The Institutional Review Board Policies and Procedures Manual for Research with Human Subjects

TEXAS TECH UNIVERSITY™

2025-2026 Academic Year

Office of Research and Innovation
Human Research Protection Program
Lubbock, TX 79409- 1075
Phone (806) 742-2064
Fax (806) 742-3947
http://www.hrpp.ttu.edu

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Section 1: Introduction

1.0 Background

Federal regulation of human subjects research began in 1971. With the background of the Nuremberg Code (Nuremberg Code - Wikipedia) in 1974 the National Research Act created the National Commission for the Protection of Human Subjects in Biomedical and Behavioral Research. This law required every institution applying for federal funds for the conduct of human research to establish an Institutional Review Board (IRB) to protect the rights of the human subjects involved in biomedical and behavioral research.

After meetings at the Smithsonian Institution's Belmont Conference Center in 1976 and extensive deliberations over the next three years, the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research issued a 1979 statement, "Ethical Principles and Guidelines for the Protection of Human Subjects of Research," (The Belmont Report | HHS.gov), laying out basic ethical principles to assist individuals in resolving ethical issues in the conduct of research with human subjects. In 1981, the Food and Drug Administration (FDA) and the National Institutes of Health (NIH) set forth the regulatory standards for the protection of human subjects and for the operation of Institutional Review Boards. In 1983, the U.S. Department of Health and Human Services (DHHS) issued new regulations and mandated special protection for vulnerable populations such as prisoners and children. In 1989, the National Institutes of Health became the coordinator of all the human subject's protection activity of the federal government through what is now known as the Office for Human Research Protections (OHRP). In 1991, OHRP issued regulations to protect human subjects in research (Title 45 of the Code of Federal Regulations, Part 46, 45 CFR 46 | HHS.gov). It is these regulations, also known as 45 CFR 46 or the Common Rule, that govern human research activity at Texas Tech University.

To certify that Texas Tech complies with these federal regulations, the university has filed a Federalwide Assurance and registered our IRB with OHRP (FWA 00001568; expires 4/17/2028 and IRB00000276; expires 1/27/2028). The assurance commits the university, the Institutional Review Board, and research investigators to the ethical principles of *The Belmont Report* and an institutional policy of compliance with the federal regulations. Importantly, as part of its assurance, Texas Tech is committed to reviewing all research involving human subjects regardless of sponsorship.

1.1 Institutional Review Board

IRB Committee Members | HRPP | Research Home | TTU

1.1.1 Administration of Research Ethics at Texas Tech University

The Vice President for Research and Innovation and Associate Vice President for Responsible Research is responsible for the application of policies and procedures governing the use of human subjects in research. The HRPP Director (742-2064) is responsible for coordinating IRB activities. The HRPP office maintains all IRB records including meeting agendas and minutes,

policies, regulations, forms, reference materials, and protocols (in Cayuse IRB). Active IRB-approved individual protocols are maintained for the life of the project. When notification is received that a project has been completed, the files are archived in Cayuse IRB. Sponsored project guidelines need to be followed on record retention.

1.1.2 Composition of the Institutional Review Board

The Protection of Human Subjects Committee (OP 74.09: Protection of Human Subjects in Research | Operating Policies & Procedures | TTU) serves as the IRB for Texas Tech University. It operates under the DHHS regulations for the protection of human research subjects (45 CFR 46), the university's Federalwide Assurance (FWA), and is guided by the ethical principles regarding human subjects research as set forth in *The Belmont Report.* Within the scope of these documents, the IRB is charged with applying both the letter and the spirit of federal regulations designed to protect the rights and welfare of human subjects.

The IRB members represent diverse backgrounds to provide the professional competency necessary to review research and to provide an understanding of the ethical, legal, and community contexts in which research takes place. The Vice President for Research and Innovation is responsible for the appointment of members for the IRB. Members are selected based on their experience and expertise and their sensitivity to issues such as community attitudes. One member is appointed specifically to represent the interests of prisoners. One member who is not affiliated with the university represents the larger community. An additional member is from the faculty of Texas Tech University Health Science Center. The rest of the IRB consists of Texas Tech University faculty members who represent expertise in a wide variety of areas of human research. The ex-officio members include the Associate Vice President for Responsible Research, a representative from Environmental Health and Safety, a representative from the Information Technology Division, representatives from the Office of Research Services, a representative from the Office of the Registrar, and a representative from Responsible Conduct of Research. There are also alternate members who may replace a regular voting member unable to attend a meeting. Members and alternates are appointed for staggered three-year terms and may be reappointed so that the Board maintains a large number of experienced members. The IRB can and does enlist the help of outside experts whenever review of a proposal requires specialized knowledge concerning research procedures or populations. These outside experts do not have voting privileges.

The Institutional Review Board for the Protection of Human Subjects Committee meets monthly on the first Tuesday of each month at 3:00 p.m.

1.1.3 Conflict of Interest Statement

In accordance with DHHS and FDA regulations (45 CFR 46.107(e) and 21 CFR 56.107(e)), these regulations prohibit IRB members from participating in the review of research protocols in which they have a conflict of interest.

It is the expectation of the University that IRB members will voluntarily disclose any circumstance that may compromise their ability to conduct an impartial review to the IRB Chair

or HRPP leadership. Conflicts of interest are normally personal, professional, or financial in nature, but any situation that could reasonably affect a member's objectivity requires disclosure and recusal from the review process.

For additional guidance, refer to **Appendix B.**

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Section 2: The IRB and Education and Training

2.0 Education/Training

The IRB helps to educate the Texas Tech University community about issues of human subjects research ethics. All research study personnel who engage with human subjects must complete human subject training prior to IRB approval. IRB approval is required before research study personnel may engage in any human research-related activities, including recruitment of participants, consenting of participants, data collection (anonymous or identifiable), accessing identifiable data, and analysis of identifiable data. These training requirements apply to all Principal Investigators, Co-Investigators, research staff, and students. This includes both individuals within TTU systems and external collaborators.

Research personnel must complete one of the following human subject trainings every 3 years:

1. CITI - Human Subjects TTU Social and Behavioral Investigators
   CITI Training | HRPP | Research Home | TTU

2. TTU Human Subject Training
   Human Subject Training | HRPP | Research Home | TTU

3. External – CITI Human Subject Training
   a. TTU IRB will accept another institution's current human subject training through CITI

Initial submissions will need to include current human subject training for all research personnel listed on the IRB protocol at the time of submission. All modifications, renewals, post-approval monitoring, and incidents submitted to the HRPP office will need to include current certificates for all research personnel. Final IRB approval on submissions will not be given until all research personnel engaged with human subjects have current human subject training.

This policy applies to all research involving human subjects, regardless of funding or sponsorship.

The IRB has the authority to suspend or withhold approval from any project that involves study personnel who fail to meet these education requirements. The IRB, Vice President of Research and Innovation, and Institutional Official for Human Subjects has the authority to require research personnel to complete additional trainings that will aid in the protection of human subjects.

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Section 3: Institutional Review Board Procedures

3.0 Does the Project Involve Human Subjects Research?

The IRB regulates all activity that constitutes *research* with *human subjects*, as defined below (see 45 CFR 46.102, Definitions) that (a) is conducted by Texas Tech University personnel in the course of their employment by the university and/or (b) uses Texas Tech University facilities or resources. Generally, this means that Texas Tech University personnel conducting research elsewhere need approval by the Texas Tech University IRB even if the work is approved by another IRB. Work that is conducted on the Texas Tech University campus needs approval by the Texas Tech University IRB even if it has approval by another institution. In some cases, Institutional Authorization Agreements can be created that allow one IRB to take the primary role of review and approval, and the other IRB to rely on that IRB. Individuals who are in doubt about whether an activity constitutes research with human subjects or who have questions about the applicability of this policy to a research project should confer with the IRB Chair, HRPP Office or a member of the IRB.

In most cases, multi-site collaborative research requires IRB review and approval. If the research activities at Texas Tech involve *any* interaction or intervention with subjects, then the protocol must be reviewed.

Under no circumstances may an investigator undertake research involving human subjects without approval by the full IRB, approval by expedited review, or approval of a claim for exemption. Retrospective approvals and exemptions cannot be granted.

