

APPLICATION FOR EXPEDITED OR FULL REVIEW

RESEARCH

**When finished, please email this form to** **irb@sfasu.edu** **and attach consent forms, recruitment, survey and/or other relevant materials (including translations).**

**SECTION 1. Researcher Information**

1. Principal Investigator (PI) Contact Information: (***PI must be SFA faculty or staff****, and will be the study supervisor at SFA****)****,. All correspondence will be directed to the PI and listed CoPIs*.)

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Name** | **Department** | **Phone** | **Email** | **CITI Completed (Yes/No)** **OPTIONAL** |
|  |  |  |  |   Y    N |

NOTE: Students, post-doctoral researchers, and visiting faculty may not serve as PI given that they are not able to comply with all the guidelines stipulated by University policy and Federal Guidelines.

1. Study Title:
2. Type of Study:

   Faculty Research    Class Project   Thesis    Dissertation   Capstone Project    Other\_\_\_\_\_\_\_\_\_\_\_

If this is for your thesis or dissertation, has it already been approved ? Yes\_\_\_\_ N0 \_\_\_\_

1. Will this be cooperative research? List any collaborators and their institution.
2. List names of Co-investigators, Coordinators, and Key personnel involved in this research *(Include all persons who will be directly responsible for the study management, data collection, consent process, data analysis, transcription, participant recruitment, or follow up****.***)

|  |  |  |  |
| --- | --- | --- | --- |
| **Name** | **E-mail** | **CITI or other Human protection training –Completed (Yes/No)** **OPTIONAL** | **Role in the research (co-PI, Student Researcher, Research Assistant, Transcriber, etc.)** |
|  |  |   Y    N |  |
|  |  |   Y    N |  |
|  |  |   Y    N |  |

**If additional lines are needed, add lines or submit on a separate page**

**SECTION 2. Specific Information**

1. Estimated Study Start Date:

**Note: Maximum approval time is one year from approval date.**

1. Is this research supported in whole or in part by a grant or contract?

    Yes    No

If yes, complete the questions below:

 Funding Agency(s), Foundation, or Business:

PI on Grant/Contract:

Grant Title/Contract:

1. Does the research requires another IRB’s review (US and International)?

   Yes    No

If already approved by another ethics board please complete below:

Name of the IRB:

Number given by the other institution or agency:

 **Note: PI is responsible for securing approval and forwarding the documentation of approval to SFASU IRB**.

1. Does the PI, Co-PI, 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 director of any outside entity whose financial interest would reasonably appear to be affected by the results of the study?

   Yes    No

If yes, complete below:

Name of the person with potential conflict of interest (COI):

Explain the potential financial conflict of interest:

Explain how the potential conflict of interest will be managed?

1. Does the proposed research study requires approval from an outside (non-SFA) facility or entity (e.g., hospitals, clinics, schools, school districts, factories, offices, etc..,)?

   Yes    No

If yes, Name (s) of the facility or entity:

**Note: The researcher has an obligation to ensure that the outside entity is aware of the proposed research study and has no objections (i.e. agrees to participate). Please include an approval letter from site, if applicable.**

**SECTION 2. Study Description**

**Provide a brief summary of the proposed research.** Use lay language and avoid technical terms. IRB members not familiar with the area of research must understand the nature of the research. **The application will be returned without further review if summary is too technical.**

1. Brief summary of research study:

Purpose:

Design:

Procedures: (**For projects involving multiple phases or complex designs, attach flow chart(s) describing the sequence of study procedures**)

**SECTION 3. Data Collection Methods**

**NOTE: WHEN SUBMITTING, ATTACH RECRUITMENT, SURVEY OR OTHER RELEVANT MATERIALS TO THE EMAIL, INCLUDING TRANSLATIONS.**

Check all method(s) to be used.

