, or incompetent individuals.
3. Collection of information or recording of behavior which, if known outside the research, could reasonably place the subject at risk of civil, or criminal liability or damage the participant's social standing, financial standing, or employability.
4. Collection of information regarding sensitive aspects of the participant's behavior such as: drug and alcohol use, illegal conduct, or sexual behavior.
5. Studies in which the anticipated risks exceed the minimal risk definition.
6. Survey and interview research involving children requires full IRB review.

Section 2.04 Classroom Assignments

Students may participate in classroom research projects to learn about the process of conducting research. These student projects may be exempt from IRB review if the following criteria are met:

- the assignment is part of a class and is conducted under faculty supervision.
- the data will not be used to increase generalizable knowledge through disseminated findings.
- the purpose of the assignment is for students to learn about the process of engaging in research or applying a pedagogical technique as opposed to engaging in research which is intended to be used for publication, formal reports, or presentations at professional conferences.
- the project is eligible for exempt or expedited review classification; and
    - the instructor has completed responsible conduct of research online training through CITI program or the Office of Research and Sponsored Programs.

Faculty members who wish to use this procedure must complete the following steps:

- Submit a *Classroom Research Form* to the Office of Research and Sponsored Programs indicating the course, the syllabus, and a copy of his/her certificate of completion of training. This form must be approved by the IRB Chair prior to any projects proceeding.
- Require students to submit *Application for Expedited or Full Board Review* for approval by the instructor.
- Review and approve the application forms submitted by the student to the instructor; and
- Submit an *Application for Exempt Designation* at the end of the semester which outlines the student's name, project title, a short description of the project and certifies that the instructor has ensured that all human subjects protections have been met, including informed consent, anonymity, and minimal risk.

Faculty members must maintain these files for no less than three years by the faculty member and may be periodically audited by the Office of Research and Sponsored Programs.

It is strongly recommended that the instructor require students to complete the online CITI training on the IRB process as part of the course work. Please note that CITI training is required of all students when they submit an IRB application to the IRB Committee for review per the UT Martin Responsible Conduct of Research policy.

Student research conducted to collect data intended to increase generalizable knowledge and/or to disseminate findings to the public via publications, conferences, presentations, honors projects, theses, dissertations, or similar projects are not eligible for this procedure and must undergo normal review according to the UTM IRB policy.

Section 2.05 Application Process

All researchers and investigators, including students, with projects or activities involving the use of human subjects must submit an application for approval to the IRB. The online application and the contact information for IRB questions are available on the Office of Research and Sponsored Programs SharePoint site. All required attachments must be included in the online application. The Office of Research and Sponsored Programs can assist with questions concerning the review process.

Application Attachments and Special Requirements

i. Questionnaires/Other Research Instruments
   - Any questionnaires, tests, survey instruments or data collections sheets must be submitted as part of the application. Structured interview questions and outlines for unstructured interviews also must be included.

ii. Informed Consent Statement
   - A copy of the informed consent statement along with a written summary of the information that will be given to subjects orally or in writing. The consent form must cover the basic elements of informed consent.

iii. Minor Assent Document
   - A copy of the minor assent document is required if children are involved in the research project.

iv. Advertisements/Notices/Recruitment Flyers
   - The text of any advertisement, video display, notice, sign, brochure or flyer used to recruit subjects should be included as an attachment.

v. Financial Conflict of Interest Form/Funded Research Proposal Narrative
   - If the research is funded, include a copy of the current Financial Conflict of Interest Form and the research proposal narrative.

vi. Permission/Approval for Research Activities Conducted at an Outside Entity
    - If research will be conducted outside of the University, documentation must be submitted from the entities giving the researcher permission to conduct the research at their facility.

vii. Responsible Conduct of Research Training Certification

viii. Data Use Agreement and/or Data Security Plan. When a study utilizes data subject to terms and conditions set forth by the data provider or custodian, the agreement and related documents must be submitted as attachments to the IRB application. Confidentiality measures and data security protections defined in the agreement and related documentation can be referenced in the IRB application in response to the questions corresponding with these topics.

Section 2.06 Collaborative Research

Collaborative research projects involve more than one institution. The oversight requirements for non-exempt and exempt research, and research conducted with international collaborators, differ as follows:

a. *Non-exempt research*. Collaborative research projects that require expedited or full board review and are conducted in the United States typically must use a single IRB (sIRB). In these instances, federal law holds each institution responsible for safeguarding the rights and welfare of human subjects and for complying with federal policy even though the review is conducted by a single entity. Identification of the sIRB of record will be made by the IRB Directors and Principal Investigators from the collaborating organizations in accordance with NIH sIRB policies and guidance or The Common Rule sIRB policy and guidance, as appropriate. This may require execution of an authorization agreement. UTM will require a copy of the IRB application and approval letter from the collaborating institution and will review to ensure that we agree with the approval.

b. *Exempt research*. The UTM IRB is responsible for ensuring that research conducted by UTM personnel receives the appropriate level of oversight. For collaborative projects that qualify for exemption from the Common Rule (see section 2.1.1), the lead Principal Investigator should submit an application for an exemption determination to their institution's IRB. If the initial exemption determination is being made by a collaborator's IRB, the UTM IRB requires a copy of the IRB application and approval letter in order to confirm the exemption determination. In some cases, the UTM researcher(s) may be required to submit a separate exempt application to the UTM IRB (e.g., if the data collection instruments and/or methods will differ across collaborating institutions). UTM will not enter into sIRB authorization agreements for any research determined to be exempt—in this scenario, the regulations related to sIRB use are not applicable.

c. *Research with international collaborators*. Such projects can have different requirements and will be reviewed on an individual basis to determine review

requirements. If a single IRB approval is appropriate, the guidelines listed above are applicable.