The following definitions from federal regulations apply:

> ***Research*** means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities which meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program which is considered research for other purposes. For example, some demonstration and service programs may include research activities.
>
> ***Human subject*** means a living individual about whom an investigator (whether professional or student) conducting research obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information.
>
> ***Intervention*** includes both physical procedures by which data are gathered (for example, venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes.
>
> ***Interaction*** includes communication or interpersonal contact between investigator and subject.

Private information includes "information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record). Private information must be individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human subjects" (45 CFR 46.102).

Non-research activities are not subject to review by the IRB and do not have to be certified as exempt from IRB review. Examples of activities that fall outside the jurisdiction of the IRB because they do not have the purpose of contributing to generalized knowledge or are not systematic investigations include, but are not limited to:

- Art
- Classroom projects that are conducted for didactic purposes and do not extend beyond the classroom (i.e., do not contribute to generalizable knowledge)
    - The student and instructor still have the responsibility to respect the rights of the study participants and to treat them in a fair and ethical manner.
    - Instructors should ensure that the projects carried out by their students are being conducted in a manner that is consistent with the ethical principles of their discipline and the federal guidelines for the protection of human subjects.
    - If a student or instructor decides to submit a class project to a conference, journal, etc. an approved IRB is needed prior to recruiting and collecting data.
- Journalism
- Marketing research designed to market the institution as a product
- Oral history is defined by the Oral History Association as "a method of gathering and preserving historical information through recorded interviews with participants in past events and ways of life." In general, oral history interviews are conducted with specific individuals with expertise in certain areas, rather than anonymous individuals selected at random. These individuals most often respond to open-ended questions, rather than a standard survey. In general, oral history interviews are not designed to contribute to "generalizable knowledge" and are therefore outside the jurisdiction of the IRB.
- Program evaluations for internal purposes
- Teacher and student evaluations
- Texas Tech employee performance evaluations

Examples of activities that fall outside the jurisdiction of the IRB because they do not involve interaction or intervention with human subjects and the data do not constitute identifiable private information include, but are not limited to:

- Studies using aggregated archival data that is de-identified
- Studies using people to obtain information that does not involve human subjects (e.g., "how many widgets did you produce last quarter?" or "how many sick days were taken last year by people who work in your school district?")

Identifiable Private Information includes information that can be either directly or indirectly linked to specific individuals. An example of information that could be directly linked to a specific individual would be that person's social security number. An example of information that could be indirectly linked to a specific individual would be coded information, if a key to decipher the code exists.

However, when the investigator(s) cannot readily ascertain the identity of the individual(s) to whom the coded private information pertains, this constitutes non-identifiable information. Examples of non-identifiable information include:

- Identifiable information that is coded (name or social security number could be replaced with a number, letter, symbol, or combination thereof), AND the key to decipher the code is destroyed before the research begins.

- Coded information in a situation in which the investigator(s) and the holder of the key enter into an agreement prohibiting the release of the key to the investigator(s) under any circumstance.

Activities that fall outside the purview of the IRB may still involve some of the same ethical issues that confront researchers (e.g., confidentiality). Such issues ought to be considered from the perspective of ethics for teachers, practitioners, clinicians, or other professions or groups whose ethical guidelines or legal authority are relevant to the activity.

3.1 Proposal Processing and Assignments

When a proposal is received, the HRPP Office may review or prescreen proposals in the Exempt category and may prescreen proposals in the Expedited or Full Board categories. Next, a primary reviewer is assigned from among the IRB members to review the proposal. The IRB reviewer has 10 working days to complete the review. Typically, questions, comments, and notations of concern are communicated to the PI through comments added in the Cayuse IRB system. Reviewers may also email, telephone, or meet with investigators in some situations. TTU IRB faculty reviewers will NOT conduct reviews when faculty are off duty (Winter Break, May and Fall Intersessions).

Principal Investigators will be notified by electronic communication of the action of the IRB. These letters will be maintained in the Cayuse IRB system for review by institutional officials.

Pending proposals with no response or communication will be closed after 90 days. IRBs created in the previous calendar year and not submitted for review will be administratively withdrawn in June of every year.

3.2 Types of Review

If a project constitutes human subjects research according to the definitions above, there are three types of proposals. Investigators should use the descriptions that follow to determine which

category of review is appropriate and check with the HRPP Director, the IRB Chair, or a member of the IRB if questions remain.

3.2.1 Exempt & Limited Category.

Research in the Exempt category includes research that involves minimal risk and fits certain precisely defined categories such as survey research in which responses are anonymous. The principles of *The Belmont Report* must still be observed in research in the exempt category. A limited review is only required if the research involves identifiable information. Limited IRB review requires the IRB to determine that there are adequate provisions for protecting privacy and confidentiality.

3.2.2 Expedited Category.

Expedited proposals involve minimal risk and fit within one of nine precisely defined categories such as research with surveys or interviews.

Research projects involving no more than minimal risk are suited for the expedited category. Projects with children or other vulnerable populations must be approved by two expediting reviewers (45 CFR 46, Subparts B-D). Projects that are not suitable for the exempt category or those that raise other than routine ethical issues will, at the discretion of the reviewer, be referred to the Full Board for review. Communication regarding the review will be contained in Cayuse IRB. The PI and primary contact will receive notification by email when a decision has been made by a reviewer in Cayuse IRB. Investigators will be notified of the final outcome of each review by an electronic letter of approval, a copy of which will be contained in the Cayuse IRB system. Expedited proposal review categories are in List of Expedited Categories (1998).

3.2.3 Full Board Proposals

Research projects involving human subjects that do not qualify for either exempt or expedited categories of review must be reviewed and approved by the full IRB at a convened meeting. The IRB meets on the first Tuesday of the month. A Full Board proposal must be submitted at least three weeks before the scheduled meeting. Investigators are urged to submit earlier in order to allow for the possibility of revisions in the proposal before the meeting of the board.

After a full discussion of a full board proposal, the IRB may take one of the following actions by majority vote:

> **Approve:** The IRB can approve the project as submitted without any changes for no more than 12 months. Projects that involve significant risks can be approved for less than 12 months at the discretion of the IRB. The decision to require a period of approval of less than 12 months is determined in the course of discussion of the proposal and is part of the motion to approve the project. Any specific findings required by 45 CFR 46 such as those needed for approval of research with prisoners (45 CFR 46.305-306), or for waivers of signed consent (45 CFR 46.117) should be documented in the minutes. Motions to approve a proposal may

include a finding that the research involves no more than minimal risk, thus making the project potentially eligible for expedited continuing review.

Minor Revisions Required: The IRB may approve a project contingent upon specific, minor modifications by the Principal Investigator. When the revised proposal with the changes incorporated is received in Cayuse IRB, it will be routed to the chair or a member designated in the minutes (usually the primary reviewer) who will compare the modifications received with the actions requested by the IRB. If the modifications are in compliance with the IRB directives, the chair or the primary reviewer will approve the project for the period of time specified by the IRB. Note: although the approval is not effective and the project may not go forward until the modifications are approved, the period of approval is a maximum of 12 months from the date of the convened meeting.

Defer Pending Resubmission: If the IRB deems that the proposal requires substantial revisions, or if unanswered questions remain, the IRB will require the investigator to resubmit the proposal and attachments with all the changes required and all the questions resolved. A revised version of the proposal with the incorporated changes will be reconsidered at the next board meeting following resubmission.

Disapprove: The IRB may disapprove a research project if it has determined that the human subjects are at a greater risk than the benefits to be accrued. This action is taken only after all negotiations with the investigator have failed to result in a resolution of the pertinent ethical issues. Notification will include the reasons for the disapproval. Upon disapproval, the Principal Investigator can submit a revised proposal to the IRB. Federal regulations specify that the administration of the university cannot approve a project which the IRB has disapproved.

3.3 Review Criteria

Letter and spirit both matter. The IRB cannot approve a proposal that is not consistent with the criteria set forth in 45 CFR 46 or the interpretations of 45 CFR 46 issued by OHRP (see Guidance Documents at http://www.hhs.gov/ohrp/policy/). At the same time, every project is reviewed with consideration of the more general ethical principles of respect for persons, beneficence, and justice described in *The Belmont Report*. The integrity and goodwill of investigators is assumed, but the IRB is required not only to ensure the protection of human subjects but also to document that their rights and welfare have been protected. In reviewing proposals, the IRB must determine that each one satisfies the following standards:

Risks to subjects. Risks to subjects are minimized by the use of procedures that are consistent with sound research and that do not unnecessarily expose the subjects to physical, psychological, social, economic, or other risks. In the case of research involving diagnosis or treatment, risk is minimized by the use of procedures already in use for diagnostic and treatment purposes whenever appropriate.

