IRB OFFICE USE ONLY
Last Name _____
IRB Log# _____

Texas A&M University- San Antonio

IRB Protocol Application

INSTRUCTIONS

1. Complete Training

- PI, Co-Investigator, and anyone interacting with potential participants and/or identifiable participant information or biospecimen must be listed in the protocol and complete necessary training.
- Refresher training must be completed every two years.
- More details can be found at: http://www.tamusa.edu/graduatestudiesandresearch/irb/index.html

2. Complete Form

- Form must be typed and free of typographical/grammatical errors. *Handwritten forms will not be accepted.*

3. Attach Documents to Application *(Be sure to label and reference material)*

- ☐ Training documentation: Social and Behavioral Research *and* The Revised Common Rule CITI completion report for all investigators
- ☐ Consent documentation *(as applicable)*: consent protocol, consent form, assent form
- ☐ Recruitment materials *(as applicable)*: flyers, letters, scripts, e-mail, etc.
- ☐ Procedural materials: Survey, Interview, Focus Group Questions, and/or Questionnaire
- ☐ Additional documentation *(as applicable)*: Any other documents referenced in this application
- ☐ Signature Assurance page signed by each listed investigator (e.g., PI, Co-Investigator, Additional Investigator)

4. Submit Application

Submit the complete IRB protocol (application and required documentation) to Graduate Studies and Office of Research by:

- Email completed scanned copy to irb@tamusa.edu,

Please see Scheduled Meeting Dates for IRB proposal applications that require IRB Full Board Review.

Incomplete submissions will be returned and you will be notified of the missing material. Applications will not be reviewed until all required material is received.

If you have any questions or need assistance completing this application, please call The Office of Research at (210)784-2317 or e-mail irb@tamusa.edu

INVESTIGATOR INFORMATION

Principal Investigator's Name: _____

☐ Faculty ☐ Staff

Department: _____ College: _____

Mailing Address (*if not A&M-SA)*: _____

Campus Phone: _____ Office Location: _____

Fax: _____ Alternate Phone: _____

Email: _____

Co-principal Investigator's Name: _____

☐ Faculty ☐ Staff ☐ Doctoral Student ☐ Graduate Student ☐ Undergraduate Student

Department: _____ College: _____

Mailing Address (*if not A&M-SA)*: _____

Campus Phone: _____ Office Location: _____

Fax: _____ Alternate Phone: _____

Email: _____

List additional Investigators: *(all investigators are required to sign the Signature Assurance page)*

_____

_____

Is this study part of a Thesis or Dissertation? ☐ Yes ☐ No

Is this study part of a Graduate Research Project? ☐ Yes ☐ No

PROJECT

Project Title: _____

Anticipated Start Date: _____ Anticipated End Date: _____

Funding Status:

☐ Externally Funded* ☐ Internally Funded* ☐ Funding Under Review* ☐ Not Funded

☐ Other *(describe)*: _____

Funding agency: _____

Must include a draft of the grant application. Once grant is completed/submitted, a final draft must be submitted to the IRB.

Does this protocol require approval from multiple IRBs?

☐ Yes (*describe)*: _____

☐ No, only A&M-SA IRB

Indicate the review category. *You can visit the Electronic Code of Federal Regulations for assistance.*

☐ Exempt *(select one of the exempt categories below)* §46.104

- ☐ Category 1
- ☐ Category 2
- ☐ Category 3
- ☐ Category 4
- ☐ Category 5
- ☐ Category 6
- ☐ Category 7 *N/A*
- ☐ Category 8 *N/A*

☐ Expedited

☐ Full

STUDY PURPOSE

Describe the purposes of this study. Your description must include:

a. Explanations in lay terminology and/or jargon with sufficient explanation.
b. Justification for conducting the research and what you propose to learn.
c. Preliminary data, references to previous research, and/or gaps in our knowledge.

