15.99.01.D1.01 Assurance of Protection of Human Research Subjects

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Procedure Statement

Texas A&M University-Central Texas (TAMUCT) recognizes the need for research activities in which human beings serve as research subjects. The University acknowledges and accepts its responsibilities for ensuring that the privacy, safety, health, and welfare of such subjects are adequately protected.

Reason for Procedure

This Procedure supplements TAMUCT 15.99.01.D1 *Assurance of Protection of Human Research Subjects*

Procedures and Responsibilities

1. GENERAL

    1.1 TAMUCT has a responsibility to protect the rights and welfare of prospective research subjects and to provide a favorable climate for the conduct of scientific inquiry. In compliance with federal regulations, the University requires all research involving human subjects to be approved by the TAMUCT Institutional Review Board (IRB).

    1.2 Researchers seeking approval for projects may obtain the appropriate forms from the IRB Chair, an IRB member, or the IRB Website.

    1.3 This document shall automatically be updated to comply with changes in federal regulations. Other changes will go through the regular University review process.

    1.4 The Chair of the IRB will report to the Research Compliance Officer in January and August of each year as to the adequacy of this document and such other matters that should be brought to the attention of the faculty related to this document.

2. SCOPE OF INSTITUTIONAL REVIEW BOARD

2.1 The IRB has the primary responsibility for maintaining ethical standards of research involving human subjects at the University. All projects will be reviewed at least annually. The IRB has authority to approve or disapprove such research. It may require modifications as a condition for approval. Following the review of the research, the IRB will notify the investigators and the institution in writing of its decision. If the IRB decides to disapprove a research activity, it will provide the reasons for its decision and give the investigator an opportunity to respond in person or in writing. Federal regulations require the IRB to conduct continuing review of approved research at intervals appropriate to the degree of risk, but not less than once per year. The IRB has authority to observe or have a third party observe the consent process and the research.

3. ETHICS

3.1 TAMUCT will use the following documents as guides for the conduct of human subject research:

3.1.1 the World Medical Association's "Declaration of Helsinki"

3.1.2 the American Psychological Association's statement, "Ethical Principles in the Conduct of Research with Human Subjects,"

3.1.3 the Belmont Report of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, and

3.1.4 the Code of Federal Regulations, 45 CFR 46, Protection of Human Subjects.

3.2 The subjects have recourse to the IRB at any time through its Chairperson or the Chief Research Officer/Human Subjects Administrator (CRO/HAS), if they feel they have not been dealt with fairly. Copies of this document and those listed above will be available for the investigator, as well as any other interested persons, upon request to the Chair of the IRB.

4. MEMBERSHIP OF THE IRB

4.1 The University has established its IRB in accordance with the compositional requirements of Section 46.107 of the Federal regulations. The IRB shall be comprised of at least 5 members from diverse backgrounds to promote complete and adequate review of research activities commonly conducted at the University. Additionally, for each IRB there must be at least one member in scientific areas; at least one member in nonscientific areas; and include at least one member who is not otherwise affiliated with the University and who is not part of the immediate family of a person who is affiliated with the University.

4.1.1 The TAMUCT IRB shall consist, whenever possible, of at least one faculty member from each College or School within TAMUCT. The majority of IRB members shall be from the tenure/tenure-track faculty members.

4.1.2 The TAMUCT IRB shall have on its committee at a minimum one scientific member.

4.1.3 The TAMUCT IRB shall have on its committee at least one individual with experience in research involving children.

4.1.4 The TAMUCT IRB shall have on its committee at least one individual who has experience with the local community. The community member may also count as a nonscientific member.

4.1.5 The TAMUCT IRB shall have one nonscientific member.

4.1.6 The IRB may also select alternate members to serve when a quorum is not possible.

4.1.7 The IRB may, in its discretion, invite individuals with competence in special areas to assist in the review of issues which require expertise beyond or in addition to that available on the IRB. These individuals may not vote.

4.2 The members will be selected based on their knowledge and expertise. Although members may be referred by current board members, volunteer for service, or be appointed by the Committee on Committees; all final appointments will be approved by the Provost.

4.3 Terms of membership for faculty members shall be three years on an alternating basis. The community members shall serve two-year terms. The Chairperson of the IRB shall be elected from within the membership of the IRB, with final approval by the Provost/Vice President for Academic and Student Affairs, for a two-year term by the IRB and shall be eligible for re-election to another two-year term. Any member may serve as acting chair when the Chair has a protocol for review or other appropriate needs. The Administrative Assistant for the Office of Graduate Studies and Research (GSR) will serve as the secretary for the meetings.