Risks vs. benefits. Risks to the subject are reasonable in relation to anticipated benefits, if any, to subjects, and to the importance of the knowledge that may reasonably be expected to

result. In order to assess the importance of the knowledge resulting from the research, the IRB must be satisfied with the soundness of the rationale and the research design. The board's concern about the scientific validity of research is in direct proportion to the risk involved. In evaluating risks and benefits, the IRB considers only those risks and benefits that may result from the research (as distinguished from the risks and benefits of therapies or services that subjects would receive even if they did not participate in the research). The IRB does not consider the long-range effects of applying the knowledge gained in the research as among those research risks or benefits that fall within its responsibility. When students are offered course credit for participation, there must be non-research alternatives for earning the same credit for similar time and effort.

Subject selection. The selection of subjects must be equitable. In making this assessment, the IRB takes into account the purposes of the research, the setting in which the research will be conducted, and the population from which the subjects will be recruited.

Other considerations. The IRB may also consider the acceptability of the research project in terms of other applicable standards of professional conduct and special vulnerabilities of the subjects.

3.4 Appeals of IRB Decisions

In virtually all instances, investigators work with the IRB to reach agreement on the best ways to meet human subjects' requirements while conducting research. In cases where the investigator and committee reach an impasse, a decision by the IRB to disapprove a project is final. Federal regulations prohibit the university from approving a project which the IRB has disapproved.

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Section 4: Background for Preparing Proposals

4.0 General

The Principal Investigator submits the human subjects research proposal in Cayuse IRB and is responsible for the proposal and for the design, conduct, and reporting of the research. Only full-time TTU faculty or a full-time employee with the terminal degree in their discipline (Ph.D., Ed.D., J.D., or M.D.) may be the Principal Investigator on proposals (OP 74.09). Proposals for research by students, other personnel, or people from outside of Texas Tech University must be submitted with a Texas Tech University eligible Principal Investigator (PI). All other investigators (students, other personnel, or people from outside of TTU) must be listed as Co-Investigators.

Investigators should be aware that consent may be required on legal, ethical, or practical grounds that do not involve the protection of research subjects.

IRB proposals may be considered public information in accordance with the Texas open records statute.

Proposals should be submitted to the IRB through the Cayuse IRB system.

4.1 IRB Approval from TTUHSC and Other Institutions

Projects that involve human subjects research at both Texas Tech University and another institution need to be reviewed and approved by the other institution's IRB as well as the TTU IRB. For projects where another institution is the primary institution, that institution's complete IRB proposal and approval letter should be submitted in the Cayuse IRB system. It is possible that an Institutional Authorization Agreement can be created that allows TTU IRB to rely on the other institution.

Research being conducted jointly by faculty at Texas Tech University and the Texas Tech University Health Sciences Center (TTUHSC) campuses may be reviewed by a single IRB. The Memorandum of Understanding between TTU and TTUHSC outlines who will be the IRB of Record. If the most appropriate assignment of an application is in doubt, the administrators and chairs of the two IRBs should reach a consensus on which IRB is most appropriate. The Memorandum of Understanding between TTU and TTUHSC

4.2 Proposals Involving External Funding

When research involving external funding involves work with human subjects, funding from federal and some private sources cannot be expended until an IRB proposal has been approved (see 45 CFR 46.122). The Office for Human Research Protections has noted (May 31, 2000) that some agencies require IRB review before a project can be funded. Regulations require that the IRB review the grant application or proposal to be certain that the grant and IRB proposals are in agreement. The IRB must have a complete copy of the grant proposal for this purpose and for records.

Occasionally a project already approved by the IRB is submitted for external funding. In such a case, the Office of Research Services requires verification from the IRB that the proposed research protocol is the same as the one previously approved by the IRB. The investigator should submit the grant proposal to the IRB in the form of a modification to the original IRB proposal. The grant proposal and the approved IRB proposal will be forwarded to an expediting reviewer who will verify that the two protocols match.

4.3 Payment to Research Subjects

The TTU O.P. 62.25 concerns Payment to Research Participants. This area is complex and goes beyond the work of the IRB.

4.4 Recruitment of Subjects by Subjects

Referral fees paid to research participants to recruit other research participants introduces possibilities of coercion in recruitment. The TTU IRB will not approve these recruitment procedures.

4.5 Risk

Minimal risk "means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests" (45 CFR 46.102).

The definition of "risk" is determined by assessing the probability of harm and the magnitude of harm. Consideration is given to both aspects of potential harm. In some cases, (perhaps research in physical exercise) one of the possible risks could be death. However, this would be an extremely rare occurrence which is likely to never occur. Thus, the probability of harm would be exceptionally low. Therefore, although the potential magnitude of harm could be high, the probability of that occurring is so low that the research does not necessarily need to be considered high risk.

4.6 Electronic Data Policy

The Electronic Data Policy Statement

4.7 Subject Pools

Departments that have written procedures for organizing pools of research subjects must submit the procedures for IRB approval. The procedures should describe the methods for recruiting and compensating subjects. If credit toward meeting a course requirement is offered to students in the pool, the nature of that credit should be specified. Non-research alternatives for earning the same credit with similar time and effort must be available and should be described. If the subject pool procedures are approved by the IRB, the details of subject recruitment and compensation need not be reported in detail in projects proposing to use the subject pool. It is sufficient to refer to

the procedures on file with the IRB. The IRB reviews existing procedures once each year and considers new procedures and modifications as they are submitted.

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Section 5: Preparing and Submitting Proposals

5.0 About Proposals

Every proposal should be submitted in the Cayuse IRB system with all applicable and required fields completed. A description of the required elements of consent, discussed below, can be found on the HRPP website. A Reviewer Checklist used to assess the inclusion of all required materials is found in Appendix A.

Expedited and Full Board IRB proposal must include copies of all materials involved in recruiting subjects. Examples of recruiting materials, consent forms, and assent forms can be found on the HRPP website. The IRB proposal must also include copies of all questionnaires, tests, interview materials, etc., that subjects will be asked to complete.

Expedited or Full Board proposals

Particular attention should be directed toward the rationale for, and the details of, research procedures that involve more than minimal risk, including the risk of the disclosure of private information that might be harmful to the subject. If these sections of the proposal do not allow the IRB to judge whether risks have been minimized and are reasonable in proportion to benefits, the investigator will be asked for additional information. Where risks are negligible or minimal, particularly when the project falls into one of the categories suitable for exempt review, a brief description of the rationale and procedures may be all that is necessary. Submission of unnecessary, lengthy material, such as an extended literature review or method sections of a dissertation proposal, *will serve only to slow down* the processing of a proposal. As detailed in the next section, all expedited or full review proposals must include a copy of a consent form or a request to waive the requirement for a consent form.

Investigators should submit their IRB proposals via Cayuse IRB system. The HRPP staff prescreens all proposals for completeness. As part of the initial screening process, the HRPP staff may ask the Principal Investigator to revise the proposal to make it suitable for review. The HRPP Staff will send exempt and expedited reviews to a reviewer. Ten working days should normally be allowed for processing. Proposals involving children or other vulnerable populations must be reviewed by two reviewers, which causes the review process to take longer. Full Board proposals must be received at least three weeks before the Full Board meeting. Full Board meetings are on the first Tuesday of each month at 3:00 pm.

Data collection may begin as soon as the human subjects research proposal has received approval from the IRB Reviewer or the Full Board. Any proposed modifications or renewals of the project must be approved prior to their implementation. This action can be completed through Cayuse IRB by submitting a modification and/or renewal.

5.1 Recruiting Materials

Recruiting materials must be described and, where relevant, included in the proposal. Examples of recruiting materials are found on the HRPP website.

5.2 Informed Consent

Note: "Consent process" and "consent form" are two terms that are used frequently in this section. Although these terms are similar, they are not interchangeable. The consent process is the overall process by which the participant is made aware of the purpose, risks, benefits, etc. of the research. The consent process often includes the use of a consent form but is not limited to that alone. The consent process also may include a dialogue between the investigator and the subjects to ensure that the subject is able to give informed consent. The consent form is the written document that the participant signs indicating consent. All participants should receive a copy of the consent form.

