# Texas A&M University—TexarkanaIRB Screening Checklist & Standard Application Form

Thank you for submitting your research for review by the TAMUT Institutional Review Board (IRB). Your attention to detail and commitment to ethical research is critical to participant safety and university success.

If you have questions about the application or the IRB review process, please contact the IRB Chair, Dr. Trisha Gerrish Ray, at irb@tamut.edu or 903-334-6680.

## Instructions

1. Before you begin, please make sure all PIs, Faculty Advisors, and other personnel will have completed the **CITI Basic course** for Social, Behavioral, and Educational Research or Biomedical research (or the previous NIH training). See the IRB page for links to the CITI training: <http://tamut.edu/irb>
2. Complete the fillable parts of this form.
3. Attach any documents, CITI certificates for PIs, Faculty Advisors, and other personnel, etc.
4. Sign the signature page.
5. Submit this form for review by a colleague experienced in Human Subjects Research. For faculty and staff, this is often a fellow faculty member, unit head, etc. For student PIs, this will be the Faculty Advisor. The reviewer will sign the signature page.
6. Submit to the college Dean for signature. The Dean will return the form to the PI or Faculty Advisor.
7. Submit the entire packet to the IRB. You may submit the packet electronically to IRB@tamut.edu if the completed Section V (signature page) is scanned and submitted with the application.
8. After submission, the IRB will let you know of there are any clarifications or corrections required before we proceed with the review.

The IRB review process typically takes 7-10 days unless the protocol requires full board review (relatively rare), which could take 30-45 days.

**Important**: Do not proceed with any recruitment or data collection until you receive notice from the IRB.

For IRB use only:
IRB #       PI Name       Title of Study

## **Section I.** Check all boxes that apply to your research.

[ ]  This is “research”: This is a ***systematic investigation*** including research development, testing and evaluation, designed to ***develop or contribute to generalizable knowledge****.*

A **systematic investigation** is an activity that involves a prospective plan that incorporates data collection, either quantitative or qualitative, and data analysis, either quantitative or qualitative, to answer a question. **Generalizable** means designed to draw general conclusions, inform policy, or generalize findings beyond a single individual, sample, or internal program. Examples of generalizable knowledge include publications or presentations outside of a program or class, theses, or dissertations, etc.

[ ]  This research involves collecting data from “human subjects”: a living individual about whom an investigator conducting research obtains (1) information or biospecimens through ***intervention*** or ***interaction*** with the individual and uses, studies, or analyzes the information or biospecimens; or (2) uses, studies, analyzes or generates ***identifiable private information*** or ***identifiable biospecimens***.

**Intervention** includes both physical procedures by which information or biospecimens are gathered (e.g., venipuncture, cheek swab) and manipulations of the subject or the subject's environment that are performed for research purposes. **Interaction** includes any communication or contact between investigator and subject via any channels (e.g., face-to-face, surveys, etc.). **Identifiable private information** is private information for which the identity of the subject is or may readily be ascertained by the investigator or associated with the information. **Private information** includes (a) information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and (b) information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (e.g., a medical record, GPA, income, sexual orientation, etc.). An **identifiable biospecimen** is a biospecimen for which the identity of the subject is or may readily be ascertained by the investigator or associated with the biospecimen.

Note that certain scholarly and journalistic activities are not intended to be generalizable, and thus not considered to be research by the IRB, such as oral history, journalism, biography, literary criticism, and historical scholarship.

If you checked **both** boxes, your research is considered Human Subjects Research (HSR) by the IRB. **Please proceed to section II.**

If you checked **neither** box, or only **one** box, your research does not require IRB review and approval. If you want guidance on whether your research qualifies as HSR, contact the IRB at IRB@tamut.edu

## **Section II.** Check all boxes that apply to your research.

These conditions may indicate the research is not eligible for Exempt review.

[ ]  The research involves vulnerable populations that may need special protections or considerations

Vulnerable populations include individuals who may have reduced autonomy or may be unduly influenced by coercion, such as children, prisoners or other institutionalized individuals, pregnant women, human fetuses or neonates, physically or mentally disabled persons, economically or socially disadvantaged individuals.

[ ]  Information obtained is recorded in such a manner that human subjects can be identified directly or through identifiers linked to the subjects, such as names, student ID, email address, IP address, etc.

[ ]  Public disclosure of any identifiable data you collect could place the participants at risk of criminal or civil liability or could be stigmatizing or damaging to the participants’ financial standing, employability or reputation.

[ ]  The research involves data collection procedures other than surveys, educational tests, interviews, or observation of public behavior.

[ ]  The research involves **greater than** **benign** behavioral interventions.

Benign behavioral intervention means intervention or manipulation that is brief in duration, painless, harmless, not physically invasive, and not likely to have a significant adverse lasting effect on the subjects).

[ ]  The research involves taste or food preference where the consumed item is wholesome but has had substances added or that contains agricultural chemicals or environmental contaminants.

[ ]  The research involves personally or culturally sensitive subject matters such as: abortion, criminal activity, sexual activity, sexually transmitted diseases, prior diagnosis for mental health disorders, prior victimization or trauma, etc.

[ ]  The research involves voice, video, digital, or image recordings of participants.

[ ]  The research involves obtaining individually identifiable information from health care plans, health care clearinghouses, or health care providers.

## **Section III.** General Information.

a. **Title of Study:**

b. **Principal Investigator** (must be affiliated with TAMUT): Please provide secondary contact information in case you become unreachable at the primary contact.

Name:       Title:

Status:  Student PIs must have a supervising faculty advisor (indicate below).