RISKS AND BENEFITS

Describe any potential risks or discomforts to the participant (including physical, psychological, and/or social) and the means by which your procedures minimize these risks:

Risks to participants are either "minimal risk" or "more than minimal risk." Do not type "none".

Describe any potential benefits to the research participants and society:

Describe the alternatives to participation and opportunity to withdraw:

PARTICIPANT RECRUITMENT

Number of participants: _____

Gender of participants: ☐ Female ☐ Male Age of participants: _____

Source of participants: ☐ A&M-SA students ☐ Community ☐ School* ☐ Other

Explain participant selection:

For studies involving schools: Does the study involve a school district? ☐ Yes ☐ No

If Yes, list which school district(s)?: (***Approval documentation from the school district must be attached.)***

Describe the selection criteria for participation:

Do the selection criteria exclude individuals based on gender, culture, language, economic status, or ethnicity? ☐ Yes ☐ No

If Yes, justify exclusion:

Are there any special physical or psychological conditions of participants? ☐ Yes ☐ No

If Yes, describe:

Vulnerable Populations (*check all that apply):*

☐ Not applicable
☐ Children
☐ Prisoners
☐ Individuals with impaired decision-making capacity
☐ Economically or educationally disadvantaged persons
☐ Employees
☐ Other, describe:

If vulnerable populations will be used, describe additional safeguards to protect their rights and welfare:

Recruitment Method *(all flyers, advertisements, etc. are subject to IRB review. Check all that apply. Labeling and referencing scripts.)*:

☐ Telephone solicitation (attach script)
☐ Radio (attach script)
☐ Television (attach script)
☐ Newspaper advertising (attach ad copy)
☐ Posted notices (attach copy)
☐ Letter (attach copy)
☐ E-mail (attach copy of text to be sent for recruitment)
☐ Direct person-to-person contact, describe:

☐ Other, describe:

Other than as an Investigator, do you have any other relationship with participants? (*e.g., doctor-patient, teacher-student, counselor-student*) ☐ Yes ☐ No

If Yes, explain the relationship and describe how you will avoid any type of coercion:

CONSENT

Name individuals or group of individuals who will be speaking directly to potential participants during the consent process:

Check all that apply and attach to the application:

- ☐ Cover Letter
- ☐ Adult Consent Form
- ☐ Minor Assent Form
- ☐ Parental Consent Form
- ☐ Telephone Script
- ☐ Information Sheet (also select Waiver of Documentation of Informed Consent)
- ☐ Waiver of Documentation of Informed Consent ***(necessary for online studies that do not collect a physical signature)***
- ☐ Other, describe:

Describe location where consent forms will be stored:

Note: Consent forms must be kept on file for 3 years after completion of the study and data analysis

Are you requesting a waiver or alteration of the informed consent process? ☐ Yes ☐ No

If Yes, provide protocol-specific reasons and justification on how *all* of the following criteria are met:
(*see 45CFR 46.117(C) Electronic Code of Federal Regulations)*

1. The research involves no more than minimal risk to the participants.
2. The waiver or alteration will not adversely affect the rights and welfare of the participants.
3. The research could not practicably be carried out without the waiver or alteration.
4. Whenever appropriate, the participants will be provided with additional pertinent information after participation.

Are you requesting a waiver of documentation of informed consent? ☐ Yes ☐ No

If Yes, provide protocol-specific reasons and justification on how *at least one* of the following criteria are met: : **(*see 45CFR 46.117(C) Electronic Code of Federal Regulations)***

☐ The only record linking the participant and the research would be the informed consent form and the principal risk would be potential harm resulting from a breach of confidentiality. Each participant (or legally authorized representative) will be asked whether the participant wants documentation linking the participants with the research, and the participant's wishes will be honored.