Human subjects research proposals submitted for research in the exempt category do not require a consent form. However, pertinent information materials such as oral scripts, project summary sheets/an information sheet, etc. are required to provide adequate information to the participant to form a decision to participate.

Documentation of informed consent is the most problematic issue in the review of proposals for human subjects research. The required modification of consent forms is the most frequent reason that proposals submitted for expedited or full review are deferred. However, because federal regulations (45 CFR 46.117) and applicable ethical principles from *The Belmont Report* are reasonably clear about the essential elements required in the consent process, delays in processing many proposals can be avoided by carefully following the guidelines in this section.

Readability is important. The content of the consent form is irrelevant if subjects cannot understand it fully. Therefore, the IRB cannot approve a consent form, even if it contains all the required information, if it will not be fully understood by the individuals expected to read it. Technical material and the purpose of the study must be explained in lay terms. Procedures should be explained from the point of view of what will happen to the subject during the study. The consent form should be written in the second person ("You will…"). A general rule of thumb used by federal regulators is that consent forms aimed at the normal adult should be written at a 7th grade reading level. Research projects involving children require parental consent and generally require assent from the children. The assent form must be written in language understandable to the age level or comprehension level of the child. The assent form allows the child a choice of whether to participate, even though the parent has given permission. Both the consent form (for parents) and the assent form (for minors) are required.

Help with **readability** and language level wording can be found at:
http://www.plainlanguage.gov/

5.2.1 Written Consent Form

Information about a study that includes the elements of informed consent required by 45 CFR 46.116 may be presented in a written consent form that is signed by the subject or a legally authorized representative. The form may be read to the subject or representative, but in any event, the investigator should give either the subject or representative adequate opportunity to read the form before it is signed. When consent is obtained with a full, written consent form that

is understood and signed by a competent subject, no witness is required, and the consent form should not contain a space for the signature of a witness or researcher. A copy of the consent form should be given to each participant. The signed consent form should be stored by the researcher for three years after the research is complete. Sponsored project guidelines must be followed on record retention.

5.2.2 Elements of Consent

The HRPP website has a list of the Required Elements of Consent. There are optional elements that must be included in the consent form if they are applicable to the study.

5.2.3 Multiple Form Written Consent – Part I, Part II and Part III

Information about a study may be presented in a short form written consent document that states that the elements of informed consent required by 45 CFR 46.116 have been presented orally to the subject or a legally authorized representative (e.g., Dr. Researcher told me the purpose of the study; Dr. Researcher told me what the risks of this study are). The short form is most useful when a study is complex, and the investigator can't be sure that a signed written consent is well enough understood to indicate a valid consent process. The short form allows the individual obtaining consent to talk with the subject to make sure the subject understands what will be involved.

In this case, the following consent process should be followed:

(a) The IRB must approve a written summary of the oral presentation
(b) For the short form consent, there must be a witness to the oral presentation, and the witness must sign both the short form consent form and the written summary
(c) The person making the oral presentation must also sign the written summary
(d) The subject or a legal representative must sign the short form consent form and be given a copy of both the short form and the summary

5.2.4 Internet Research Consent

Researchers should provide necessary information to potential subjects to assist in the decision-making process to participate. This could be done electronically by having an email recruitment letter which provides all the required information before the participant begins and/or a short information paragraph or page before the survey

In internet research, the consent process must still be followed.

5.2.5 Waiver or Alteration of the Elements of Consent

Sometimes an element of consent can be waived. For example, some research involving deception cannot be done with full disclosure in advance. An element of consent might be waived and not disclosed until the subject's participation is complete. Here are two regulations that concern the form.

(1) The research involves no more than minimal risk to the subjects; the waiver or alteration will not adversely affect the rights and welfare of subjects; the research could not be practicably be carried out without the waiver or alteration; If the research involves using identifiable private information or identifiable biospecimens, the research could not practicably be carried out without using such information or biospecimens in an identifiable format. and whenever appropriate, the subjects will be provided with additional pertinent information after participation.
(2) The research involves the evaluation of public benefit or service programs as specified in 45 CFR 46.116(e).

In section 9.2 the investigators should select the appropriate boxes that describe the justification of the request for the waiver or alteration.

5.2.6 Waiver of Written Consent Form

Sometimes the IRB can waive the requirement for a signed consent form.

(1) 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.

(2) 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.

(3) If the participants or legally authorized representatives are members of a distinct cultural group or community in which signing forms are not the norm, that the research presents no more than minimal risk of harm to subjects and provided there is an appropriate alternative mechanism for documenting that informed consent was obtained.

In section 9.2 the investigators should select the appropriate boxes that describe the justification of the request for the waiver or alteration. In the Risks and Benefits section (12.2) of the Cayuse IRB proposal**,** when a research study involves no risks beyond those of everyday life or routine physical or psychological tests, the investigators should simply say: "Since there are no risks beyond those of everyday life."

5.3 Continuing Review, Annual Progress Reports, and Termination of Projects

Texas Tech University's assurance of compliance with the federal government requires at least annual review by the IRB of all expedited approved proposals prior to January 21, 2019, and full board proposals involving human subjects research. As part of continuing review, the IRB has regulatory authority to observe, or have observed, the consent process and the research itself and to audit records such as consent forms at any time. When the approval for a project nears expiration, the investigator should complete the Renewal submission in Cayuse IRB. The procedures below apply depending on the level of initial review.

Exempt, Limited, and Expedited research. Exempt research is not subject to continuing review. Any modifications that (a) change the research in a substantial way, (b) might change the basis for exemption, or (c) might introduce any additional risk to subjects should be reported to the IRB for review before they are implemented.

Timing of review. When a proposal is approved or renewed by either expedited or full review, approval normally extends to the last day of the month preceding the anniversary of the approval. The anniversary is determined by the date of final approval (initial or continuing) by an expediting reviewer or the date of the convened full IRB meeting at which approval (including contingent approval) occurs, not the date of final approval of required changes. When continuing review is required for a period of less than a year, the expiration date is determined in a similar manner.

Approximately 30 days prior to the expiration of the approval, the HRPP staff will send an email through the Cayuse system to the Principal Investigator noting the date of expiration and the need to complete a renewal submission. The Renewal requires a report on the status of the project, descriptions of all adverse events affecting the rights or welfare of human subjects, and any changes contemplated in the research protocol and/or informed consent/assent forms. A complete clean proposal may be required every three years if the initial proposal has been amended within the three years.

Expedited continuing review/renewal. (Expedited Proposals approved prior to January 21, 2019) Projects initially approved by expedited review will normally undergo expedited continuing review/renewal unless changes to the research are contemplated that might move it out of the expedited category. Because 10 working days should be allowed for processing a proposal and due to the volume of expedited reviews, prompt completion of the Renewal submission is important to ensure that the approval of a project does not lapse. Expediting reviewers will be assigned the renewal and will have access to the original proposal including the current consent form, any subsequent modifications, and access to the complete file on each project. Criteria are the same as for initial review but continuing expedited review of research involving children requires review by only one expediting reviewer. At the discretion of the reviewer, independent verification that no material changes have occurred since the previous IRB review may be required.

Full Board continuing review/renewal. Projects initially approved by the Full Board will normally not undergo Full Board continuing review unless the progress report identifies additional risks. Prompt completion of the Renewal in Cayuse IRB is important to ensure that the approval of a project does not lapse.

For continuing review/renewal conducted by the Full Board, a primary reviewer will be designated. When deemed appropriate, protocols requesting Full Board review are distributed to all IRB members and include the renewal, current consent forms, prior modifications, and the original proposal. The primary reviewer will be provided with the renewal, the original proposal, any subsequent modifications, and access to the complete file on each project. Criteria are the same as for initial review. At its discretion, the board may require independent verification that no material changes have occurred since the previous IRB review.

Termination. All Principal Investigators must maintain an active IRB-approved protocol until the project is complete. Once data has been rendered non-identifiable, they no longer constitute identifiable private information and further data analysis does not require continuing approval.

If the HRPP does not receive the request for renewal by the due date noted on the form, IRB approval automatically expires, and a letter of termination is sent to the Principal Investigator. By not completing the renewal or otherwise notifying the IRB that the project has been terminated, the investigator certifies that during the preceding period of approval there were no changes to the protocol or consent form and no adverse events. Projects that continue without IRB approval or projects initiated without IRB approval are out of compliance with federal regulations and with Texas Tech University policy. In such cases a report of non-compliance will be filed with the Vice President for Research & Innovation for further action. The university is required to inform OHRP of any serious or continuing non-compliance.