5. MEETINGS OF THE IRB

5.1 The IRB will convene meetings as needed to conduct Full Review, or at least twice a year, whichever is greater. Research will be reviewed at convened meetings at which a quorum is present. Quorum for the meeting is defined as a simple majority, including at least one member whose primary concerns are in non-scientific areas. The IRB may establish its own operating procedures within these prescribed guidelines.

6. CRITERIA FOR APPROVING RESEARCH

6.1 To be approved by the IRB, human subjects research which is covered by federal policy must meet all the following criteria:

6.1.1 risks to subjects are minimized by using procedures that are consistent with sound research design and whenever appropriate, use procedures already being performed on the subjects for diagnostic or treatment purposes;

6.1.2 risks to subjects are reasonable in relation to anticipated benefits to subjects, and the importance of the knowledge that may reasonably be expected to result;

6.1.3 selection of subjects is equitable in terms of the purposes of the research and the setting in which it will be conducted;

6.1.4 informed consent is sought from each prospective subject and documented to include all appropriate information;

6.1.5 the protocol makes adequate provision for monitoring the data collected to ensure the safety of the subjects;

6.1.6 adequate provision is made and documented to protect the privacy of subjects and to maintain the confidentiality of the data; and

6.1.7 where some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as children, prisoners, pregnant women, persons with acute or severe physical or mental illness, or persons who are economically or educationally disadvantaged, appropriate safeguards have been included in the study to protect their rights and welfare.

7. RESEARCH REVIEW CATEGORIES

The extent of the IRB review will depend upon the nature of the research. There are three research review categories: exempt research, expedited review, and full review.

7.1 Exempt Research

7.1.1 Certain broad categories of research projects that involve human subjects that do meet the definition under the regulations are "exempt" from IRB review. Federal regulations permit the principal investigator to make an initial judgment as to whether the project is exempt; however only the IRB may determine that an exemption is appropriate. "Exempt" in this context means that a project is not subject to, or is exempted from the requirements of the regulations spelled out in 45 CFR 46. Although exempt research is not regularly reviewed by the IRB, the exempt research form (and other supplemental forms, if applicable) must be on file with the IRB, and the research may be reviewed at the committee's discretion. If the committee deems necessary, it may require a full review.

7.1.2 Unless otherwise required by federal departments or agencies, research activities in which the only involvement of human subjects will be in one or more of the following categories are generally exempt from full review by the IRB:

7.1.2.1 [No age limitations on subjects] Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as

(i) research on regular and special education instructional strategies, or

(ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

7.1.2.2 [Note: Subjects must be adults – legal age of adulthood] Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless:

(i) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and

(ii) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.

7.1.2.3 Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under paragraph 7.1.2.2of this section, if:

(i) the human subjects are elected or appointed public officials or candidates for public office; or

(ii) federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

7.1.2.4 Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

7.1.2.5 Research and demonstration projects which are conducted by or subject to the approval of department or agency heads, and which are designed to study, evaluate, or otherwise examine:

(i) Public benefit or service programs;

(ii) procedures for obtaining benefits or services under those programs;

(iii) possible changes in or alternatives to those programs or procedures; or

(iv) possible changes in methods or levels of payment for benefits or services under those programs.

7.1.2.6 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.

7.1.2.7 To qualify as an exempt study, the research must fall within one of the above-specified regulatory categories and satisfy all TAMUCT institutional requirements. Only the IRB may determine when research is exempt or requires a full or expedited review. Therefore, researchers must submit an application requesting exempt status to the IRB ensure that the research meets the criteria for an exemption.