1. Survey/Questionnaire

    Phone    In person    Internet    E-mail    Postal mail

1. Participation

    One-on-one    Focus group    Oral history    Other:

1. Observation of Public Behavior

   Classroom    Public meetings    Other:

1. Examination of Archived Data/Secondary or Records

Briefly describe the record:

1. Taste Evaluation

   Wine/alcohol    Non-wholesome food    Genetically altered food

1. Examination of Human Pathological or Diagnostic Tissue Specimens (ex: blood, bodily fluids…)
2. Unproven or Untested Procedures

   Biomedical    Psychological    Other:

1. Recordings

   Voice    Video    Digital    Image

 Check the Purpose of the recordings:     For transcription    Other

1. Other:       Please explain below:

**SECTION 4. Confidentiality and Protection of Data**

1. Level of identification and confidentiality at each phase of the data in the research.

   Anonymous

(No identifiers that link the data to a specific participant)

   Confidential

 Unlinked (Collected with identifier, but all identifiers & codes are removed)

   Confidential

Coded (Linked to a specific participant by a code, not by a direct identifier)

Intentionally Identified: (Linked to a specific participant by personal identifiers)

1. Method(s) of protection and location of data storage: (Check all that apply)
2. Locked Office (not private)

   Locked Cabinet

   Coded to a Master List

If checked, answer the following

 i. Will the master list be kept separate from the data?    Yes    No    N/A

   Restricted Computer

   Password Protected

   Locked Private Office

   Encrypted Data

   Fire Wall System

   Other:

1. Location of data:

Building and Room Number:

1. When will all research materials be destroyed, including voice/video/digital/image?

**Note: Federal guidelines require all research materials (consent forms, surveys etc...) to be kept for a minimum of five (7) years after completion of the study.**

**SECTION 5. Human Participant Population**

1. Approximate number of participants to be enrolled (Answer for each participant group. For example: minors’ #s, elderly #s.):
2. Please identify participants that will be recruited by checking all that apply. Submit additional materials as required.

|  |  |
| --- | --- |
| **Approximate** Age | Consent/Permission /Assent forms Required |
|    Birth to 3 years | Parental Permission Form |
|    4-7 years | Parental Permission Form and Child's Assent |
|    8-17 years | Parental Permission Form and Child's Written Assent |
|    18 & over | Written Consent |

**Note: The above ages are only for reference. The researcher should take into consideration cognitive capacity when determining whether an assent is required.**

1. Populations

|  |
| --- |
|    Children |
|    Prisoners |
|    Pregnant women |
|    Decisionally impaired |
|    Crime victims |
|    Substance abusers |
|    Persons living outside the U.S. |
|    Non-English speaking |
|    Terminally ill |
|    Institutionalized individuals |
|    College Students |
|    Other:       |

1. Are there groups of people you are purposefully excluding?    Yes    No

If yes, please explain the population excluded and the reasons for the exclusion criteria:

**SECTION 6. Human Participant Recruitment**

1. Recruitment/advertising methods:

 Check all that apply

   Person to person solicitation    Phone    Social Media    E-mail    Poster    Media (TV, newspaper, radio, Web site)    Other:          None

1. How will potential participants be identified? How will potential participants be approached (**Answer for each participant group**)?

**Explain in detail:**

1. Who will obtain consent/assent and when will that be done (**Answer for each participant group**)?

**Explain in detail:**

1. Describe any screening tools/procedures (**Answer for each participant group**)?

**Explain in detail:**

1. Will participants be compensated (including class credit)?

   Yes    No

**Explain in detail:**

1. When will the participants be compensated?

   Before the study    Installments during the study    Withdraw/complete the study

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**SECTION 7. Informed Consent/Parental Permission/Assent Process**

Choose all that apply and **attach appropriate forms to this application.**

**Note: For a list of required elements of informed consent and templates see** [**www.sfasu.edu/researchcompliance**](http://www.sfasu.edu/researchcompliance)**)**

1. Adult(s)    Parent(s)    Guardian(s)    Children    Vulnerable Population
2. What steps have you taken to prevent potential coercion or undue influence in recruiting participants and obtaining consent or assent?

**Explain in detail:**

**SECTION 8. Risk and Benefit Assessment**

1. Indicate which of the categories listed below accurately describes the specific potential risk level of the experiment:

   Not greater than minimal risk[[1]](#footnote-1)

   Greater than minimal risk, but presenting the prospect of direct benefit to individual participants

   Greater than minimal risk, no prospect of direct benefit to individual participants, but likely to yield generalizable knowledge about the participant’s disorder or condition

1. Potential risks to participants: **(Check all that apply if greater than minimal risk)**

   Invasion of privacy to the participant or family

   Breach of confidentiality

   Physical harm or discomfort

   Psychological/emotional discomfort or distress

   Psychological effect that is more than discomfort or distress

   Social stigmatization

   Economic (e.g., employment, insurability)

   Legal

   Any study related activity which participants might consider sensitive, offensive, threatening, or degrading?