Section 2.07 Review Process

Exempt Review: Please allow a two-week review process from the time the application for exempt review is received by the Office of Research and Sponsored Programs. The application will be reviewed to ensure that the research qualifies for an exemption designation review. If the research meets exemption criteria an exemption designation letter will be sent to the principal investigator. If the information on the application seems incomplete or raises any concerns (e.g., regarding eligibility for exempt status, invasion of the subjects' privacy, or confidentiality of research records), the applicant will receive an Action Form. The Action Form will outline the concerns that must be addressed to continue the review process. It also may indicate that the research does not qualify as Exempt and indicate that Expedited or Full Board Review will take place.

Expedited Review: The review process for expedited review typically takes about two to three weeks from the time the application is received by the Office of Research and Sponsored Programs, provided there are no modifications or clarifications needed to the application. An expedited review will normally be conducted by two IRB committee members who will be assigned by the Office of Research and Sponsored Programs. Expedited reviews will be rotated among IRB committee members based on expertise and workload. Under certain circumstances, the IRB Chair alone may conduct the expedited review. If reviewers indicate approval at the expedited level, the Office of Research and Sponsored Program will send a letter of approval to the principal investigator or the student and faculty advisor noting that the research has been approved. (In some cases, reviewers may provide feedback regarding their evaluation of the research project that is not related to the approval process. This information only is intended as feedback and the investigator is not required to make modifications to the study.) If the information on the application seems incomplete or raises any concerns (e.g., regarding eligibility for expedited status, invasion of the subjects' privacy, or confidentiality of research records) on the part of either reviewer, the applicant will receive an Action Form from the Office of Research and Sponsored Program. The Action Form will outline the concerns that must be addressed in order to continue the review process. If the investigator does not agree with the comments of the reviewer or feels that any suggested changes conflict with the investigator's vision of the research project, he or she may request a hearing by the full board. Likewise, the Executive Director of Research, Outreach, and Economic Development, the IRB Chair, or any reviewer may refer the application to the Full IRB for review. If the reviewers or the IRB Chair have concerns about an application, they must refer it to the full board for a hearing. An application cannot be withheld at the expedited level without a full board hearing.

Full Board Review: The IRB full board meets on a monthly schedule. Investigators should consult the Office of Research and Sponsored Programs to ensure that they are scheduled for review. The full IRB membership will review applications during their meetings. Every attempt will be made to schedule a meeting to review these applications within 3-5 weeks from the time the application is received by the Office of Research and Sponsored Programs (provided there are no modifications or clarifications needed to the application). Votes are taken and recorded at the meeting of the full board after a discussion of the proposal. A quorum is required to hear applications and a nonscientific committee member must be present. If the majority of the members vote to approve the proposal, then it is considered approved at the meeting. The Office of Research and Sponsored Programs will promptly notify the investigators in writing of the decision. If the IRB committee has unanswered questions or concerns about the proposal, a majority vote may result in a request for additional information, clarification, or changes to the application. The Office of Research and Sponsored Programs will issue a letter explaining the issues or problems discussed in the meeting. On very rare occasions, the IRB may encounter major difficulty in making a risk/benefit assessment, and an outside reviewer may be asked to consider the protocol and provide input based on their specific expertise; however, this reviewer will not be allowed to vote under any circumstances. The IRB Committee also may request the principal investigator to attend a full board meeting to discuss or clarify issues with the application. (These comments also will be reflected in the IRB Committee minutes). The principal investigator must then address a response and/or revise the application to obtain approval. The investigator also may request to meet in person with the Committee.

Section 2.08 Conditions of Approval

Once a project is approved as exempt or expedited, no further action is needed. There are no annual reviews required for exempt and expedited applications. Projects approved under the Full Board Review process where the research is still on-going require an Annual Review by the full board committee membership

Section 2.09 Changes, Annual Review, or Final Reports

If substantial changes are planned, the investigator should submit a new IRB application. For minor changes (e.g., a change in principal investigator, minimal changes in wording of a survey instrument, or increasing the sample size from the same sample pool), the investigator must submit a Change and/or Termination Form to the Office of Research and Sponsored Programs outlining the modifications. Once the changes are approved by the IRB Chair, the investigator will receive written notification of approval. The IRB Chair or his/her designee will contact the investigator in writing if the changes submitted on the Change and/or Termination Form are not acceptable.