7.1.3 Research involving protected populations or involving the following practices CANNOT be Exempted:

- research involving prisoners;
- research involving the elderly;
- research involving pregnant women;
- research involving the handicapped;
- surveys or interviews of children;
- observation of children when the investigator will interact with them;
- data obtained from adults through administration of educational tests, survey procedures, interview procedures, or by observation of public behavior IF:

  1. the information is recorded in such a way that the identity of individuals can be identified either directly or through identifiers linked to the individuals

  AND

  2. disclosure of subjects' responses could reasonably place them at risk of criminal or civil liability or be damaging to an individual's financial standing, employability, or reputation;
- observation of behavior that takes place in settings in which subjects have a reasonable expectation of privacy;
- research techniques which expose subjects to discomfort or harassment beyond levels encountered in daily life (i.e., greater than minimal risk); or
- research that deceives subjects

7.1.4 A research project that is determined to meet the criteria for Exempt status is exempt from annual continuing review by the IRB. The PI, however, is required to report to the IRB any expected revisions in the research activity that will cause the research to change from exempt to Expedited or Full review status. The PI is also required to report to the IRB any unexpected or adverse events that occur or new information obtained that may cause the

research activity to change from exempt to Expedited or Full review status. When the research project is completed, the PI is required to notify the IRB. The Exempt status expires when the research project is completed (closed) or when the review category changes as described above.

7.1.5 Criteria for Protection of Human Subjects in Exempt Research
A research project that has received an Exempt designation is not exempt from protection of the human subjects:

7.1.5.1 The PI assures that all those persons listed on the application as being involved in the research have completed the IRB human subjects training requirements.

The PI assures that human subjects will voluntarily consent to participate in the research when appropriate (e.g. surveys, interviews, interactions with subjects) and will provide subjects with pertinent information (e.g. the activity involves research, a description of procedures, that participation is voluntary, risks and benefits, contact information for PI and IRB Chair).

7.1.5.2 The PI assures that the IRB will be immediately informed of any information, unexpected or adverse events that would increase the risk to the human subjects and cause the category of review to be upgraded to Expedited or Full review.

7.1.5.3 The PI assures that the IRB will be immediately informed of any complaints from subjects regarding their risks and benefits; and

7.1.6 These criteria are specified on the *Principal Investigator Assurance Form of an Exempt Project*, and the PI's signature acknowledges that s/he understands and accepts these conditions.

7.2 Expedited Review

7.2.1 Expedited review procedures are available for certain kinds of research involving no more than minimal risk, and for minor changes in approved research. Specifically, research is eligible for expedited review if it involves no more than minimal risk (see 45 CFR as amended) to the subjects and the only involvement of human subjects will be in one or more of the categories listed below:

7.2.1.1 Collection of hair and nail clippings, in a non-disfiguring manner; deciduous teeth; and permanent teeth if patient care indicates a need for extraction.

7.2.1.2 Collection of excreta and external excretion including sweat, uncannulated saliva, placenta removed at delivery, and amniotic fluid at the time of rupture of the membrane prior to or during labor.

7.2.1.3 Recording of data from subjects 18 years of age or older using noninvasive procedures routinely employed in clinical practice. This includes the use of physical sensors that are applied either to the surface of the body or at a distance and do not involve the input of matter or significant amounts of energy into the subject or an invasion of the subject's privacy. It also includes such procedures as weighing, testing sensory acuity, electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, diagnostic echography, and electroretinography. It does not include exposure to electromagnetic radiation outside the visible range (for example, X-rays, microwaves).

7.2.1.4 Collection of blood samples by venipuncture, in amounts not exceeding 450 milliliters in an eight-week period and no more often than two times per week, from subjects 18 years of age or older who are in good health and not pregnant. Subjects must be informed orally of the risk of bruising and infection.

7.2.1.5 Collection of both supra- and subgingival dental plague and calculus, provided the procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques.

7.2.1.6 Voice recording made for research purposes such as investigation of speech defects.

7.2.1.7 Moderate exercise of healthy volunteers. Moderate exercise does not include stress testing.

7.2.1.8 The study of existing data, documents, records, pathological specimens, or diagnostic specimens.

7.2.1.9 Research on individual or group behavior or characteristics of individuals, such as studies of perception, cognition, game theory, or test development, where the research investigator does not manipulate subjects behavior and the research will not involve stress to the subjects.

7.2.1.10 Research on drugs and devices for which an investigational new drug exemption or an investigational device exemption is not required.

7.2.1.11 Any other category specifically added to this list by HHS and published in the Federal Register.

7.2.2 Informed consent is required, but the requirement to obtain a signed consent form may be waived if:

7.2.2.1 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

7.2.2.2 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.

7.2.3 In cases where the documentation requirement is waived, the IRB may require the investigator to provide subjects with a written statement regarding the research.

7.3 Full Review

All those projects not exempt or qualifying for expedited review shall be subject to full review by the IRB.