   Withholding standard care and procedures

   Significant time or inconvenience

   Other:

1. Does the study pose risk to individuals other than the participants?    Yes    No

**Explain in detail:**

   Research not otherwise approvable which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of participants

1. How will you minimize these potential risks in order to protect participants' rights and welfare?

**Explain in detail:**

1. In the event that any of these potential risks occur, how will it be handled (e.g. compensation, counseling, etc.)?

**Explain in detail:**

1. Is it possible that you will discover a participant's previously unknown physical or psychological condition (e.g. disease, depression, suicidal ideation, genetic predisposition, etc.) as a result of your procedures?

   Yes

   No

**If yes,** what would they be and how will you handle these situations?

**Explain in detail:**

1. Describe the expected benefits of this project *(NOTE:* ***compensation is not considered a benefit****)*:
2. To the individual participants:

**Explain in detail:**

1. To society:

**Explain in detail:**

1. Explain how, in your assessment, benefits of this study outweigh the risks. (e.g. risk/benefit ratio)

**Section 8.1 Only for Research Involving Potential Reportable Activity**

1. Will the project involve the potential discovery of child abuse?

   Yes    No

**If yes, there are legal obligations to disclose to the proper authorities certain information about reportable activities obtained during research. This obligation and intended course of action must be communicated to the participants in the consent form.**

**Section 8.2. Only for Research Involving Deception**

1. Why is the deception necessary?

**Explain in detail:**

1. How and when will the participants be debriefed? **Attach debriefing script.**

**Explain in detail:**

**Section 8.3 Only for Research Involving Health Insurance Portability and Accountability Act (HIPAA)**

Address the following questions regarding the use of protected health information:

1. Yes    No Will health information be obtained from a covered entity (a health care provider who bills health insurers?
2. Yes    No Does the research involve the provision of healthcare in a covered entity?
3. Yes    No If the study involves the provision of healthcare, will a health insurer or billing agency be contacted for billing or eligibility?
4. Yes    No Does the research involve the use or creation of protected health information?

**Please explain the individuals who will have HIPAA responsibility in detail:**

**Section 8.4. Only for Research Involving Investigational Drugs, Devices, Alcohol, Blood, Tissue, Bodily Fluids or other Biological Specimens**

1. Will drugs or investigational devises be used in this study OR blood, tissue, bodily fluids, or other biological specimens be collected?    Yes    No

If yes, please explain in detail

**Note: If you are using blood, tissue, bodily fluids or other biological specimens, you may also need to seek Institutional Biosafety Approval before you begin the research.**

**Section 9. Principal Investigator’s Responsibilities and Assurances**

**Indicate that you have read and will comply with each statement.**

1. I certify that the information provided in this application, and in all attachments, is complete and correct.
2. I understand that I have ultimate responsibility for the protection of the rights and welfare of human participants, the conduct of this study, and the ethical performance of this research.
3. I agree to comply with all SFASU policies and procedures, the terms of its Federal Wide Assurance, and all applicable federal, state, and local laws regarding the protection of human participants in research.
4. *I certify that I have followed departmental and college guidelines before sending this application.*

I certify that:

* 1. the study will be performed by qualified personnel according to the information contained in this application.
	2. The equipment, facilities, and procedures to be used in this research meet recognized standards for safety.
	3. Unanticipated problems, adverse events, and new information that may affect the risk–benefit assessment for this research will be reported to the SFASU Office of Research and Sponsored Programs (936-468-6606 or irb@sfasu.edu).
	4. I am familiar with the latest edition of the *SFASU Policy for Human Research Participants Protection*, available at <http://www.sfasu.edu/researchcompliance/103.asp> and I will adhere to the policies and procedures explained therein.
	5. I further certify that the proposed research has not yet been done, is not currently underway, and will not begin until exemption has been certified.

PI Name or Signature\*: Date:

\* Only required if not submitted from the PI’s SFASU or Chair/Dean’s email account.

Stephen F. Austin State University

Office of Research and Sponsored Programs

Institutional Review Board (IRB)
PO Box 13019 | Human Services and Technology/ Communications Bld.

 | Nacogdoches, TX | (936) 468-1153

Email: irb@sfasu.edu

1. Minimal risk” means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves from those ordinarily encountered in daily life or during the performance of routine physical or psychological examination or tests. 45 CFR 46.102(i) [↑](#footnote-ref-1)