5.4 Reporting Adverse Events or Noncompliance

If a project is not being conducted in accordance with a protocol approved by the IRB, if there is harm to a subject, or there is any other failure to conform to the requirements of 45 CFR 46 and/or these policies and procedures, the Principal Investigator is required to report the details of these deviations *immediately* to the HRPP office. The investigators will create an incident submission in Cayuse IRB. The HRPP office will send the incident submission to the Chair and Associate Chair for Review. The Chair may ask the IRB to consider the matter. The IRB or IRB Chair has the authority in such cases to suspend or terminate the research and/or to report them to the Vice President for Research & Innovation. Reports to the Vice President for Research & Innovation will be made as soon as possible. In the case of serious adverse events or deviations from an approved protocol, Texas Tech University is required by its assurance of compliance with the federal government to report such incidents to the federal Office for Human Research Protections. In addition, the university may need to report the events to research sponsors. Thus, the reporting requirement for investigators is an extremely serious one.

Incident reports will be reviewed and investigated by HRPP staff prior to assignment to the TTU IRB Chair. If the incident report results in a study modification, the primary reviewer assigned to the modification will be notified of the associated incident report. The IRB members will be made aware of all incidents at the monthly Full Board meeting. All necessary documentation as well as notes and letters from the incident report will be stored within the Cayuse system.

5.5 Modifications to Approved Protocols

Changes to currently approved projects require approval by the IRB. Such modifications may include, but are not limited to, changes which affect the participation of human subjects, changes to informed consent forms and/or assent forms, additional sites for conducting the research, changes in Principal Investigators or key personnel, and the discovery of unanticipated risks to subjects. Substantive changes to projects must not be implemented until approval has been granted. If a project is not being conducted in accordance with the protocol approved by the IRB, the IRB has the authority to suspend or terminate its approval of the research.

The process for reviewing changes is the same as for initial review. Modifications must be submitted through the Cayuse IRB system.

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Section 6: Post Approval Monitoring

6.0 Post Approval Monitoring Overview

Post-Approval Monitoring (PAM) is the process by which active research protocols are reviewed to ensure adherence to applicable regulatory requirements and to confirm that research activities are being conducted in accordance with the protocol approved by the Texas Tech University's Institutional Review Board (TTU IRB). These assessments are designed to be collaborative and improvement-focused engagements where researchers and Human Research Protection Program (HRPP) staff work jointly to ensure compliance with all applicable regulations and to safeguard the rights and welfare of human research participants. Research that falls under the purview of the TTU IRB is subject to post approval monitoring in accordance with 45 CFR 46.109(g).

6.1 Procedure

All active or published research studies, including those determined to qualify for exempt status, are subject to PAM. There are three types of PAMs: random, for cause, and principal investigator initiated.

PAMs considered "random" are those that have been selected through a random process and not due to any specific requests that the research be investigated. These PAMs are considered routine and do not signify that any wrongdoing is suspected.

Reviews classified as "for-cause" are initiated by the Institutional Review Board (IRB), TTU leadership, HRPP office, sponsor/funding agency, fellow researchers, community members, and/or participants. For-cause reviews may be prompted by concerns related to potential non-compliance, participant safety, or other reportable events.

PAMs that are requested by the principal investigator (PI) are used to confirm that the protocol is being followed in their own research. This can be specific to a part of the protocol like consent/assent or recruitment but can extend to the entire protocol if requested by the PI.

Routine, for-cause, and principal investigator-initiated PAMs may involve a combination of the following methods: self-assessment, on-site evaluation, and direct observation of selected research procedures. Receipt of a PAM selection notice does not imply suspicion or evidence of non-compliance or misconduct.

Upon receipt of a PAM request, a member of the research team is required to respond within 10 business days. This request will be made through emails, phone calls, or meeting requests. Failure to provide a timely response may result in suspension of the study's IRB approval.

6.1.1 Self-Assessment

The most common self-assessment method of PAM is conducted through the Cayuse system. The PI, or a designated member of the research team, is responsible for completing the self-

assessment within 10 business days of receipt. The purpose of the self-assessment portion of the PAM is to share information regarding the research.

This process provides an opportunity for the research team to communicate updates on study progress, identify any concerns, and disclose anticipated/unanticipated changes to the protocol. The self-assessment is intended to serve as a mechanism for collaboration and mutual benefit between the researcher(s) and HRPP staff.

6.1.2 On-Site Assessment

On site assessments are the process by which an HRPP staff member and/or IRB member visits the site where the research is being conducted to verify the protocol is being followed. This can include the observation, verification, and documentation of, but is not limited to:

- Research Team/Training
- Human Subjects
- Recruitment
- Consent/Assent
- Data Collection
- Data/Consent Storage
- Compensation
- Funding
- Publications
- Incidents/Adverse Events
- Permissions

The process of the on-site assessment will vary depending on the type of data collection methods in use. Most on-site visits will be scheduled beforehand, but in some instances where imminent harm to participants is a concern, an unscheduled PAM visit will be conducted.

6.2 Results of the PAM Process

After the completion of PAM, the results report will be available within 10 business days. Depending on the findings, the next steps will be communicated to the research team within the report.

- No Issues - In the case that there were no issues found, the researcher(s) will be informed of this finding. This is also an opportunity for the researcher(s) to ask any questions regarding the process, next steps, or any other questions the research team may have overall.

- Recommendations for Best Practices - While no official protocol violation may be present, HRPP staff may provide additional recommendations to improve on any issues communicated during the PAM. The goal of this is to promote collaboration and share ideas and solutions to common issues that arise in research.

- Corrective Action Plan - If any significant findings are revealed or HRPP staff find there is a need for the submission of a modification or an incident report, the PI will be informed of the findings. The modification or incident report must be filed within 10 business days of the communication of the findings. The HRPP staff member may share additional education resources intended to mitigate issues for the researchers in their current and all future studies. The findings of the PAM may require a report to be filed with TTU's institutional official, OHRP, and/or sponsor/funding agency.

6.3 PAM Data Storage

The storage of data regarding PAM reviews is the responsibility of the office of Human Research Protection Program. Self-assessments and findings will be stored within the Cayuse system. All other materials collected during an on-site PAM visit will be digitized and stored within the TTU OneDrive.

6.4 Failure to Respond

Failure to respond to PAM requests within the specified period constitutes noncompliance with federal regulations and with Texas Tech University policy. In such cases a report of non-compliance will be filed with the TTU institutional official for human subject research for further action.

6.5 Appeal Process

In most instances, HRPP staff/IRB members will work with researchers to reach a favorable outcome for the research. If the PI or research team objects to the findings of the PAM, the research team may appeal the decision in writing within 15 business days of the PAM being finalized and sent to the research team. The appeal should be sent to the IRB Chair, who will review the PAM findings and respond to the appeal within 30 business days.

6.6 PAM Resources

Elements of a PAM Visit:

Before the PAM visit – An HRPP staff member schedule the on-site PAM visit with the PI and research team based on availability. Prior to the scheduled visit, an HRPP staff member will have reviewed all IRB approved documentation. Note that there may be more than one HRPP staff/IRB member who participate in the PAM visit. In this instance, a lead investigator will be designated.

During the PAM visit – The HRPP staff member will compare the procedures being conducted with those listed in the most recently approved protocol. Any discrepancies will be documented and brought to the attention of the PI. If the discrepancies are something that can be easily remedied, the HRPP staff member will make those suggestions and work with the PI and/or research team to achieve the most favorable outcome for the research during the visit.

After the PAM visit – After the visit has concluded, the HRPP staff member will complete a report and send the findings to the research team withing 10 business days.

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Section 7: Procedures for Research with Vulnerable Populations

7.0 Procedures for Research with Vulnerable Populations

The IRB has a special obligation to protect the rights and welfare of subjects who are particularly vulnerable including all those who cannot give informed and legal consent themselves. Three classes of subjects, (a) Pregnant Women, Human Fetuses and Neonates Involved in Research; (b) prisoners, and (c) children are singled out in federal regulations for additional protective measures.

7.1 Inclusion of Fetuses, Pregnant Women, and Human In Vitro Fertilization

Any research activity that may involve more than minimal risk to a fetus is covered by 45 CFR 46 Subpart B. This includes research that may pose minimal or low risk for subjects themselves, but might present risks if subjects were pregnant or become pregnant during the course of the study. In such cases, screening for pregnancy and exclusion of pregnant subjects is advised. Researchers who are doing research that is directed toward fetuses, pregnant women, or in vitro fertilization should be familiar with the requirements of 45 CFR 46 Subpart B.

