**IRB USE ONLY**

Last name \_\_\_\_\_\_\_\_\_\_\_\_\_\_

IRB # \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

IRB FORM-01

Revised 09/27/2023

**TEXAS A&M INTERNATIONAL UNIVERSITY**

**IRB Protocol Application**

**INSTRUCTIONS**

|  |
| --- |
| 1. **Complete Form**

Form must be typed and free of typographical/grammatical errors. |
|  |
|  |
| 1. **Complete Training**

PI, Co-I and anyone interacting with potential participants must complete CITI Training. Refresher training must be completed every 3 years. More details can be found at: [www.tamiu.edu/irb/irb\_training.shtml](http://www.tamiu.edu/irb/irb_training.shtml)  |
|  |
| **PRINCIPAL INVESTIGATOR MUST BE FACULTY OR STAFF MEMBER.** **STUDENTS CANNOT SERVE AS PI, BUT MAY BE A CO-INVESTIGATOR.** |
|  |
|  |
| 1. **Attach Documents to Application**
 |
|  |
| **[ ]**  | Recruitment materials as applicable: flyers, letters, scripts, e-mail, etc. |
|  |  |
| **[ ]**  | Consent documentation as applicable: consent protocol, consent form or assent form |
|  |  |
| **[ ]**  | Survey  |
|  |  |
| **[ ]**  | Any documents in a language other than English, if applicable to your study |
|  |  |
| **[ ]**  | Any other documents referenced in this application as applicable |
|  |  |
|  |  |
| 1. **Submit Application**

Submit the **original** of the complete IRB protocol (application and required documentation) to the Office of Research and Sponsored Projects in **KL426**, 5201 University Blvd., Texas A&M International University - Laredo, TX 78041. Review of proposal will not begin until **complete protocol** is received. |
|  |
|  |
| 1. **Electronic Survey Administration**

If Principal Investigator will require assistance with dissemination of electronic survey, TAMIU IRB will forward itsecurity@tamiu.edu the approved survey and approval letter, PI needs to contact itsecurity@tamiu.edu for assistance.  |
|  |
|  |
| 1. **Other Compliance Issues**

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. |
|  |
|  |
|  |
| **IF YOU HAVE ANY QUESTIONS OR NEED ASSISTANCE COMPLETING THIS APPLICATION,** **PLEASE CALL DR. ELIZABETH TERRAZAS-CARRILLO (956) 326-2656, OR E-MAIL** **IRB@TAMIU.EDU** |

**INVESTIGATOR INFORMATION**

|  |  |
| --- | --- |
| Principal Investigator Name: |       |
|  |  |
| [ ]  Faculty  |  |  |
| [ ]  Staff |  |  |
|  |  |
| Department: |       | College: |       |
|  |  |
| Phone: |       | E-mail: |       |
|  |  |
| Co-Investigator Name: |       |
|  |  |
| [ ]  Faculty  |  |  |
| [ ]  Staff |  |  |
| [ ]  Undergraduate Student  |  |  |
| [ ]  Graduate Student  |  |  |
| [ ]  Outside TAMIU  |  |  |
|  |
| Department: |       | College: |       |
|  |  |
| Phone: |      Fax:      | E-mail: |       |
|  |  |
| Please list additional investigators (if applicable): |
| *One name per line* |  |
|       |  | [ ]  Faculty  | [ ]  Student  | [ ]  Outside TAMIU  |
|       |  | [ ]  Faculty  | [ ]  Student  | [ ]  Outside TAMIU  |
|       |  | [ ]  Faculty  | [ ]  Student  | [ ]  Outside TAMIU  |
|       |  | [ ]  Faculty  | [ ]  Student  | [ ]  Outside TAMIU  |
|       |  | [ ]  Faculty  | [ ]  Student  | [ ]  Outside TAMIU  |
|       |  | [ ]  Faculty  | [ ]  Student  | [ ]  Outside TAMIU  |
|       |  | [ ]  Faculty  | [ ]  Student  | [ ]  Outside TAMIU  |
|       |  | [ ]  Faculty  | [ ]  Student  | [ ]  Outside TAMIU  |
|  |
| For protocols involving student Co-Investigators:  |
| Is this study part of their Thesis or Dissertation? |  [ ]  | [ ]  Yes  | [ ]  No  |  |
| If yes, has it been approved by the committee chair? |  | [ ]  Yes  | [ ]  No  |  |
|  |
| Thesis Committee Chair/Faculty Advisor Name: |       |
|  |
| Project Title: |       |
|  |
| Anticipated Future Start Date: |       | Anticipated End Date: |       |
|  |
| Funding Status: |
| [ ]  Externally Funded | [ ]  Not Funded |  |
| [ ]  Internally Funded | [ ]  Grant Application\* |  |
| [ ]  Other: |       |
|  |  |  |  |  |  |  |
| Funding Agency (if applicable): |       |
|  |
| ***\*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 – explain below | [ ]  No – only TAMIU IRB |  |
|  |
|       |

**PURPOSE OF STUDY**

|  |
| --- |
| Provide a brief statement, in lay terminology, outlining the purposes of this study. The following issues must be addressed:1. Why are you doing this research project and what do you propose to learn?
2. What is the justification for doing the study? Include, as appropriate, preliminary data and/or references to previous research, or gaps in our knowledge.

