TEXAS STATE UNIVERSITY

The rising STAR of Texas

IRB Application

Texas State University Institutional Review Board

Section I: Filling Out and Saving the Form

Save this application on your desktop. Upon completion, upload it along with all supplemental documents to the applicable project listed on your on-line IRB Home Page.

Section II: General Information

1. Title of Study

Insert the project name below. It should be identical to the title of any related internal or external grant proposal.

2. Investigator (Primary Research)

First Name	Last Name	Title (i.e. grad student, student, etc.)
Degree Program/Department	**Texas State Email Address**	**Phone Number**

If you are a student, is this application for your thesis or dissertation research?

- ☐ Yes
- ☐ No

3. Co-Investigator or Texas State University Sponsoring Faculty (if applicable)

First Name	Last Name	Title (i.e. grad student, student, etc.)
Degree Program/Department	**Texas State Email Address**	**Phone Number**

4. Project Dates

Anticipated Start Date:

Anticipated End Date:

5. Key Personnel

List the names of all other Key Personnel (including students) who are responsible for the design, conduct, recruitment of participants, data collection, or reporting of the study.

	Name	Email
1.		
2.		
3.		

6. CITI IRB Training

Have you, any Co-Investigator, Student Investigator, and all other Key Personnel completed the CITI training course ("Social and Behavioral Research")?

☐ Yes

☐ No

If you answered "No," this training is required for all Key Personnel before your study can be approved. The CITI course may be accessed by visiting: https://www.citiprogram.org/. Training is valid for 3 years and will require a refresher course when it expires. Your application will not be approved until all required training is completed and current.

7. Funding Information (if applicable)

Has ***external or internal funding*** been proposed or awarded for this project?

☐ Yes

☐ No

If yes, please include the OSP Proposal/Project Number (external) or Texas State account number (internal) for this project.

OSP Proposal/Project Number:

Texas State Account Number:

8. Financial Conflict of Interest Disclosure (if applicable)

Do you or any other person responsible for the design, conduct, or reporting of this research have an economic interest in, or act as an officer or a director of, any outside entity whose financial interests would reasonably appear to be affected by the research?

☐ Yes

☐ No

For externally funded research, Texas State University requires the Principal Investigator, Co-Investigator, project director, and all other personnel with responsibility for designing, conducting, or reporting of externally funded research to complete an online Financial Conflict of Interest disclosure each fiscal year.

Section III: Risk Review

Please click the box indicating your answer to each of the following questions:

1. Will your research study involve any vulnerable populations such as children, prisoners, pregnant women, mentally disabled persons, cognitively impaired elderly , or minority ethnic groups?
   - ☐ Yes
   - ☐ No
2. Could public disclosure of any identifiable data you collect place the participants at risk of criminal or civil liability or be damaging to the participants' financial standing, employability or reputation?
   - ☐ Yes
   - ☐ No
3. Will your study involve data collection procedures other than surveys, educational tests, interviews, or observation of public behavior?
   - ☐ Yes
   - ☐ No
4. Will your study involve the collection of sensitive data such as: illegal drug use, alcohol abuse, victims of violence, health history, prior diagnosis of mental disorders, sexual activity, criminal activity, or personal academic history?
   - ☐ Yes
   - ☐ No
5. Will your study involve audio or video-recording research participants?
   - ☐ Yes
   - ☐ No
6. Will your study involve obtaining individually identifiable information from health care providers, clearinghouses, or plans?
   - ☐ Yes
   - ☐ No
7. Will you be collecting anonymous data (results cannot be linked to individual participants)?
   - ☐ Yes
   - ☐ No
8. Will you be using data that was previously approved by the Texas State IRB?
   - ☐ Yes
   - ☐ No

   If yes, please provide the Texas State IRB approval number:

   ☐

9. Will you be using data that was previously approved by a non-Texas State IRB at an another institution, organization, center?

   ☐ Yes

   ☐ No

   If yes, please provide the name of the institution/organization and upload the applicable original IRB approval that authorized the data collection:

   Were you provided and instructed to sign and complete a Data Use Agreement (DUA)?

   ☐ Yes

   ☐ No

   If yes, please provide a copy of the agreement. Please note that the AVPR is the only University official authorized to sign this legally binding document.