7.2 Inclusion of Children in Research

All research with children receives special scrutiny. Children are defined (45 CFR 46.402) as "persons who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted." In Texas, the legal age for consent is 18. All research for which consent is required must also, where possible, obtain the assent of the child subject. Most often, assent is obtained with the use of a child "assent form" which is a version of the consent form in language appropriate for the child's ability to understand the elements of consent. Expedited proposals with children as subjects (except those enrolled as regular students at Texas Tech University) will be reviewed by *two* reviewers which may result in a somewhat longer time to process the proposal.

7.3 Inclusion of Prisoners in Research

Any research activity that involves prisoners as subjects must undergo Full Board review subject to 45 CFR 46 Subpart C.

The regulations require the IRB to provide additional safeguards because incarceration per se could affect the ability of prisoners to make truly voluntary and un-coerced decisions about whether to participate in research. It is required that at least one member of the IRB be a prisoner or prisoner representative in order to approve prisoner research. The Texas Tech University IRB has one member who serves on the board at meetings to represent interest in prisoner research. In order to approve research on prisoners, the board must make specific findings about the research.

7.4 Inclusion of People with Impaired Decision-Making Capacity

Under some circumstances it is possible to conduct research with subjects who may not be competent to fully consent to research. In such cases, the consent must be signed by a legally authorized representative, if there is one, and generally an assent must be agreed to by the subject. When no legally authorized representative exists and the competence of the subject might be in doubt, the subject's signature on a consent form should be validated by someone believed to be able to speak on behalf of the subject. That person (a) should be a close relative or family member or a friend of long standing, if possible, and (b) must also sign a declaration stating that s/he knows the subject well enough to be able to express the subject's wishes.

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Section 8: Clinical Trial Registration

8.0 Clinical Trial Registration

Researchers of any clinical trial must register the study on a publicly accessible trial registration site (i.e. ClinicalTrials.gov) prior to enrolling the first subject. ClinicalTrials.gov is a directory of federally and privately supported research trials designed to test the effect of experimental drugs, devices and procedures for many diseases and conditions.

The FDA mandates the registration of clinical trials prior to enrollment of the first participant. Other entities, including NIH, have similar requirements for registration of applicable clinical trials. Visit the funding agency's policy regarding clinical trial registration and dissemination. The dissemination plan is included in your grant proposal. Researchers will be required to comply with all terms and conditions of award, including following their plan for the dissemination of clinical trial information. If an IRB-approved study is a clinical trial that has not been registered, it is the Principal Investigator's responsibility to register the trial. The Protocol Registration and Results System provides specific information regarding how to register a new trial. The HRPP Director serves as the TTU administrator for registration at ClinicalTrials.gov and should be contacted for account set-up.

In addition, FDA regulations (21 CFR 50.25c) requires the following statement in informed consent documents for all clinical trials overseen by the agency: "A description of this clinical trial will be available on http://www.ClinicalTrials.gov as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time."

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Appendix A

TTU IRB Initial Submission
Reviewer Checklist

PROTOCOL INFORMATION: STUDY DETAILS	YES	NO	N/A
The study title is consistent throughout the submission and on attachment documents where applicable (protocol, consent, assent, information sheet, etc.).			
SUMMARY & PURPOSE	**YES**	**NO**	**N/A**
The information is concise, in lay terms and is consistent with the protocol and consent documents.			
EXPEDITED SUBMISSIONS	**YES**	**NO**	**N/A**
Does this study meet the definition of human subject research?			
The research meets regulatory requirements for an expedited submission:			
No more than minimal risk:			
Involves one or more of the expedited categories:			
The appropriate Expedited Category or Categories are selected:			
PARTICIPANT POPULATION	**YES**	**NO**	**N/A**
Based on review of the protocol all applicable populations have been selected.			
Research Participation is based on gender and/or race/ethnicity with appropriate scientific justification.			
VULNERABLE POPULATIONS INCLUDED:			
Children:			
Prisoners:			
Individuals with Impaired Decision-Making Skills:			
Other:___			

COERCION OR UNDUE INFLUENCE:	**YES**	**NO**	**N/A**
Is there potential for coercion or undue influence of potential participants?			
If yes, has the research team mitigated the coercion and undue influence?			
RECRUITMENT PROCESS https://www.depts.ttu.edu/research/irb/Recruitment.php	**YES**	**NO**	**N/A**
Recruitment procedures are clearly defined.			
Recruitment material is included (i.e., flyers, notices, advertisements, verbatim scripts, etc.):			
CONSENT PROCEDURES https://www.depts.ttu.edu/research/irb/ConsentProcess.php	**YES**	**NO**	**N/A**
Is the consent process clearly defined?			
Are the individuals listed as obtaining consent also included under the Research Team?			
Is the appropriate type of consent/information sheet selected and included with the submission?			
Uses TTU Template(s):			
ASSENT PROCEDURES https://www.depts.ttu.edu/research/irb/assentminors.php	**YES**	**NO**	**N/A**
Is the assent process clearly defined?			
Are the individuals listed as obtaining assent also included under the Research Team?			
Is the appropriate type of assent selected and included with the submission?			
Uses TTU Template(s):			

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COERCION OR UNDUE INFLUENCE:	**YES**	**NO**	**N/A**
Is there potential for coercion or undue influence of potential participants?			
If yes, has the research team mitigated the coercion and undue influence?			
RECRUITMENT PROCESS https://www.depts.ttu.edu/research/irb/Recruitment.php	**YES**	**NO**	**N/A**
Recruitment procedures are clearly defined.			
Recruitment material is included (i.e., flyers, notices, advertisements, verbatim scripts, etc.):			
CONSENT PROCEDURES https://www.depts.ttu.edu/research/irb/ConsentProcess.php	**YES**	**NO**	**N/A**
Is the consent process clearly defined?			
Are the individuals listed as obtaining consent also included under the Research Team?			
Is the appropriate type of consent/information sheet selected and included with the submission?			
ASSENT PROCEDURES https://www.depts.ttu.edu/research/irb/assentminors.php	**YES**	**NO**	**N/A**
Is the assent process clearly defined?			
Are the individuals listed as obtaining assent also included under the Research Team?			
Is the appropriate type of assent selected and included with the submission?			

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MANDATORY REPORTING	YES	NO	N/A
College students or TTU employees are asked about sexual misconduct, discrimination, harassment, or violence. https://www.depts.ttu.edu/research/irb/CandR.php			
Appropriate text has been added to the consent form.			
Appropriate information has been added to the debriefing.			
Abuse and Neglect of a Child, Elderly Individual or Adults with Disabilities https://www.depts.ttu.edu/research/irb/AbuseandNeglect.php			
Appropriate text has been added to the consent form.			
Appropriate information has been added to the debriefing.			
Mental Health, Self-Harm, Criminal Behavior, & Substance Abuse https://www.depts.ttu.edu/research/irb/abuse.php			
Appropriate text has been added to the consent form.			
Appropriate information has been added to the debriefing.			
WAIVER OR ALTERATION OF CONSENT https://www.depts.ttu.edu/research/irb/waivers.php	**YES**	**NO**	**N/A**
Waivers Of Written Consent (use of an information sheet-no signed consent document, ex: online survey)			
If there is an alternative to written consent requested, is the justification stated and appropriate?			
Waiver of Consent (no consent is obtained from the participant or parent)			
Alteration of informed consent or elements of consent (ex: deception)			
If a waiver or alteration of consent is requested (e.g., secondary data, database, chart review), has the PI provided protocol specific justification and have all the regulatory criteria been met?			