*If you need additional space, put "see attached" in the box below and attach your complete purpose of study statement.* |
|  |
|       |

**RISK AND BENEFITS**

|  |
| --- |
| Describe any potential risks or discomforts to the participant (including physical, psychological and/or social):Risks to participants are rated as “minimal risk“or “more than minimal risk”. **Do not say “none”.** |
|       |

|  |
| --- |
| Describe any potential benefits to the research participant or society: |
|       |

|  |
| --- |
| Describe alternatives to participation/opportunity to withdraw: |
|       |

**PARTICIPANT RECRUITMENT**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Number of Participants: |       |  |  Ages of Participants: | [ ]  18 years and older |
|

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  |  |  | Other (specify) |       |

 |
| Gender of Participants: | [ ]  Male | [ ]  Female |  |
|  |
| What are the selection criteria for participation? |
|      |

|  |
| --- |
| Does the criteria for selection exclude individuals based on gender, culture, language, economic status or ethnicity? |
| [ ]  Yes |  |
| [ ]  No |  |
|  |
| If yes, please justify exclusion: |
|       |
|  |
| Special physical or psychological conditions of participants, if any. If none, put “none”. |
|       |
|  |
| Source of Participants: |
| [ ]  TAMIU students (provide explanation below) |
| [ ]  Community (provide explanation below) |
| [ ]  Schools\* (provide explanation below) |
| [ ]  Other (provide explanation below) |
|  |
|       |
|  |
| For studies involving schools: |
| Does the study involve a school district? |
| [ ]  Yes |
| [ ]  No |
| If yes, which school district(s)?: |       |
|  |
| ***\*Note: If the study involves a school district, approval must FIRST be obtained from the school district - except in the case of grant applications. A copy of school district approval MUST be included with the protocol. If the study involves school children, the PARENTAL Consent form MUST be in English and Spanish. The language of the Child Assent form will be determined on a case-by-case basis, in most cases English is sufficient.*** |
|  |
| Vulnerable Populations: |
| [ ]  Not applicable |
| [ ]  Children **(a child assent form must be attached if the children are 7 years or older)** |
| [ ]  Pregnant women |
| [ ]  Prisoners |
| [ ]  Adults who lack the ability to consent |
| [ ]  Employees of the PI |
| [ ]  Other:  |       |
|  |
| If vulnerable populations will be used, please describe additional safeguards to protect their rights and welfare: |
|       |

|  |
| --- |
| Recruitment Methods (**all flyers, advertisements, etc. are subject to IRB Review)**: |
| [ ]  Telephone solicitation (attach script) |
| [ ]  Radio (attach script) |
| [ ]  Television (attach script) |
| [ ]  Newspaper advertising (attach ad copy) |
| [ ]  Posted notices (attach copy) |
| [ ]  Letter (attach copy) |
| [ ]  Email (attach copy of text to be sent for recruitment)\* |
| [ ]  Direct person-to-person contact, describe: |       |
| [ ]  Other:  |       |
|  |
|  |
| How will initial contact be made with potential participants? ***(be specific)*** |
|       |
|  |
| Other than as investigator, do you have any other relationship with participants?*(i.e. doctor-patient, teacher-student, counselor-student, etc.)* |
| [ ]  Yes |
| [ ]  No |
|  |
| If yes, explain the relationship and describe how you will avoid any type of coercion: |
|       |

**CONSENT**

|  |
| --- |
| **LOCATION** |
| Describe the setting where the consent process will take place (*i.e. classroom, office, park, personal computer, etc.*): |
|       |

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

|  |
| --- |
| **CONSENT TOOLS** |
| Please check all that apply and **attach to the application**: |
| [ ]  Cover letter |
| [ ]  Information sheet |
| [ ]  Telephone script |
| [ ]  Consent form |
| [ ]  Minor assent form |
| [ ]  Parental consent form |

|  |
| --- |
| **WAIVER** |
| Request for waiver of documentation of informed consent: |
| [ ]  Yes |
| [ ]  No |
|  |
| If yes, explain below and submit information sheet: |
|       |
|  |
| ***\*Note: For almost all electronic surveys, PI should request a waiver of documentation of informed consent, documenting actual signature isn’t usually possible.*** |