Section 2.10 Definition of Changes (Minor vs. Substantial)

Minor project changes have no impact upon the original goals and protocols outlined in the original application and do not affect overall harm-benefit profile of the study or the willingness of current subjects to participate in the study. Examples include change of project title, minimal changes in wording of a survey instrument, minor grammatical changes to an informed consent and/or child's assent form, change in collaborators or co-PIs, or additional sites for the performance of the research.

Substantial changes affect the research protocol, purpose, or process. Examples include changes in the sampling population, survey instruments, interview protocols, administration of a treatment of any kind, or the informed consent process. Any research, by definition, that increases the level of risk to the participant relative to the initial application MUST assume that the changes are substantial.

The initial evaluation as to whether an addendum/modification is substantial or minor starts with the principal investigator, who should assess the degree of change in procedures and risks. The IRB Chair or committee reviewers may change the status of that designation if they deem the designation inappropriate. The IRB Chair must approve any proposed changes to the approved protocol before any modifications proceed, and the investigator must receive a letter from the Office of Research and Sponsored Programs confirming this decision. There is no such thing as an emergency exemption and no university official other than the IRB Chair may grant approval.

Submission of Change Request

Minor changes should be submitted via the Change and/or Termination Form. Substantial changes should be submitted as a new application with the investigator noting the modifications to the project. Change and/or Termination Forms and new applications for substantial change may be submitted at any time. The forms are available on the Office of Research and Sponsored Programs SharePoint site.

Section 2.11 Annual Review Definition and Process

After July 19, 2018, no annual review is required for Exempt or Expedited protocols. For NON-FDA research where a Full Board Review was required, an annual review is not required if only long-term follow up activities or data analysis is being done. FDA regulated research requires annual reviews.

For those projects requiring annual renewal, the investigator must receive a letter from the Office of Research and Sponsored Programs stating that the research is renewed prior to the anniversary date, or the research must be suspended pending an approved renewal notice. There is no such thing as an emergency approval and no university official other

than the IRB Chair may grant approval for the research to continue past the anniversary date.

For those projects requiring an annual review, the Investigators are required to complete an *Application for Change, Annual Review, or Termination/Completion* and submit it electronically to the Office of Research and Sponsored Programs at least six weeks before the anniversary date. If any project activity occurs or continues after the expiration date, the investigator is out of compliance with both federal and university policy. If the initial project was approved via Expedited Review, the annual renewal form will be forwarded to the IRB Chair for review and approval. All IRB applications that were originally approved as a result of a Full Board Hearing also require a hearing of the full committee for renewal. The Office of Research Integrity will schedule these meetings. If the Chair determines if a full IRB review is warranted, because of the on-going nature of the research or because of major changes outlined in the update, she/he will notify the Principal Investigator in writing and request that a new application be completed for review by the full IRB Board.

Section 2.12 Conditions of Approval

Approval for renewal status is valid for one year. At that time, investigators must file an additional Form B noting the project is complete or request a renewal. Unless major changes have been made and approved (necessitating a new Form A), the anniversary date of the project will always remain the date of the original IRB formal letter of approval. Projects which are found to be continuing without IRB approval are in non-compliance with UTM policy and federal regulations. In these circumstances, a non-compliance report will be sent to the Provost for further action.

Section 2.13 Definition of Termination/Completion

Projects are considered completed when the study is officially closed to new participants and follow up and all data collection is complete. If the investigators continue to actively follow research participants, the study is not considered closed and may require annual renewal based on the category of the research (please refer to research categories). Normally, projects may be considered complete during the process of analyzing data, unless the data contains identifiable private information that can be linked to specific individuals. In these cases, the project is considered complete when data analyses are completed. Projects are considered terminated if they received IRB approval and are abandoned for any reason (regardless of whether or not the project actually began the research process.)

Section 2.14 Termination/Completion Process

The Principal Investigator must complete a Form B within four weeks of termination/completion of a project and submit it to the Office of Research Integrity. The Investigator should simply indicate the project is completed or that the project will not be conducted at all by marking the appropriate box on Form B.

For thesis/dissertation research: IRB-approved projects should NOT be terminated until the thesis/dissertation committee has approved and signed off on the final submission.

Section 2.15 IRB Approvals Involving Externally Funded Applications

Investigators are encouraged to submit IRB applications for approval prior to securing funding. However, if there is insufficient time to do so, proposals may be submitted with the assurance that IRB approval will be sought and received prior to pursuing any research related activities. In these cases, the researcher must articulate the specific portion of the grant that will require IRB approval in the funding application and provide an anticipated start date for these activities.

Section 2.16 Appeals

All appeals of IRB decisions shall be submitted to the ORSP for forwarding to the IRB for reconsideration.

Article III. INFORMED CONSENT

"The informed consent process involves three key features: (1) disclosing to potential research subjects information needed to make an informed decision; (2) facilitating the understanding of what has been disclosed; and (3) promoting the voluntariness of the decision about whether or not to participate in the research. Informed consent must be legally effective and prospectively obtained. HHS regulations at 45 CFR 46.116 and 45 CFR 46.117 describe the informed consent requirements" (https://www.hhs.gov/ohrp/regulations-and-policy/guidance/faq/informed-consent/index.html).