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PARTICIPANT COMPENSATION	YES	NO	N/A
Participant Compensation meets IRB policy guidelines.			
Details of compensation are noted in the consent form.			
A description of the incentive/compensation:			
Any restrictions or requirements for participant compensation:			
If it is a drawing the odds of winning:			
The time frame of when the participant will receive the incentive/compensation:			
DATA COLLECTION PROCEDURES	**YES**	**NO**	**N/A**
Research procedures are described appropriately:			
Indicates who will conduct the research activities:			
Frequency of study visits and total duration of study participation (total time commitment) is provided.			
Consistent throughout the proposal and **consent form**.			
If there are data collection instruments, all instruments, surveys and/or educational materials are included in the attachments section and are in easy-to-understand language.			
AUDIO/VIDEO RECORDING	**YES**	**NO**	**N/A**
If audio/video recording this information is listed in consent with a statement regarding when recordings will be destroyed.			
USE OF DECEPTION https://www.depts.ttu.edu/research/irb/deception.php	**YES**	**NO**	**N/A**
When there is a potential for deception is justification provided and the reviewer agrees.			
If yes, the study must meet the criteria for an alteration to informed consent.			
There is an acceptable plan to debrief participants:			

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DEBRIEFING https://www.depts.ttu.edu/research/irb/debriefing.php	**YES**	**NO**	**N/A**
Participants will be debriefed as the conclusion of the research.			
Deception			
Title IX			
Abuse and Neglect			
Mental Health, Self-Harm, Criminal Behavior, & Substance Abuse			
RISKS	**YES**	**NO**	**N/A**
The nature and degree of potential risks to participants (physical, psychological, legal, economics, and social) is stated.			
Risks are minimized by using procedures that are consistent with sound research design and that do not unnecessarily expose participants to risk.			
Are the risks to participants more than minimal?			
Are the risks described accurately and included in the consent/assent forms?			
BENEFITS	**YES**	**NO**	**N/A**
Are the benefits described accurately?			
Are the benefits described also included in the informed consent/assent documents? (Compensation is not considered a benefit.)			
PRIVACY & CONFIDENTIALITY	**YES**	**NO**	**N/A**
Are the measures to maintain confidentiality clearly stated?			
There is an adequate plan for storage and disposal of data (including audio or video recordings).			
There are adequate provisions to protect the personal privacy interests of the participant(s).			

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Required Elements Consent https://www.depts.ttu.edu/research/irb/ConsentProcess.php	**YES**	**NO**	**N/A**
Statement it is research			
Purpose of the research			
Description of the procedures			
Identification of any procedures that are experimental			
Participation is voluntary			
Can stop at any moment and skip questions			
That refusal to participate involves no penalty or loss of benefits to which the participant is otherwise entitled, and that the participant may discontinue participation at any time without penalty or loss of benefits.			
Time of Procedures			
Foreseeable risks or discomforts to the participant			
If there are no such risks or discomforts, the consent form should so state.			
Benefits to the participant			
If there are no such benefits, the consent form should so state.			
Participant Payment			
Not listed as a benefit			
A description of the incentive/compensation:			
Any restrictions or requirements for participant compensation:			
If it is a drawing the odds of winning:			
The time frame of when the participant will receive the incentive/compensation:			
The following statement about participants' rights: "Dr. (Principal Investigator) will answer any questions you have about the study. You can call (phone number) or email (email address). Questions can also be directed to the Human Research Protection Program (HRPP), Office of Research and Innovation, Texas Tech University, Lubbock, Texas 79409, 806-742-2064."			

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TTU IRB Initial Submission
Reviewer Checklist

PROTOCOL INFORMATION: STUDY DETAILS	**YES**	**NO**	**N/A**
The study title is consistent throughout the submission and on attachment documents where applicable (protocol, consent, assent, information sheet, etc.).			
SUMMARY & PURPOSE	**YES**	**NO**	**N/A**
The information is concise, in lay terms and is consistent with the protocol and consent documents.			
EXPEDITED SUBMISSIONS	**YES**	**NO**	**N/A**
Does this study meet the definition of human subject research?			
The research meets regulatory requirements for an expedited submission:			
No more than minimal risk:			
Involves one or more of the expedited categories:			
The appropriate Expedited Category or Categories are selected:			
PARTICIPANT POPULATION	**YES**	**NO**	**N/A**
Based on review of the protocol all applicable populations have been selected.			
Research Participation is based on gender and/or race/ethnicity with appropriate scientific justification.			
VULNERABLE POPULATIONS INCLUDED:			
Children:			
Prisoners:			
Individuals with Impaired Decision-Making Skills:			
Other:			
COERCION OR UNDUE INFLUENCE:	**YES**	**NO**	**N/A**

Is there potential for coercion or undue influence of potential participants?			
If yes, has the research team mitigated the coercion and undue influence?			
RECRUITMENT PROCESS https://www.depts.ttu.edu/research/irb/Recruitment.php	**YES**	**NO**	**N/A**
Recruitment procedures are clearly defined.			
Recruitment material is included (i.e., flyers, notices, advertisements, verbatim scripts, etc.):			
CONSENT PROCEDURES https://www.depts.ttu.edu/research/irb/ConsentProcess.php	**YES**	**NO**	**N/A**
Is the consent process clearly defined?			
Are the individuals listed as obtaining consent also included under the Research Team?			
Is the appropriate type of consent/information sheet selected and included with the submission?			
Uses TTU Template(s):			
ASSENT PROCEDURES https://www.depts.ttu.edu/research/irb/assentminors.php	**YES**	**NO**	**N/A**
Is the assent process clearly defined?			
Are the individuals listed as obtaining assent also included under the Research Team?			
Is the appropriate type of assent selected and included with the submission?			
Uses TTU Template(s):			

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MANDATORY REPORTING	YES	NO	N/A
College students or TTU employees are asked about sexual misconduct, discrimination, harassment, or violence. https://www.depts.ttu.edu/research/irb/CandR.php			
Appropriate text has been added to the consent form.			
Appropriate information has been added to the debriefing.			
Abuse and Neglect of a Child, Elderly Individual or Adults with Disabilities https://www.depts.ttu.edu/research/irb/AbuseandNeglect.php			
Appropriate text has been added to the consent form.			
Appropriate information has been added to the debriefing.			
Mental Health, Self-Harm, Criminal Behavior, & Substance Abuse https://www.depts.ttu.edu/research/irb/abuse.php			
Appropriate text has been added to the consent form.			
Appropriate information has been added to the debriefing.			
WAIVER OR ALTERATION OF CONSENT https://www.depts.ttu.edu/research/irb/waivers.php	**YES**	**NO**	**N/A**
Waivers Of Written Consent (use of an information sheet-no signed consent document, ex: online survey)			
If there is an alternative to written consent requested, is the justification stated and appropriate?			
Waiver of Consent (no consent is obtained from the participant or parent)			
Alteration of informed consent or elements of consent (ex: deception)			
If a waiver or alteration of consent is requested (e.g., secondary data, database, chart review), has the PI provided protocol specific justification and have all the regulatory criteria been met?			

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PARTICIPANT COMPENSATION	YES	NO	N/A
Participant Compensation meets IRB policy guidelines.			
Details of compensation are noted in the consent form.			
A description of the incentive/compensation:			
Any restrictions or requirements for participant compensation:			
If it is a drawing the odds of winning:			
If it is a drawing does not refer to it as a raffle:			
The time frame of when the participant will receive the incentive/compensation:			
TTU Tax information is included:			
DATA COLLECTION PROCEDURES	**YES**	**NO**	**N/A**
Research procedures are described appropriately:			
Indicates who will conduct the research activities:			
Frequency of study visits and total duration of study participation (total time commitment) is provided.			
Consistent throughout the proposal and **consent form**:			
If there are data collection instruments, all instruments are included in the attachments section and are in easy-to-understand language.			
Survey(s):			
Interview Questions:			
Focus Group Questions:			
Observation Rubric:			
Vignettes/Prompts/Tasks:			
Intervention:			
Educational Tests:			
Biospecimens:			
Devices:			
TDCS, ECG, EEG:			

FMRI, DXA, CT Scan:			
1. Are there questions about substance and alcohol use?			
2. Are there questions about sexuality or sexual acts?			
3. Are there questions about mental health?			
4. Are there questions about residency/nationality/immigration status?			
5. Are there questions about self-harm or harm to others?			
6. Are there any attention check questions?			
7. Are there any demographic questions?			
If the answer is yes to any of questions 1-5 this must be disclosed in the consent/assent form.			
AUDIO/VIDEO RECORDING	**YES**	**NO**	**N/A**
Use of audio recordings.			
Use of video recordings.			
Use of photography.			
If audio/video recording this information is listed in consent with a statement regarding when recordings will be destroyed.			
USE OF DECEPTION https://www.depts.ttu.edu/research/irb/deception.php	**YES**	**NO**	**N/A**
When there is a potential for deception is justification provided and the reviewer agrees.			
If yes, the study must meet the criteria for an alteration to informed consent.			
There is an acceptable plan to debrief participants:			

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DEBRIEFING https://www.depts.ttu.edu/research/irb/debriefing.php	**YES**	**NO**	**N/A**
Participants will be debriefed as the conclusion of the research.			
Deception			
Title IX			
Abuse and Neglect			
Mental Health, Self-Harm, Criminal Behavior, & Substance Abuse			
RISKS	**YES**	**NO**	**N/A**
The nature and degree of potential risks to participants (physical, psychological, legal, economics, and social) is stated.			
Risks are minimized by using procedures that are consistent with sound research design and that do not unnecessarily expose participants to risk.			
Are the risks to participants more than minimal?			
Are the risks described accurately and included in the consent/assent forms?			
BENEFITS	**YES**	**NO**	**N/A**
Are the benefits described accurately?			
Are the benefits described also included in the informed consent/assent documents? (Compensation is not considered a benefit.)			
PRIVACY & CONFIDENTIALITY	**YES**	**NO**	**N/A**
Are the measures to maintain confidentiality clearly stated?			
There is an adequate plan for storage and disposal of data (including audio or video recordings).			
There are adequate provisions to protect the personal privacy interests of the participant(s).			