**COMPENSATION / COURSE CREDIT**

|  |
| --- |
| Will monetary compensation be given to the participant? |
| [ ]  Yes |  |
| [ ]  No |  |
|  |
| If yes, explain and attach a detailed compensation of payment including amount and schedule of payments to participant: |
|       |
|  |
| Will course credit be given to the participant as compensation? |
| [ ]  Yes |  |
| [ ]  No |  |
|  |
| If yes, provide details and alternate assignment to obtain equal credit: |
|       |

**SUBJECT MATTER**

|  |
| --- |
| Check the appropriate box(es) concerning the subject matter of the research: |
| [ ]  No sensitive matters  | [ ]  Criminal activity | [ ]  Psychological inventory |
| [ ]  Abortion | [ ]  Depression | [ ]  Review of criminal records |
| [ ]  AIDS/HIV  | [ ]  Drugs | [ ]  Review of educational records |
| [ ]  Alcohol | [ ]  Learning disability | [ ]  Sexual activity |
| [ ]  Body composition  | [ ]  Physical disability | [ ]  Suicide |
| [ ]  Other – specify: |       |
|  |

**DECEPTION OR COERCION**

|  |
| --- |
| Will deception or coercion be used? |
| [ ]  Yes |  |
| [ ]  No |  |
|  |
| If yes, **attach debriefing form** and briefly describe deception: |
|       |

**PROCEDURES**

|  |
| --- |
| What will participants be asked to do? (*be specific*) |
| *If you need additional space, put "see attached" in the box below and attach complete description of procedures.* |
|       |

|  |
| --- |
| Describe the location where research activities will take place: |
|       |

|  |
| --- |
| How long will the participants be engaged in research? (*length of time, i.e. 15 min, 45 min on day 1, etc.*): |
|       |

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

|  |
| --- |
| Is the research anonymous or confidential? ***(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: |
| [ ]   | Secured storage **(required)** |
| [ ]   | Replies coded |

|  |
| --- |
| What specific steps will be followed to ensure anonymity or confidentiality of participants’ responses? |
|       |

**DATA COLLECTION**

|  |
| --- |
| Research Type: |
| [ ]  Qualitative |
| [ ]  Quantitative |
| [ ]  Both |

|  |
| --- |
| Provide details on statistical analysis you plan to use (example: t-test, regression, conversion analysis, or qualitative comparative analysis): |
|       |

|  |
| --- |
| Will recordings be made? |
| [ ]  Yes |
| [ ]  No |

|  |
| --- |
| If yes, what type? |
| [ ]  Video taping |
| [ ]  Audio taping |
| [ ]  Other – specify type of recording |       |

|  |
| --- |
| Is recording? |
| [ ]  Mandatory |
| [ ]  Voluntary |
| Is the use of recordings detailed in the consent form? |
| [ ]  Yes |
| [ ]  No |

|  |
| --- |
| Will recordings be retained? |
| [ ]  Yes |
| [ ]  No |
| [ ]  If yes, how long will records be retained before they are destroyed/erased?  |       |

**CLINICAL RESEARCH**

[ ]  **CHECK BOX IF NOT APPLICABLE, AND SKIP THIS SECTION**

|  |
| --- |
| Request for waiver of HIPAA authorization: |
| [ ]  Yes |
| [ ]  No |
|  |
| If yes, explain below: |
|       |

|  |
| --- |
| Does the study involve the use of human fluid tissue and/or blood (either new specimens or existing samples)? |
| [ ]  Yes |
| [ ]  No |

|  |
| --- |
| Check all that apply to your study: |
| [ ]  Blood samples |
| [ ]  Physical measurements (electrodes, etc.) |
| [ ]  rDNA |
| [ ]  Stress exercise |
| [ ]  Urine samples |
| [ ]  Other - specify:  |       |

|  |
| --- |
| Describe below how specimens will be obtained and how they will be used: |
|       |

**DOCUMENT RETENTION**

**Federal regulations require that human research documents be retained for a minimum of three years AFTER the completion of the study AND data analysis. Some disciplines or granting agencies require longer retention times.**

|  |
| --- |
| Location where consent forms will be filed:(***Consent forms must be kept on file for 3 years after completion of the study and data analysis***) |
|       |

|  |  |
| --- | --- |
| Length of time retained after completion of study and data analysis: |       |
|  |  |
|  |  |
| Name of Principal Investigator responsible for data retention: |       |
|  |  |
|  |  |
| Signature of Principal Investigator responsible for data retention: |  |