Informed consent means that except as provided elsewhere in this policy, no investigator may involve a human being as a subject in research covered by this policy unless the investigator has obtained the legally effective informed consent of the subject or the subject's legally authorized representative. An investigator shall seek such consent only under circumstances that provide the prospective subject or the representative sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence. A subject's participation in research should at all times be voluntary on the basis of informed consent. It is incumbent upon the investigator to provide the subject with all information about the study that is likely to bear upon the subject's willingness to participate. No informed consent, whether oral or written, may

include any exculpatory language through which the subject or the representative is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution, or its agents from liability for negligence.

Examples of Exculpatory Language:

a) By agreeing to this use, you should understand that you will give up all claims to personal benefit from commercial or other use of these substances.
b) I voluntarily and freely donate any and all blood, urine, and tissue samples to the U.S. Government and hereby relinquish all right, title, and interest to said items.
c) By consent to participate in this research, I give up any property rights I may have in bodily fluids or tissue samples obtained in the course of the research.
d) I waive any possibility of compensation for injuries that I may receive as a result of participation in this research.

Examples of Acceptable Language:

a) Tissue obtained from you in this research may be used to establish a cell line that could be patented and licensed. There are no plans to provide financial compensation to you should this occur.
b) By consenting to participate, you authorize the use of your bodily fluids and tissue samples for the research described above.
c) This hospital is not able to offer financial compensation nor to absorb the costs of medical treatment should you be injured as a result of participating in this research.
d) This hospital makes no commitment to provide free medical care or payment for any unfavorable outcomes resulting from participation in this research. Medical services will be offered at the usual charge.

Section 3.01 Required Basic Elements of Consent

The regulations require that the following information must be conveyed to each subject: a statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental;

- a description of any reasonably foreseeable risks or discomforts to the subject;
- a description of any benefits to the subject or to others which may reasonably be expected from the research;
- a disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;
- a statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained;
- for research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are

available if injury occurs and, if so, what they consist of, or where further information may be obtained;
- an explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject; and
- 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.

Section 3.02 Additional Elements of Consent

When appropriate, one or more of the following elements of information shall also be provided to each subject:

- A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) which are currently unforeseeable;
- Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent;
- Any additional costs to the subject that may result from participation in the research;
- The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject;
- 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;
- The approximate number of subjects involved in the study;
- A statement that the subject's biospecimens (even if identifiers are removed) may be used for commercial profit and whether the subject will or will not share in this commercial profit;
- A statement regarding whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions; and
- For research involving biospecimens, whether the research will (if known) or might include whole genome sequencing (i.e., sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen).

Alternate elements of consent must be included when using broad consent, as documented in CFR Part 46.116.(d). However, UTM is not permitting the use of broad consent as defined under Exempt categories 7 and 8 (CFR Part 46.104(d)(7).

Section 3.03 Exceptions to Required Elements of Consent

An IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent set forth above (in Sections 3.2.1 and 3.2.2), or waive the requirement to obtain informed consent provided the IRB finds and documents that:

- The research or demonstration project is to be conducted by or subject to the approval of state or local government officials and is designed to study, evaluate, or otherwise examine: (i) programs under the Social Security Act, or other public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in methods or levels of payment for benefits or services under those programs; or (iv) possible changes in methods or levels of payment for benefits or services under those programs, and
- The research could not practicably be carried out without the waiver or alteration.

An IRB also may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent set forth in this section, or waive the requirements to obtain informed consent provided the IRB finds and documents that:

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

The informed consent requirements in these regulations are not intended to preempt any applicable Federal, State, or local laws which require additional information to be disclosed in order for informed consent to be legally effective.

Section 3.04 Documentation of Informed Consent

Informed consent shall be documented by the use of a written consent form approved by the IRB and signed by the subject or the subject's legally authorized representative. A copy shall be given to the person signing the form. The consent form may be either of the following:

1. A written consent document that embodies the elements of informed consent outlined previously in this policy (see Section 3.2). This form may be read to the subject or the subject's legally authorized representative, but in any event, the investigator shall give either the subject or the representative adequate opportunity to read it before it is signed; or

2. A short form written consent document stating that the elements of informed consent required by this policy have been presented orally to the subject or the subject's legally authorized representative. When this method is used, there shall be a witness to the oral presentation. Also, the IRB shall approve a written summary of what is to be said to the subject or the representative. Only the short form itself is to be signed by the subject or the representative. However, the witness shall sign both the short form and a copy of the summary, and the person actually obtaining consent shall sign a copy of the summary. A copy of the summary shall be given to the subject or the representative, in addition to a copy of the short form.

Section 3.05 Exceptions/Waivers for Documentation of Informed Consent

An IRB may waive the requirement for the investigator to obtain a signed consent form for some or all subjects if it finds one of the following:

1. The only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern; or
2. The research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context.