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Required Elements Consent https://www.depts.ttu.edu/research/irb/ConsentProcess.php	**YES**	**NO**	**N/A**
Statement it is research			
Purpose of the research			
Description of the procedures			
Identification of any procedures that are experimental			
Participation is voluntary			
Can stop at any moment and skip questions			
That refusal to participate involves no penalty or loss of benefits to which the participant is otherwise entitled, and that the participant may discontinue participation at any time without penalty or loss of benefits.			
Time of Procedures			
Foreseeable risks or discomforts to the participant			
If there are no such risks or discomforts, the consent form should so state.			
Benefits to the participant			
If there are no such benefits, the consent form should so state.			
Participant Payment			
Not listed as a benefit			
A description of the incentive/compensation:			
Any restrictions or requirements for participant compensation:			
If it is a drawing the odds of winning:			
The time frame of when the participant will receive the incentive/compensation:			
A statement describing the extent to which confidentiality of records identifying the participant will be maintained.			

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One of the following statements must be included in the consent process for limited review, expedited review, or full board review that involves the collection of identifiable private information or identifiable biospecimens:			
A statement that identifiers might be removed from the identifiable private information or identifiable biospecimens and that, after such removal, the information or biospecimens could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from the subject or the legally authorized representative, if this might be a possibility. or A statement that the subject's information or biospecimens collected as part of the research, even if identifiers are removed, will not be used or distributed for future research studies.			
The following statement about participants' rights: “Dr. (Principal Investigator) will answer any questions you have about the study. You can call (phone number) or email (email address). Questions can also be directed to the Human Research Protection Program (HRPP), Office of Research and Innovation, Texas Tech University, Lubbock, Texas 79409, 806-742-2064.”			

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Additional Elements of Consent	YES	NO	N/A
An explanation concerning compensation for research-related injury as follows: "If this research project causes injury (physical, psychological, social, economic, legal, etc.), Texas Tech University or the Student Health Services, may not be able to treat your injury. You will have to pay for treatment from your own insurance. The University does not have insurance to cover such injuries. More information about these matters may be obtained from Dr. Alice Young, Associate Vice President, Research Integrity, Office of the Vice President for Research, (806) 742-3905, 355 Administration Building, Texas Tech University, Lubbock, Texas, 79409." If there is a specific plan for liability, it should be described in place of this statement.			
For research that involves any procedures or treatments that a participant might reasonably construe to be therapeutic: A description of any procedures that are experimental and a disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the participant.			
A statement that the treatment or procedure may involve risks to the participant which are currently unforeseeable.			
Anticipated circumstances under which the participation may be terminated by the investigator without regard to the participant's consent.			
Any additional costs to the participant that may result from participation in the research.			
The consequences of a participant's decision to withdraw from the research and procedures for orderly termination of participation by the participant.			
The approximate number of participants involved in the study			
A statement that significant new findings developed during the research, which may relate to the participant's willingness to continue participation, will be provided to the participant.			
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 research results will be disclosed to subjects.			
For research involving biospecimens, whether the research will or might include whole genome sequencing.			
Full Board: A statement about the expiration date of the project's approval: "This consent form is not valid after (expiration date)." The expiration date is the anniversary of last day of the month preceding the approval. The letter informing the investigator of the approval of a proposal specifies the date of expiration.			

***** If you responded yes to a red line above information needs to be included in the consent/assent form. *****

Required Elements of Broad Consent	YES	NO	N/A
A general description of the types of research that may be conducted with the identifiable private information or identifiable biospecimens. This description must include sufficient information such that a reasonable person would expect that the broad consent would permit the types of research conducted.			
A description of the identifiable private information or identifiable biospecimens that might be used in research, whether sharing of identifiable private information or identifiable biospecimens might occur, and the types of institutions or researchers that might conduct research with the identifiable private information or identifiable biospecimens.			
A description of the period of time that the identifiable private information or identifiable biospecimens may be stored and maintained (which period of time could be indefinite), and a description of the period of time that the identifiable private information or identifiable biospecimens may be used for research purposes (which period of time could be indefinite).			
A statement that they will not be informed of the details of any specific research studies that might be conducted using the subject's identifiable private information or identifiable biospecimens, including the purposes of the research, and that they might have chosen not to consent to some of those specific research studies.			
A statement that such results may not be disclosed to the subject.			
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.			
For research involving biospecimens, whether the research will or might include whole genome sequencing.			

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Appendix B

Institutional Review Board
Conflict of Interest Statement

DHHS and FDA regulations [45CFR 46.107(e) & 21CFR 56.107(e)] prohibit members from participating in IRB reviews if they have a conflict of interest.

> *No IRB may have a member participate in the IRB's initial or continuing review of any project in which the member has a conflicting interest, except to provide information requested by the IRB.*

Texas Tech HRPP Policy for Conflict of Interest Disclosure

- It is the expectation of the University that IRB members will voluntarily **recuse themselves from review and discussion** of research protocols if they have a conflict of interest.
- Members of the IRB must disclose to the IRB Chair or HRPP Section Manager any conflict of interest that may arise in the review of research or compliance matters for the IRB.

Conflicts of Interest that Require Member Recusal

- Members who are an **investigator or faculty sponsor** on the project under review, or whose *parent, spouse or child* is an investigator or faculty sponsor
- Members who have any **financial interests** (i) that would reasonably appear to be affected by the research; or (ii) in entities whose financial interests would reasonably appear to be affected by the research
- Members who serve as a **committee member** on the research project
- Members who believe **existing circumstances may directly affect their objectivity** should recuse themselves from the review

Other Circumstances for Recusal from IRB Review

- A member has access to funding or intellectual information that may create an unfair competitive advantage

and/or

- A member's personal biases may interfere with his or her impartial judgment

What to Do if You Have a Conflict of Interest

- Inform the IRB Chair or HRPP Section Manager as soon as possible
- Details of the conflict of interest should not be divulged unless it is for the betterment of the board and research community
- HRPP staff will capture those submissions and assign to the proper reviewer
- Recusals are recorded in the IRB meeting minutes

Conflict of Interest Standard Operating Procedures

- Members who are the Principal Investigator on a submission will have the IRB reviewed by the IRB Chair or Associate Chair

- IRB submissions submitted by the IRB Chair will be reviewed by the Associate IRB Chair
- IRB submissions submitted by the Associate IRB Chair will be reviewed by the IRB Chair
- Members who are a co-investigator on a submission will have the IRB reviewed by another member that has no conflict of interest with the study or reviewer
- Members who have a conflict of interest with another member will not review one another's IRB submissions
- Members who have a conflict of interest with a member of the research team will have the IRB reviewed by another member that has no conflict of interest with the study, researcher or reviewer
- Members who have a conflict of interest with another IRB member will not serve on a review or mentor team together
    - The member may be asked to recuse themselves from the discussion and vote
- HRPP staff who are the Principal Investigator on a submission will have the IRB reviewed by the IRB Chair or Associate Chair
    - The staff will not serve as the analyst on the IRB
- HRPP staff who are a co-investigator on a submission will have the IRB reviewed by an IRB member that has no conflict of interest with the study or analyst
- HRPP staff who have a conflict of interest with a member of the research team will not serve as the analyst or reviewer

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