**SIGNATURE ASSURANCES**

|  |
| --- |
| **PRINCIPAL INVESTIGATOR** |
| I understand Texas A&M International University’s rule 15.99.01.L1 Use of Human Participants in Research, and **by initialing** below, I certify: |
|  |
|       | 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 information sheet. |
|  |
|  |  |
|       | I will immediately report to the IRB any serious adverse events and/or unanticipated effects on participants which may occur as a result of this study. |
|  |
|  |  |
|       | I will complete, on request by the IRB, the Continuation/Final Review forms. |
|  |
|  |  |
|       | I do not have a personal/financial conflict of interest.  |
|  |
|  | **(*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 experimental results.)*** |
|  |
|  |
| **Principal Investigator Name:** |       |  **Date:** |       |
|  |  |  |  |
|  |  |  |  |
| **Signature :** |  |
|  |  |

|  |
| --- |
| **CO-INVESTIGATOR OR RESEARCH ASSISTANT** |
| I understand Texas A&M International University’s rule 15.99.01.L1 Use of Human Participants in Research and **by initialing** below, I certify: |
|  |
|       | 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. |
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|  |  |
|       | I will obtain prior approval from the Institutional Review Board (IRB) before amending or altering the research protocol or implementing changes in the approved information sheet. |
|  |
|  |  |
|       | I will immediately report to the IRB any serious adverse events and/or unanticipated effects on participants which may occur as a result of this study. |
|  |
|  |  |
|       | I do not have a personal/financial conflict of interest.  |
|  |
|  | **(*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 experimental results.)*** |
|  |
| **Co-Investigator Name:** |       |  **Date:** |       |
|  |  |  |  |
|  |  |  |  |
| **Signature :** |  |

|  |
| --- |
| **CO-INVESTIGATOR OR RESEARCH ASSISTANT** |
| I understand Texas A&M International University’s rule 15.99.01.L1 Use of Human Participants in Research and **by initialing** below, I certify: |
|  |
|       | 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 information sheet. |
|  |
|  |  |
|       | I will immediately report to the IRB any serious adverse events and/or unanticipated effects on participants which may occur as a result of this study. |
|  |
|  |  |
|       | I do not have a personal/financial conflict of interest.  |
|  |
|  | **(*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 experimental results.)*** |
|  |
| **Co-Investigator Name:** |       |  **Date:** |       |
|  |  |  |  |
|  |  |  |  |
| **Signature :** |  |
|  |  |

**TRAINING**

**(FOR OFFICE USE ONLY)**

|  |
| --- |
| **PRINCIPAL INVESTIGATOR** |
|  |
| IRB Member Course: | [ ]  Yes | [ ]  No | Expiration Date: |  |
|  |  |  |  |  |
| Social/Behavioral Research Course: | [ ]  Yes | [ ]  No | Expiration Date: |  |
|  |  |  |  |  |
| Biomedical Research Course: | [ ]  Yes | [ ]  No | Expiration Date: |  |
|  |  |  |  |  |

|  |
| --- |
| **CO-INVESTIGATOR OR RESEARCH ASSISTANT**  |
|  |
| IRB Member Course: | [ ]  Yes | [ ]  No | Expiration Date: |  |
|  |  |  |  |  |
| Social/Behavioral Research Course: | [ ]  Yes | [ ]  No | Expiration Date: |  |
|  |  |  |  |  |
| Biomedical Research Course: | [ ]  Yes | [ ]  No | Expiration Date: |  |
|  |  |  |  |  |

|  |
| --- |
| **CO-INVESTIGATOR OR RESEARCH ASSISTANT**  |
|  |
| IRB Member Course: | [ ]  Yes | [ ]  No | Expiration Date: |  |
|  |  |  |  |  |
| Social/Behavioral Research Course: | [ ]  Yes | [ ]  No | Expiration Date: |  |
|  |  |  |  |  |
| Biomedical Research Course: | [ ]  Yes | [ ]  No | Expiration Date: |  |

|  |  |  |  |
| --- | --- | --- | --- |
| Reviewer: |  | Date: |  |

**PROTOCOL APPROVAL**

**(FOR OFFICE USE ONLY)**

|  |
| --- |
| [ ]  **EXEMPT** |
|  |
| Reviewer: |  | Date: |  |

|  |
| --- |
| [ ]  **EXPEDITED** |
|  |
| Approved – Reviewer 1: |  | Date: |  |
|  |
|  |
| Approved – Reviewer 2: |  | Date: |  |

|  |
| --- |
| [ ]  **FULL REVIEW** |
|  |
| Referred for Full Review: |  | Date: |  |
|  |
|  |
| Approved: |  | Date: |  |
|  |
|  |
| Minutes Attached: | [ ]  Yes [ ]  No | Date of Full Review: |  |