The IRB will usually waive the requirement of signed consent in the following situations:

1. when the identities of subjects will be completely anonymous if the consent form is not signed, and there is minimal risk involved in the study;
2. when obtaining a signed consent is not appropriate or feasible according to the cultural standards of the population being studied, and there is minimal risk involved in the study;
3. when there is a possible legal, social, or economic risk to the subject entailed in signing the consent form, e.g., for HIV antibody-positive individuals who might be identified as such by signing the consent form.
4. retrospective chart review or use of pathological specimens where the patients need not be contacted as part of the study, and appropriate precautions to protect the confidentiality of the data are described;
5. use of extra blood which is taken at the time of a venipuncture being done for clinical reasons;
6. or use of leftover biological material taken from another study for which consent was obtained.

If an investigator does request a waiver of signed consent, then the application should

provide a written justification for doing so and cite one of the above categories.
In cases where the documentation requirement is waived, the IRB may require the investigator to provide subjects with a written statement regarding the research. The IRB is likely to require the use of such a written statement, in the form of an information sheet, which includes most or all of the same elements as a consent form, but does not require the signature of the subject.

The U.S. Department of Health and Human Services provides an informed consent checklist, FAQs, and tips at https://www.hhs.gov/ohrp/regulations-and-policy/guidance/informed-consent/index.html.

Section 3.06 Recommendations for Researchers Regarding Informed Consent

Researchers are accountable for the quality of the informed consent protocol and for assessing comprehension of information for an informed consent. Accountability should take two forms: (a) researchers should incorporate empirically-based strategies that have been shown to increase comprehension and (b) researchers should assess research subjects' level of comprehension of information for an informed consent prior to admitting them into a study. If comprehension is inadequate, the researcher should make an effort to enhance the research subject's comprehension based on empirically effective strategies or, if impossible to attain adequate comprehension, the researcher should exclude the subject from the study (or obtain a proxy).

The IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent set forth above, or waive the requirement to obtain informed consent provided that the IRB finds and documents that various conditions under the federal common rule regulations are met. Researchers should consider the following:

1. present an amount of information for an informed consent that research subjects perceive to be the right amount for them;
2. present information clearly;
3. present any necessary anxiety-producing information (e.g., risks, complications, side effects) in as non-threatening a manner as possible;
4. present information simply -- ensure that level of difficulty of information in consent forms does not exceed research subjects' preferences or capabilities;
5. have the investigator, a nurse, or a health care team present (or follow up) information for an informed consent;
6. if possible, leave the informed consent form with research subjects so that they have adequate time to reflect upon it;
7. possibly use an audiovisual format to present information for an informed consent; and

8. actively involve research subjects in the processing of information for an informed consent.

Section 3.07 Appropriate Methods for Obtaining Consent

Conducting the proposed research in violation of this principle of informed consent may be justified only when all the following conditions are met:

- the risk to any subject is minimal;
- the rights and welfare of any subject will not be adversely affected;
- the research objectives cannot be realized without concealment;
- any reasonable alternative means for attaining those objectives would be less advantageous to the subjects;
- there is sufficient reason for concealment so that when the subject is later informed, he/she can be expected to find the concealment reasonable and suffer no serious loss of confidence in the integrity of the investigator or others involved in the situation;
- the subject is allowed to withdraw his/her data from the study if he/she so wishes when the concealment is revealed to him/her before publication and/or publicity of data; and
- the investigator takes full responsibility for detecting and removing stressful aftereffects and, insofar as possible, for providing the subject with positive gain from the research experience.

In recruiting subjects for research and obtaining their informed consent, the investigator must give potential subjects an honest description of the study without misrepresenting the purposes, procedures, benefits, or sponsorship of the research. Potential subjects should also be informed of the investment being asked of them (e.g., amount of time involved).

Where private information is sought or where risk may be involved, the subject should be fully informed regarding the nature of the information he/she will be asked to divulge and/or the possible risks, discomforts, or harm that he/she may undergo as a result of participating.

Where minors are used as the subjects for research outside of a school system or institution, only the parent or guardian shall give informed consent. In addition to this consent, children must have the research and informed consent information discussed with them so that they can understand these items and must be asked if they will participate in the research, thus providing their assent to participate in the research.

Contact the UTM Office of Research and Sponsored Projects for information on obtaining implicit consent from the parent or guardian if signing the consent form presents

difficulties (e.g., some researchers send letters home to the parents/guardians asking them to contact the school if they do not want their child[ren] to participate in the described research; if the parents/guardians do not contact the school, they are told that they have given their implicit consent for the child[ren] to participate in the research).

.1 In the circumstances that the research is conducted in an institutional setting, such as a school or hospital, where minors or committed patients are used as the subjects for research, informed consent should be secured both from the appropriate official and from the parent or guardian if any, as well as assent from the children or patients. Conditions noted under C.4.1. and C.4.2. above also apply.

.2 In the circumstance of captives and/or dependents as found in institutions, prisons, hospitals, schools, etc., and relationships such as employer/employee, teacher/student, etc., where control is inherent in the circumstance, particular care is necessary to obtain informed consent using procedures that maximize the freedom of the subject to refuse participation. In the case of prisoners, UTM will follow the Department of Health and Human Services regulations. Any value offered as a participation reward should not take advantage of any subject's deprived state. Conditions noted under C.4.1. and C.4.2. above also apply.

