File Number:

Approval Date:

**For IRB Use Only**

|  |  |
| --- | --- |
| Type of Review |  |

**IRB Review Application**

**Texas State University Institutional Review Board**

**Section I: Filling Out and Saving the Form**

Save this form on your desktop and when ready submit this application along with all supplemental documents to the IRB Office as an attachment. All documents should be saved as First Name or Initial, Last Name, and one-word description, with no extra spaces or special characters other than underscores. Acceptable examples: JohnSmithapplication, J\_Smith\_application.doc, JohnSmith\_consentformEnglish.pdf, JSmithconsentformSpanish.doc

Type only in the blue fields, and closely follow all stated length limits. **Handwritten forms will not be accepted.**

**Section II: 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, elderly, or minority 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 any sensitive subject matters such as: abortion, criminal activity, sexual activity, sexually transmitted diseases, prior diagnosis for mental health disorders, victims of violence, alcohol use, alcohol abuse, illegal drug use or drug abuse? | [ ]  Yes[ ]  No |
| 5. Will your study involve audio-recording or video-recording the participants? | [ ]  Yes[ ]  No |
| 6. Will your study involve obtaining individually identifiable information from health care plans, health care clearinghouses, or health care providers? | [ ]  Yes[ ]  No |

|  |  |
| --- | --- |
| 7 .Is the data you are collecting anonymous data? Anonymous meaning you as an investigator cannot be linked in any way back to the source of the data.  | [ ]  Yes[ ]  No |
|  |  |
| 8. Will you be using public available data banks? | [ ]  Yes[ ]  No |
| 9. Will you be using data that was previously collected by another researcher, institution, second vendor, third party authorized by Texas State IRB, or intellectual property of another institution/researcher? | [ ]  Yes[ ]  No |

Upload Data Usage Agreement **if Yes** to question # 9

**Section III: General Information**

Type only in the blue fields, and closely follow all stated length limits. **Handwritten forms will not be accepted.**

|  |
| --- |
| **1. Title of Study** |
| Must be identical to the title of any related internal or external grant proposal. |
|       |

|  |
| --- |
| **2. Investigator (Primary Researcher)** |
| First Name |  | Last Name | Title (i.e. grad student, faculty, ect.) |  |
|  |  |  |  |  |
|  |  |  |
| Degree program/Department | Texas State Email Address | Phone Number |
|   |  |  |  |  |

|  |
| --- |
| **3. Co-Investigator/ Texas State University Supervising Faculty (if applicable)**Must be a full-time Texas State University faculty member or a full-time staff employee whose job responsibilities include conducting human subject’s research. A faculty Supervising Investigator is required for all student studies which require IRB review, including all theses and dissertations that use humans as research participants. Student Investigator information is entered in Section III question 2.  |
| First Name | Last Name | Texas State E-mail Address |
|  |  |  |  |  |
|  |  |  |
| Department or University  |  | Title (Associate Professor, Professor, Dean, ect) |
|  |  |  |

|  |  |  |
| --- | --- | --- |
| Phone number  |  |  |
|  |  |
|  |

|  |
| --- |
| **4. Key Personnel** |
| List the name of all other Key Personnel (including students) who are responsible for the design, conduct, or reporting of the study (including recruitment or data collection).  |
|  |
|  |
| **5. CITI IRB Training** |
| Have you, any Co-Investigator, any Student Investigator, and all 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 only valid for 3 years** and will require a refresher course if expired. Your **application will not be approved till all required training is completed and current.** |

Upload CITI Certificates

|  |
| --- |
| **6. Funding Information (if applicable)** |
| Has **external or internal funding** been proposed or awarded for this project?  |
| [ ]  Yes[ ]  No |
| **If yes**, please submit the statement of work or a project summary that was included with the proposal. Also please provide the OSP or Texas State Project Number for any external funding or the account number for any internal funding for this project. |
| Proposal Number or Project ID Number \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Statement of work or project summary attached? [ ]  Yes[ ]  No |
| Upload Grant docs |
| **7. Financial Conflict of Interest Disclosure (if applicable)** |
| Has **external funding** been proposed or awarded for this project? |
| [ ]  Yes[ ]  No |
| **If yes,** Texas State University requires the Principal Investigator, any Co-Investigator, any project director, and any other person with responsibility for designing, conducting, or reporting of externally funded research to complete an online Financial Conflict of Interest disclosure each fiscal year. Have all Investigators and other key personnel for this proposed project completed an online Financial Conflict of Interest disclosure for the current fiscal year? (The online process for submitting a Financial Conflict of Interest Disclosure is available at http://www.txstate.edu/research/orc/researcher-conflict-of-interest.html.[ ]  Yes[ ]  No |
|  |
| **Section IV: Research Protocol Information**1. **Purpose of Study**
 |
| **In no more than a page,** briefly state the purpose of your study in **lay language,** including the research question(s) you intend to answer. A brief summary of what you write here should be included in the informed consent form. |
|       |
|  |
| **2. Previous Research** |
| **In no more than half a page,** 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 (including citations and references.) |
|  |
|  |
| **3. Recruitment of Participants** |
| Describe the projected number of subjects. |
|       |
|  |
| Describe the population from which subjects will be recruited (including gender, racial/ethnic composition, age range, occupation, institution, ect). |
|       |
|  |
| Describe how you will recruit subjects (face-to-face, e-mail, flyer, classroom announcement, etc.). |
|       |
|  |
| Please upload all of the recruitment materials such as flyers, e-mails, scripts for classroom announcements, ect.  |
| Upload recruitment **all** documents |
| **4.. Vulnerable Populations** |
| Please Identify any vulnerable populations who will be participating in this study: |
| [ ]  Children (under 18 years of age)[ ]  Prisoners[ ]  Elderly who are not emancipated, in a nursing home, or receive hospice care | [ ]  Pregnant Women[ ]  Mentally Impaired or Mentally Retarded[ ]  minority populations that do not speak English (i.e. migrant workers) |
| If any boxes are checked, describe any special precautions to be taken in your study due to the inclusion of these populations. |
|  |
|  |
| **5. Location of Study** |
| Identify all locations where the study will be conducted. |
|       |
|  |
| For data collection sites other than Texas State, have you attached a signed and dated letter on the cooperating institution’s letterhead giving approval for data collection at that site? |
| [ ]  Yes[ ]  NoUpload supporting documents |
| **6. Anticipated Project End Date****7. Informed Consent Process** |
| Describe the steps for obtaining the subjects’ informed consent (by whom, where, when, etc.). |
|  |