☐ The research presents no more than minimal risk of harm to participants. The research involves no procedures for which written consent is normally required outside of the research context ***(e.g., participants are completing an online study without submitting a physical signature).***

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

COMPENSATION / COURSE CREDIT

Will monetary compensation be given to the participant? ☐ Yes ☐ No

If Yes, provide details including amount and schedule of payments to participant:

Will course credit be given to the participant as compensation? ☐ Yes ☐ No

Will other non-financial incentive be given? ☐ Yes ☐ No

If Yes, provide details and describe alternate assignment to obtain equal credit:

Will other non-financial incentive be given? ☐ Yes ☐ No

If Yes, provide details:

SUBJECT MATTER

Check the appropriate box(es) concerning the subject matter of the research:

- ☐ No sensitive matters
- ☐ Abortion
- ☐ AIDS/HIV
- ☐ Alcohol
- ☐ Body composition
- ☐ Drugs
- ☐ Learning disability
- ☐ Physical disability
- ☐ Psychological inventory
- ☐ Review of criminal records

☐ Criminal activity ☐ Review of educational records
☐ Depression / Suicide ☐ Sexual Activity
☐ Other, describe:

DECEPTION

Does the research involve deceiving the participants regarding the nature or purposes of the research, in which the participant is informed that he or she will be unaware of or misled regarding the nature or purposes of the research? ☐ Yes ■ No

If Yes, describe and justify the deception, attach the debriefing form, and explain the debriefing procedures:

PROCEDURES

What will participants be asked to do? (Describe the study in detail from recruitment to completion. Description must include how the participants will be recruited, where the consent process and research activities will take place, and how long the participants will be engaged in the research).

During data collection, describe what steps will be taken to ensure participant privacy:

Is the research anonymous or confidential*? **(*Note: Cannot be both*)**

☐ **Anonymous**: The identity of the participant cannot be readily determined by the investigator AND the identity of the participant is not connected to information gathered.

☐ **Confidential**: Research participants can be identified; however, information gathered will be protected.

Provisions for anonymity/confidentiality:

☐ Secure storage (**required**)

☐ Information and biospecimens coded

What specific steps will be followed to ensure anonymity or confidentiality of participants' responses?

During data collection will recordings be made? ☐ Yes ☐ No

If Yes, *check all that apply*:

☐ Video Recording ☐ Audio Recording ☐ Mandatory Recording ☐ Voluntary Recording

If Yes, is the use of recordings detailed in the consent form? ☐ Yes ☐ No

If Yes, will recordings be retained? ☐ Yes ☐ No

If Yes, how long will recordings be retained before they are destroyed/erased?

DOCUMENT RETENTION

Length of time retained after completion of study: ***(Note: Federal regulations require that human research documents be retained for a minimum of three years AFTER the completion of the study. Some disciplines or granting agencies require longer retention times.)***

Describe information and biospecimen retention & storage location: (***Note: If the study involves the use of animals, infectious biohazards (e.g. blood), and/or recombinant DNA, it is required that approval be granted for the use of such through the appropriate compliance committee.)***

INVESTIGATOR RESPONSIBILITIES

Investigators assume the following responsibilities:

- I have read The Belmont Report "Ethical Principles and Guidelines for the Protection of Human Subjects of Research" and subscribe to the principles it contains.
- I accept responsibility for the scientific and ethical conduct of this research study.
- I will obtain prior approval from the Institutional Review Board (IRB) before amending or altering the research protocol or implementing changes in the approved consent form and/or information sheet.
- I will immediately report to the IRB any unanticipated effects on participants, which may occur as a result of this study.
- I will retain the consent forms and other research documents in a locked/secure manner for a minimum of three years. Students must turn over all documents to the primary faculty advisor upon completion of the study in most cases.
- I will complete, on request by the IRB, the Continuation/Final Review forms.
- I do not have a personal/financial conflict of interest and I have submitted my Financial Conflict of Interest Disclosure Statement in Maestro (if applicable).

(***If you have a conflict of interest, you must specify - as an attachment - the conflict of interest and describe what safeguards are in place to ensure that the conflict of interest does not affect the results.)***

- I have reviewed all forms and documents being submitted.

Principal Investigator's Signature: _____ Date: _____

Co- Investigator's Signature: _____ Date: _____