.3 Care must be taken that the subject's decision concerning participation is truly free and voluntary. To be avoided are:

a) being required to participate in research as a course requirement where no course-related pedagogical benefit can be justified;
b) direct or implicit suggestions that needed services (such as counseling, employment, housing) may be withheld or reduced if the subject refuses to participate in the research it is the responsibility of the investigator to make clear to the subject that such services are not contingent upon participation;
c) pressure to participate because the subject's relationship to the investigator creates a situation where it is difficult to refuse (e.g., teacher/student, superior/subordinate relationships); and
d) pressure to participate put on subjects by arousing anxieties concerning personal shortcomings (e.g., cowardice, defensiveness) or by the use of undue social influence or moral appeals.

.4 Once involved in the study, the subject should still have the prerogative, at any time, to refuse to participate or to withdraw from an experiment, regardless of the reasons. Should he/she choose to exercise this prerogative, this right must be respected without obstruction or coercion by the investigator. An opportunity to discuss the reasons for withdrawal may be offered to the subject for the purpose of clarifying misunderstandings or reducing anxiety or other discomfort that may have been aroused by participation as a subject.

A minor under age 18 may refuse to participate in the research even if the minor's legally authorized representative (parent or guardian) has given permission for the minor to participate. The information that is given to the subject or the representative shall be in

language understandable to the subject or the representative; in addition, minors must be informed about the research in language they can comprehend and asked if they want to participate in the research.

Article IV. ADVERSE EVENTS

All investigators conducting research on human subjects must report two types of incidents: if there are 1) any injuries or adverse events associated with the study procedures and/or problems involving the conduct of individuals associated with the study which occur during the course of their research project or 2) any possible breach of human subject protections that an investigator becomes aware of associated with research activities at UTC conducted by other investigators. As the standard approval letter for the IRB applications states, "All problems involving risks and adverse events must be reported to the IRB immediately." Specifically, the following must be reported, in writing:

- All serious adverse events associated with the study procedures, and/or
- Any incidents or problems involving the conduct of the study or participation by research subjects, including problems with the recruitment and/or consent process.

The following information clarifies IRB policy regarding reporting of adverse events as well as problems involving the conduct of the study.

All serious adverse events associated with the study procedures must be reported. All deaths, whether they are directly related to study procedures or not, must be reported. If there is a question on the seriousness of an event, investigators should err on the side of "over-reporting." In general, any serious or recurring problem, any unanticipated side effect, any adverse event reported to a study sponsor and/or to the FDA, any adverse event requiring treatment, or any side effect about which a subject is concerned, should be reported to the Executive Director of Research, Outreach, & Economic Development.

Any problems involving the conduct of the study or patient participation, including problems with the recruitment and/or consent processes also require reporting. For example, if a person who is contacted about participating in a study becomes upset about the recruitment process, this reaction should be reported.

Any deviations from the approved protocol should be reported in writing. Examples of a more serious nature include incidents of a person being enrolled in a study before signed consent has been obtained, an investigational drug being given prior to signed consent, or a subject being given a higher or lower dose of the drug than stated in the approved protocol.

Adverse event reports submitted to study sponsors and/or to the FDA may not be sufficient in that they rarely include an assessment of whether changes in the protocol or consent form should be made because of the adverse event.

If a study sponsor sends updated drug or device brochures, safety reports or other summaries of adverse effects, please forward to the Executive Director of Research, Outreach, & Economic Development. The Principal Investigator should include an appropriate analysis and assessment.

A report is not an admission of any liability. However, for adverse events, the investigator should make an initial determination as to whether any changes are needed in the discussion of the risks and/or benefits in the consent form. In response to incidents, the investigator may need to re-evaluate the recruitment or consent process and modify existing procedures appropriately.

The full IRB Committee will review all adverse event reports and/or incident reports to re-evaluate the risks/benefits of the study and/or the appropriateness of the recruitment/consent process to determine if any changes should be made in the protocol or consent form. If the investigator has already modified the protocol or consent form in response to these events, the appropriateness of these changes is also reviewed.

The IRB is responsible for continuing review of all human subject research. This is done through the annual renewal process as required. Thus, all reported adverse events should also be included when a renewal application is submitted for the study, so that the IRB may consider renewal of the protocol in light of such information.

Serious adverse events or incident reports are forwarded to the Provost and Signatory of the IRB who must be informed in case of inquiries, institutional liability, publicity, or to apply for university compensation policies. If the FDA or DHHS is involved, and if the problem is of sufficient magnitude, the appropriate agency officials will be informed. The Executive Director of Research, Outreach, & Economic Development will be responsible for notification in all these instances. Failure to report is a breach of the conditions under which IRB approval is given and could result in suspension or revocation of approval. Suspension or revocation of approval could result in loss of support by funding agencies and loss of the right to publish.

The Executive Director of Research, Outreach, & Economic Development will conduct an inquiry following any report of possible misconduct related to human research activities that may come from subjects, study personnel, staff, students, or faculty. If, for instance, a research project is being conducted without IRB approval, or an improper method of recruiting subjects is being used, or undue influence is being placed upon prospective subjects to participate in a study, the IRB has no means of learning about such situations and rectifying them unless it is informed that they are taking place. Thus, in order to

fulfill its obligation to protect human subjects in research, the institution depends upon concerned individuals, including investigators, to inform the Executive Director of Research, Outreach, & Economic Development of any possible misconduct related to research activities of which they become aware.