10. Does this project SOLELY involve analysis of publicly available existing database?

    ☐ Yes

    ☐ No

    If yes, please provide the complete URLs for all databases that are relevant to this application:

    **If you answered yes to questions 8, 9, or 10, please submit the appropriate documents and only complete the Purpose of Study (1), Previous Research (2), and Publication of Results (11) in Section IV of this application.*

Section IV: Research Protocol Information

1. Purpose of Study

Provide a brief summary of the proposed research. Include the hypothesis and research design.

2. Previous Research

Briefly summarize previous research leading to the formulation of this study, including any past or current research conducted by the Investigator that leads directly to the formulation of this study.

3. Recruitment of Participants

Describe the source(s) of subjects and the selection criteria. Include the gender, racial/ethnic composition, age range, occupation, etc. Specifically describe how will you recruit and contact potential subjects. Also, include the anticipated number of research participants. All recruitment materials such as flyers, e-mails, verbal scripts, advertisement, etc. are required to be submitted and approved by the IRB.

4. Vulnerable Populations

Please identify any vulnerable populations that will be recruited to participate in this study:

- ☐ Children
- ☐ Pregnant Women
- ☐ Prisoners
- ☐ Mentally Impaired
- ☐ Cognitively Impaired Elderly
- ☐ Ethnic Minorities, Non-English Speaking Individuals
- ☐ Other: Please list:
- ☐ N/A, this study will not use vulnerable populations as research participants.

If applicable, describe any special precautions that will be taken for the inclusion for identified vulnerable populations. I.e.., use of informed assent and parental consent for minors or consent documents in an alternative language for individuals who do not speak English.

5. Informed Consent

Describe the consent process and upload all consent documents. If you are requesting a waiver of signed informed consent, please state the rationale and how consent will be alternatively obtained (verbal, “clicking” an on-line button or link, participation will imply consent, etc.)

6. Procedures

Provide a step-by-step description of each procedure, including the frequency, duration, and location of each procedure. Also, for data collection sites other than Texas State that involves the authorization and coordination with an outside agency, please upload a signed and dated letter on the cooperating institution’s letterhead granting approval for the data collection.

7. Confidentiality

Describe the procedures that will be used to maintain the confidentiality of all personally identifiable data. (Please note: All data must be securely kept for a minimum of three years on campus. The location of the secured data should be listed below.)

8. Risks

Describe any foreseeable or anticipated risks that may be presented to the participants as a result of taking part in the study. Please describe all of the precautions that will be implemented to minimize such risks.

9. Benefits

Describe the anticipated benefits to subjects, and the importance of the knowledge to your field that may reasonably be expected to result.

10. Compensation

Describe any compensation subjects will receive for participating in the study. Include a description of the compensation, timing for payment, and conditions for receipt of such compensation. Please note: If extra course credit is offered as an incentive for participation, the instructor must provide an alternative form of extra credit to students who do not want to participate in the research.

11. Publication of Results

Please identify all methods in which you may publicly disseminate the results of your study.

- ☐ Academic Journal
- ☐ Academic Conference Presentation
- ☐ Academic Conference Poster
- ☐ Book or Textbook Chapter
- ☐ Thesis or Dissertation
- ☐ Texas State University Scholarly Works Respository
- ☐ Other: Please list

Section V: Investigator Certification

☐ By checking this box, I am certifying that the information in this application is complete and accurate. I agree that this study will be conducted in accordance with Texas State IRB Guidelines. I will request IRB approval before making any modification to the research procedures or forms. I understand that neither recruitment nor data collection will be initiated until final IRB approval is received. I will notify the IRB any unexpected or otherwise significant adverse events and general problems within one week of the incident. I understand that if these conditions are not met, this research could be suspended and/or not recognized by Texas State University.

This application and all supplementary documents must be submitted together to be processed for review. The IRB will contact you if additional information or revisions are needed for approval. All revisions must be submitted within 30 days of the request. After that time all the application will be discontinued. If your application is discontinued you will be required to resubmit another application.

Contact The Office of Research Integrity and Compliance at (512) 245-2334 or avpr-irb@txstate.edu for any questions concerning the approval status of your application.