College:  Program/Department:

Primary Email:       Secondary Email:
Office/Primary Phone:       Mobile/Secondary Phone:
Office/Primary Address:
Home/Secondary Address:

c. **Co-Principal Investigator** (If applicable):

Name:       Title:

Status:

Affiliated Institution (if not TAMUT):       Program/Department:

Primary Email:

Office/Primary Phone:
Office/Primary Address:

d. **Additional PIs (**Provide all information as requested for Co-PI.):

e. **Faculty Advisor** (required only for student PIs): Faculty advisor holds ultimate responsibility for ensuring that this research complies with all University, regulatory, and fiscal requirements. Please provide secondary contact information in case you become unreachable at the primary contact.

Name:       Title:

College: Program/Department:

Primary Email:       Secondary Email:
Office/Primary Phone:       Mobile/Secondary Phone:

Office/Primary Address:
Home/Secondary Address:

f. **Additional Personnel:** If applicable; include any individual who obtains information or biospecimens from participants **or** who uses, studies, or analyzes such data (e.g., research assistants, data analysts, etc). Include full name, status (faculty, grad student, etc.), and their role in the research.

g. **Ethics Certification:** All investigators, faculty advisors, and additional personnel have completed the Collaborative Institutional Training Initiative (CITI) **Basic course** for either Social, Behavioral, and Educational or Biomedical research (previous NIH training also applies): [ ]  Yes. [ ]  No.

If you answered “no”, you must complete training before submitting this application. See <http://tamut.edu/irb> for access to the CITI training. If you answered “yes” please include proof of training (printed completion certificates) with this application.

h. **Funding**: Is your research funded by an external source (e.g., NIH, FDA, etc.)?
[ ]  No. [ ]  Yes, and the agency is:

## **Section IV.** Description of Proposed Research.

a. **Purpose of Research:** In plain language, briefly state the purpose of the proposed research, including the research question(s) you intend to answer.

b. **Benefits and Scholarly Contribution:** Please describe what you hope will come as a result of conducting this study. For example, what benefits will accrue to the scholarly community and greater society?

c. **Location of Study:** Specifically identify and describe all locations where interaction or intervention will occur and where data will be collected.

d. **Participants/Sample Demographics:** Identify (a) about how many participants data will be collected from, (b) their demographics (e.g., gender, sexual orientation, biological sex, race/ethnic groups, age range, etc.) of the population from which the participants will be recruited. If participants will include minors (under 18), specifically identify the ages being included.

e. **Sampling Procedure:** Please describe exactly where and how you will recruit participants, and any inclusion or exclusion criteria you will use. Provide or attach the text or copies of any communications you will have with prospective participants (e.g., scripts, eMail, text messages, flyers, mailings, etc.).

f. **Informed Consent:** Please check and complete one of the following options. Attach a copy of any informed consent forms, scripts, etc. if applicable.

[ ]  I am seeking a waiver of the requirement for informed consent, and this is the justification:
[ ]  I will be conducting informed consent and/or assent. Describe in detail the procedure by which you will conduct informed consent and/or assent including verbal or other interactions you will engage in to obtain informed consent:

g. **Method:** Please provide a detailed description of the study’s methods and procedures. Include (a) any interactions researchers will have with participants, (b) any interventions that researchers will conduct with participants, (c) any equipment participants will be interacting with, (d) descriptions of any instruments, tests, surveys, etc. (attach copies as necessary), and (e) the expected duration of time participants will be involved in the study.

h. **Compensation:** Describe any incentives, compensation, or other direct benefit participants will receive in exchange for their participation. When will this be provided to participants relative to their participation (e.g., before, immediately after, one day after, etc.)?

i. **Confidentiality:** Describe whether and how you will ensure confidentiality of participants’ personally identifiable information. Include information about specifically how you will store and protect the information on computers, paper files, etc. Also include how and when you will destroy the information.

j. **Risk-Benefit Ratio:** Describe how the benefits of the research will outweigh its risks. Specifically identify any foreseeable risks to participating in the study (e.g., physical pain, temporary emotional upset) and how you will minimize them, as well as the anticipated benefits to the participants (or to others) as a result of this work that will help offset the risks.

k. **Notes**: Include any notes or additional information you’d like to communicate to the IRB.

## **Section V.** Signature page

You may submit the application electronically if this page is printed, signed, scanned, and submitted to the IRB with the application.

Primary Investigator must sign this form. For students submitting as PI, faculty advisor must sign as Departmental/Peer Reviewer.

The **Primary Investigator** certifies that the information in this form and any attached documents is accurate to the best knowledge of the PI. The PI also agrees that any changes to the research protocol after submission will be communicated promptly to the IRB.

**Departmental / Peer Reviewer** certifies that this research is conducted within generally accepted scientific norms and merit for the discipline.

**Faculty Advisors** certify that they have reviewed this research protocol and assume ultimate responsibility for ensuring that this research complies with all university, regulatory, and fiscal requirements.

**College Dean** certifies only that they have seen the application and are aware of this research.

 Primary Investigator (printed) Signature Date

 Departmental / Peer Reviewer (printed) Signature Date

 College Dean (printed) Signature Date

#### NOTE: After College Dean signs, please return the signed form to the Primary Investigator or Faculty Advisor.

## **Section VI.** IRB decision and level of oversight.This section is to be completed by the IRB.

IRB#

###### Level of review determination: Indicate the category number for Exempt and Expedited determination, and also provide the reasoning behind the determination.

[ ]  This protocol is not Human Subjects Research as defined by the IRB. Reasoning:

Level: [ ]  Exempt, Category #       Reasoning:
[ ]  Exempt with Limited Review, Category #       Reasoning:
[ ]  Expedited, Category #       Reasoning:
[ ]  Full Review. Meeting date:       Reasoning:

Decision: [ ]  Approved

 [ ]  Not Approved
 Reason for non-approval:

Notes:

Signature:

 IRB Chair or designee (printed) Signature Date