Such incidents are usually reported by telephone or in writing to the provost and other appropriate administrative officials by the Executive Director of Research, Outreach, & Economic Development. An inquiry is made to the investigator conducting the research activity, maintaining requested anonymity of the individual submitting the report whenever possible.

Depending upon the outcome of the initial inquiry, information about the incident may be forwarded to the Institutional Official, the Provost, or the Chancellor for appropriate resolution.

Article V. NONCOMPLIANCE BY INVESTIGATORS, INSTITUTIONAL REVIEW BOARDS, AND INSTITUTIONS

Section 5.01 Investigators

Research investigators are the most frequent source of noncompliance with human subject regulations. The most common lapses in investigator compliance include:

a. unreported changes in protocols,
b. misuse or nonuse of the informed consent document, and
c. failure to submit protocols to the IRB in a timely fashion. Problems such as these are often caused by communication difficulties. With investigator goodwill, these cases can be resolved by the IRB without jeopardizing the welfare of research subjects.

Occasionally, an investigator will either avoid or ignore an IRB. Such cases present a more serious challenge to the IRB and to the institution. Regardless of investigator intent, unapproved research involving human subjects places those subjects at an unacceptable risk. When unapproved research is discovered, the IRB and the institution should act promptly to halt the research, assure remedial action regarding any breach of regulatory or institutional human subject protection requirements, and address the question of the investigator's fitness to conduct human subject research. Beyond the obvious need to protect the rights and welfare of research subjects, the credibility of the IRB is clearly at stake. In addition, any serious or continuing noncompliance with DHHS human subjects regulations or the determinations of the IRB must be promptly reported to the Office of Human Research Protections (OHRP) or the department or agency head.

Section 5.02 Institutional Review Boards

IRB noncompliance occurs whenever the IRB deviates from the duties imposed upon it by the federal regulations. Such deviations include:

a. the inadequate review of research protocols by failing to ensure that the consent document and process provide sufficient information to allow prospective subjects to make an informed decision whether to participate in the research;
b. failing to ensure that the research design includes adequate monitoring of the data and any additional safeguards necessary to protect the welfare of particularly vulnerable subjects; and
c. failing to conduct continuing review of research at intervals appropriate to the degree of risk.
d. failing to maintain adequate records of IRB business, and
e. failing to hold their meetings with a majority of members present, including a nonscientific member.

A demonstrated inability to carry out IRB responsibilities in accordance with DHHS regulations can be cause for the suspension or withdrawal of approval of an institution's Assurance.

Section 5.03 Institutions

Although institutions are accountable for the actions of individual investigators and the IRB, institutional noncompliance is more broadly described as a systemic failure of the institution to implement practices and procedures contained in the institution's Assurance. Prime examples are (1) the failure of the institution to ensure that the IRB is appropriately constituted and functions in accordance with the regulations, (2) that the IRB receives appropriate institutional support and staffing, and (3) that investigators meet their obligations to the IRB. Systemic failure to abide by the terms and conditions of an institution's Assurance will result in withdrawal of approval of the Assurance.

Article VI. THE HEALTH INSURANCE PORTABILITY AND ACCOUNTABILITY ACT (HIPAA)

Section 6.01 Definition of Terms

Article VII. ETHICAL CONSIDERATIONS

Section 7.01 Protection of Individual Rights

Only qualified investigators should conduct research or by others only where a close supervisory relationship exists and is maintained with qualified individuals. Should an investigator become involved in areas that extend beyond his/her level of competence, appropriate consultation must be obtained.

Each research project must be evaluated in terms of its potential benefit to the subject

and to society as well as in terms of its potential risk to the emotional and physical welfare of the subjects. Where risk is involved, or where information obtained is of a private nature, extra protection must be afforded the subject. Every effort should be made to minimize the risks or discomfort entailed in the subject's participation.

The investigator assumes responsibility for the procedures used throughout the course of the investigation. It is the investigator's responsibility to report to the IRB for project review any planned changes in format or procedures from those originally approved. A Change and/or Termination Form must be filed (see Appendix F in this Guide). Should problems or harmful effects arise out of the experimental procedures, such responsibility would continue until the problem or effect is removed or until the subject is referred to an appropriate professional who has assumed responsibility for the subject.

The investigator must not only take any immediate steps required to undo harmful effects but must also initiate appropriate follow-up procedures to detect unpredicted harm if the study presents a potential to produce harm that may only manifest itself later.

The investigator must be sensitive to individual factors that may predispose certain individuals to experience enduring harmful psychological or physical consequences from participation in the study and to exclude such individuals from the research sample.

The investigator is obligated to keep the subject's data in confidence. This includes keeping the data in confidence from relatives, friends, employers, school officials, and from other professional associates of the investigator unless: (a) the subject or an authorized representative consents to disclosure, or (b) regulations of the Secretary of the Department of Health and Human Services so provide, or (c) as otherwise required by law. It is the investigator's responsibility to report to the IRB how the data will be used and any subsequent changes in use.