|  |
| --- |
| **8. Informed Consent Forms** |
| Written informed consent forms to be signed by the subject after IRB approval are required for most research projects with human participants. A waiver of informed consent can be requested in certain situations such as:1. Telephone surveys
2. Internet surveys
3. Subject not present
4. Collecting consent signature places identity of participant at risk or prevents anonymity
5. If signing informed consent is not standard practice for your type of research and project is of minimal risk

When Informed consent is waived the principal investigator needs to provide a written statement to participant informing them of the research project and that participation will imply consent.Templates for creating informed consent forms are located on the IRB website at http://www.txstate.edu/research/orc/IRB-Resources.html**. Final drafts of all informed consent documents you plan to use must be submitted before IRB review can begin.** |
|

|  |
| --- |
| Will you be requesting a waiver of informed Consent?[ ]  Yes[ ]  NoIf requesting waiver of Consent explain rationale and how consent will be obtained.(i.e. Verbal, participation implied consent, clicking on link provides consent, ect.) |
|  |

 |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|

|  |
| --- |
| What is the estimated time for a subject’s participation in each study activity (including time per session and total number of sessions)? |
|  |

**9. Compensation**

|  |
| --- |
| Describe any compensation subjects will receive for participating in the study. Include the timing for payment and any conditions for receipt of such compensation. If extra credit for a course is offered, an alternative non-research activity with equivalent time and effort must also be offered. |
|  |

**10. Foreign Languages** |
| Will your study involve the use of any language other than English for informed consent forms, data collection instruments, or recruitment materials? |
| [ ]  Yes[ ]  No |
| If “Yes,” submit copies of all translated consent forms, recruitment documents, surveys, questionnaires, ect. to the IRB. Specify all foreign languages below: |
|  |
| Upload all translated documents**11. Data Collection** |
| Which methods will you use to collect data? |
| [ ]  Interviews[ ]  Surveys[ ]  Focus Groups[ ]  Assessment Instruments | [ ]  Internet Surveys[ ]  Review of Existing Records[ ]  Observation[ ]  Other - Please list below |
|  |  |
| If “Review of Existing Records” and/or “Observation” are checked above, please describe below the records you plan to review and/or the observations you plan to make for your study. |
|  |
|  |
| Will your study involve audio-recording or video-recording the participants? |
| [ ]  Yes[ ]  No |
| Have you attached a copy of all data collection instruments, interview scripts, focus group topics, questionnaires, and intervention protocols to be used? |
| [ ]  Yes[ ]  NoUpload data collection documents |
|  |
| **12. Risks and Benefits**  |
| Describe any foreseeable risks outside normal activities subjects may be presented by the proposed study and explain precautions you will take to minimize such risks.  |
|       |
|  |
| Describe the anticipated benefits to subjects or others (including your field of study). |
|       |

|  |
| --- |
| **13. Confidentiality** |
| Describe the procedures you will use to maintain the confidentiality of any personally identifiable data. |
|       |
|  |
| Please note if student investigator the sponsoring faculty/staff member **must store the data for 3 years per federal regulations**. After three years the **IRB will contact the principal investigator or sponsoring faculty/staff member to confirm data destruction**.Please specify how and where your research records will be maintainedPlease specify any coding or other steps you will take to separate participants’ names/identities from research data |
|       |
|  |
| **14. Publication of Results** |
| Please identify all methods in which you may publicly disseminate the results of your study. |
| [ ]  Academic Journal[ ]  Academic Conference Paper or Public Poster  Session[ ]  Book or Chapter | [ ]  A Thesis or Dissertation for One of Your Students[ ]  Texas State University Scholarly Works Repository[ ]  Other – Please list below. (Website, blog, etc.) |
|       |

**Investigator or Supervising 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 and the study procedures and forms approved by Texas State IRB.

The application and all supplementary documents must be submitted together to be processed for review. All applications will be reviewed and if revisions or additional information is needed you will be contacted by the IRB. **If revisions or additional information is needed you have 30 days to submit requests** from the date the IRB first contacted you. **If all revisions or additional information is not submitted within the 30 day window of initial contact your application will be discontinued**.If your application is discontinued you will need to resubmit another application.

**Contact The Office of Research Integrity and Compliance at (512) 245-2334 for any questions about completion of your application.**