8. REVIEW PROCEDURES

8.1 Exempt Review

Under the exempt procedure, the researcher shall submit the IRB Exemption Request Form (Request) to the Chair of the IRB. The IRB Chair will electronically circulate the Request to the IRB. The members will have 24 hours to vote or post questions. The Request may be passed with a majority of yes votes, unless questions have been posed. Any questions posed will be mitigated before a vote is counted.
The IRB may choose to review the forms on file at its discretion. If the IRB deems necessary, it may require a full review.

8.2 Expedited Review

8.2.1 Research which involves no more than minimal risk to the subject and falls under the categories established by the Secretary of Health and Human Services (46 FR 8392), or research previously approved needing minor changes, will normally be reviewed by the expedited review procedures. However, the IRB may consider any such research through a full review procedure, if it so chooses.

8.2.2 Informed consent is required in the expedited review, but the IRB may waive the requirement to obtain a signed consent form, in accordance with the guidelines discussed above in section 7.2.2.

8.2.3 In cases where the documentation requirement is waived, the IRB may require the investigator to provide subjects with a written statement regarding the research.

8.2.4 Under the expedited review procedure, the researcher shall submit IRB Protocol Submission Form (Protocol) with appropriate supplemental forms to the IRB Chair. The Chair will review the proposal. A member of the IRB shall not review his/her own proposal. If the Chair finds that the research falls

under the guidelines for expedited procedures, he/she will electronically circulate the Protocol to the IRB. The members will have 24 hours to vote or pose questions. The Protocol may be passed with a majority of yes votes, unless questions have been posed. Any questions posed will be mitigated before a vote is counted.
If the request is not passed, it will be presented at the next full review meeting. A research activity may be disapproved only after a review by the full IRB.

The Chair shall forward to the PI and the full IRB the decision to approve the proposed research activity, or modifications required to secure approval, or a recommendation for full IRB review.

8.3 Full Review

8.3.1 Investigators are required to submit proposals to the IRB Chair, using the Protocol Submission Form, at least 5 working days in advance of the meeting in order to provide time for prior review. The IRB may approve the research as proposed; it may approve the research pending specified modifications; or it may reject the research proposal. If the IRB gives approval pending specified modifications, the principal investigator is required to submit written assurance that conditions, restrictions, report requirements, or changes imposed on the project will be followed.

8.3.2 The ultimate protection of safety, confidentiality, and the rights of human subjects will in all cases take precedence over the importance and results of the project. The definition used to determine if the subject is "at risk" will be contained in the Code of Federal Regulations on Protection of Human Subjects (45 CFR 46 as amended).

8.3.3 No project or activity which involves humans will be approved unless assurances of legally effective informed consent are provided for or a waiver of signed informed consent is approved on Form B by the IRB. The elements of informed consent as outlined by 45 CFR 46.116 are to be observed in all projects. The Board will decide whether the method for securing consent of the subject (by the principal Investigator) is sufficient and appropriate. Additionally, in connection with any project involving fetuses or pregnant women, the IRB will oversee the actual process by which individual consents are secured by sampling and monitoring the progress of the activity at timely intervals.

9. RECORDS

9.1 The IRB Chair will obtain and maintain all appropriate records--including, but not limited to, copies of all projects, documentation of informed consent procedures, minutes, and records of formal notification to/from principal investigators of official actions.

9.2 All records obtained for compliance with 45 CFR 46 are considered privileged institutional records and principal investigators must protect and maintain the confidentiality of information on individual subjects. Certification of approval of federally funded projects including any required changes will be forwarded by the IRB Chair to the Department of Health and Human Services.

10. STATEMENT ON STUDENT RESEARCH

10.1 According to federal regulations, research is defined as "a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalized knowledge." If student projects are not designed to contribute to further academic knowledge in the discipline (e.g., conference presentations, professional publications), then they are not considered research for the purposes of this rule and therefore are not under the review of the IRB. Student projects that are designed to contribute to generalized knowledge should be submitted for review to the IRB just as any other research project.

10.2 Research conducted by students must follow the same ethical guidelines as all university research. The responsibility for the ethical conduct of student research is jointly held by the instructor and the student, each being fully responsible for the research.

Related Statutes, Policies, or Requirements

System Regulation *15.99.01 Use of Human Subjects in Research*

University Rule *15.99.01.D1 Assurance of Protection of Human Research Subjects*

Contact Office

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