Where information about private or personal matters is obtained from the subject for scientific purposes, the subject must be properly informed of how such information will be used, who will or might have occasion to examine such information, and how it might affect his/her future, including his/her civil rights. The subject must be advised that at any point he/she may withdraw from the experiment without penalty.

Where feasible, any private information obtained from a subject should be obtained anonymously or, if this is not possible, it should be immediately coded with care taken to keep the code separate from the data and in a secure place.

At the completion of the experiment, the investigator has the obligation to remove any misconceptions acquired by the subject, whether deliberately created or developed as an accidental byproduct of the procedure.

Whenever possible, subjects should receive something of value for their participation. This benefit may be material (e. g., money, gifts, etc.) or educational (e. g., information, self-knowledge, etc.).

When the methodological requirements of research lead some subjects to experience failure or require the withholding of a potentially beneficial program or treatment from control subjects, the investigator must, insofar as possible, provide these subjects with a beneficial experience when the experiment is concluded.

It is unacceptable to intentionally cause a research subject to suffer embarrassment, fear, anxiety, or loss of self-esteem. Such research may be justified only when (a) the research objectives can be realized in no other way, and (b) the suffering of the research subject is limited in degree and duration to that minimum required to accomplish the research objectives.

An individual has the right to control any use of his/her person. Where a condition or circumstance exists which interferes with the right to freely control the use of his/her person, special precautions must be instituted to safeguard his/her rights and welfare. It is incumbent upon the investigator to make sure that all subjects are treated with respect and dignity, and that the subjects are not imposed upon for the convenience of the researcher.

Rather than adopting an ethical code, the University encourages researchers to follow the ethical codes established by their disciplines. Ethical codes or statements of principles established by the American Psychological Association, American Dental Association, American Sociological Association, and the World Medical Association will be referred to when appropriate to the conduct of the research.

Section 7.02 Participant Data and Identity Confidentiality Considerations

Whenever researchers promise participants that their responses and data will be maintained in confidence, all research project members (investigators, directors, transcribers, students, and staff) are required to prevent accidental and intentional breaches of confidentiality. In most cases, confidentiality can be assured by following simple practices (e. g., substituting codes for identifiers, removing survey cover sheets that contain names and addresses, limiting access to identified data, and/or storing research records in a locked cabinet). However, all measures used to assure confidentiality of data need to be understood by all research staff before research is initiated, and followed once research is initiated. Confidentiality procedures must be described in research applications that come before the UTM IRB.

Researchers should recognize that the assurance of confidentiality includes keeping the identity of participants confidential. Researchers proposing projects that will address

sensitive, stigmatizing, or illegal subjects must explicitly outline the steps they will take to assure any information linking participants to the study is maintained in confidence. The requirement of signed consent forms is often waived in sensitive studies, if the consent document is the only written record linking participants to the project and a breach of confidentiality presents the principal risk of harm anticipated in that research.
If there is any chance that data or participants' identities might be sought by law enforcement agencies or subpoenaed by a court, a grant of confidentiality should be obtained. Under federal law (Public Health Act § 301(d)), researchers, prior to the initiation of the research project, may request grants of confidentiality to protect against forced data and participant identity disclosures. These grants provide protection for specific research projects where protection is judged necessary to achieve research objectives.

To take advantage of § 301(d), the investigator must request a grant of confidentiality from the appropriate official. Protection for research on mental disorder or the use and effect of alcohol and other psychoactive drugs can be obtained from the National Institute on Alcohol Abuse and Alcoholism (NIAAA), the National Institute on Drug Abuse (NIDA), or the National Institute of Mental Health (NIMH). Certificates for confidentiality for biomedical, behavioral, clinical, or other research that does not fall into these categories are issued by the Assistant Secretary of Health. A more complete discussion of § 301(d) can be found at the OHRP website (www.hhs.gov/ohrp/humansubjects/guidance).

Section 7.03 Risks versus Benefits

Each research project is evaluated in terms of the potential benefits to new knowledge, to society, and to the research subject as against the potential risks to the individuals involved. Where a proposed project involves substantial potential risks to subjects, the investigator has the responsibility to justify the possible benefits of the project, and must be cognizant of previous research, both animal and human, done in the subject area.

Any project in which there exists a possibility of alteration or impairment of physical or psychological functions; of acute discomfort; or of emotional, social, or other harm constitutes a risk. Such projects require special precautions and must follow approved procedures as set forth in Section XII, below, to obtain approval. Furthermore, any project which solicits private or confidential information as defined by the subject or qualified person (or if this is not possible, by a parent, guardian, or other designated authority) must also be reviewed according to approved procedures under PART X.A.

Article VIII. SUSPENSION OR TERMINATION OF IRB APPROVAL OF RESEARCH

An IRB shall have authority to suspend or terminate approval of research that is not being conducted in accordance with the IRB's requirements or that has been associated with

unexpected serious harm to subjects. Any suspension or termination or approval shall include a statement of the reasons for the IRB's action and shall be reported promptly to the investigator, appropriate institutional officials, and the Department or Agency head.