**IRB USE ONLY**

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

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

IRB FORM-02

Revised 5/2/2019

**TEXAS A&M INTERNATIONAL UNIVERSITY**

**IRB Continuing Review Application**

|  |  |  |
| --- | --- | --- |
| IRB Protocol # |       |  |
|  |  |
| Project Title: |       |
|  |  |
| Initial Approval Date: |       | Most Recent Approval Date: |       |
|  |  |

**INVESTIGATOR INFORMATION**

|  |  |
| --- | --- |
| Principal Investigator Name: |       |
|  |  |
|  | [ ]  Faculty |  |  |
|  | [ ]  Staff |  |  |
|  |  |
| Department: |       | College: |       |
|  |  |
| Phone: |       | E-mail: |       |
|  |  |
|  |  |
| Are there any changes to project personnel?  |  | [ ]  Yes |   | [ ]  No |
|  |
| If yes, please list: |  |
| [ ]  Add | [ ]  Remove |       |  | [ ]  Faculty  |  | [ ]  Student |
| [ ]  Add | [ ]  Remove |       |  | [ ]  Faculty  |  | [ ]  Student |
| [ ]  Add | [ ]  Remove |       |  | [ ]  Faculty  |  | [ ]  Student |
| [ ]  Add | [ ]  Remove |       |  | [ ]  Faculty  |  | [ ]  Student |
| [ ]  Add | [ ]  Remove |       |  | [ ]  Faculty  |  | [ ]  Student |
| [ ]  Add | [ ]  Remove |       |  | [ ]  Faculty |  | [ ]  Student |
| [ ]  Add | [ ]  Remove |       |  | [ ]  Faculty |  | [ ]  Student |
| [ ]  Add | [ ]  Remove |       |  | [ ]  Faculty |  | [ ]  Student |
| [ ]  Add | [ ]  Remove |       |  | [ ]  Faculty |  | [ ]  Student |
| [ ]  Add | [ ]  Remove |       |  | [ ]  Faculty |  | [ ]  Student |
| [ ]  Add | [ ]  Remove |       |  | [ ]  Faculty |  | [ ]  Student |
| [ ]  Add | [ ]  Remove |       |  | [ ]  Faculty |  | [ ]  Student |
|  |
| 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: |       |

**EXTERNAL FUNDING**

|  |
| --- |
| Funding Status:  |
|  | [ ]  Externally Funded | [ ]  Not Funded |  |
|  | [ ]  Internally Funded | [ ]  Grant Application\* |  |
|  | [ ]  Other: |       |
|  |
| Funding Agency (if applicable): |       |
|  |
| ***\*Note: A copy of the grant application must be included with this form. Once grant is completed/submitted, a final draft must be submitted to the IRB.*** |

**CONTINUING DATA COLLECTION**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| Will **ONLY** already collected data be used? |  | [ ]  Yes |   | [ ]  No |  | [ ]  N/A |
| Will **ONLY** already collected clinical specimens be used? |  | [ ]  Yes |   | [ ]  No |  | [ ]  N/A |
|  |
| Does the study involve children? |  | [ ]  Yes |   | [ ]  No |  |  |
| Does the study involve a school/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.*** |

**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.
3. What is the objective of the study?

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

**RISK AND PARTICIPANT RECRUITMENT**

|  |
| --- |
| Subjective Estimate of Risk: |
|  | [ ]  minimal risk |
|  | [ ]  more than minimal risk |
|  |
| Invasive/Sensitive Procedures: |
|  | [ ]  Yes |
|  | [ ]  No |
|  |
| Sensitive Subject Matter: |
|  | [ ]  Yes |
|  | [ ]  No |
|  |
|  |
| Gender of Participants: |
|  | [ ]  Male |
|  | [ ]  Female |
|  |
| Includes all races? |
|  | [ ]  Yes |
|  | [ ]  No |
|  |
| If no, please explain: |
|       |
|  |
| Ages of Participants: | [ ]  18 years and older | [ ]  Other (specify) |  |
|  |
| Special physical or psychological conditions of participants, if any: |
|       |

|  |
| --- |
| Any changes in participant recruitment? |
|  | [ ]  Yes |
|  | [ ]  No |
|  |
| If yes, please explain and submit new recruitment material: |
|       |
|  |
| Total Participants Approved: |       |  |
|  |
| Total Participants Currently Utilized: |       |  |

**PROTOCOL STATUS**

|  |
| --- |
| Was the research ever initiated?  |
|  | [ ]  Yes |
|  | [ ]  No (when checking this box, complete the signature assurances page only and submit to IRB) |
|  |
| Is the research still in progress?  |
|  | [ ]  Yes - Data collection stage |
|  | [ ]  No - Data analysis stage |
|  |
| Any changes to the research protocol? |
|  | [ ]  Yes |
|  | [ ]  No |
|  |
| Was the research protocol **modified** during the project including: for example, a change in the informed consent document, or any other modification to the research?  |
|  | [ ]  Yes |
|  | [ ]  No |
| ***\*Note: Any change to the protocol must be reviewed and approved by the IRB before initiated.*** |
|  |
| The research protocol will be modified and revised documents are attached. |
|  | [ ]  Yes |
|  | [ ]  No |
|  |
| Have there been any adverse events regarding human participants in your investigation? |
|  | [ ]  Yes |
|  | [ ]  No |
| ***If yes, complete and attach an Adverse Event Report. Any adverse event must be reported to the IRB immediately.*** |
|  |
| To your knowledge, is there any change in the risks or benefits of participation in this study since initial review? |
|  | [ ]  Yes |
|  | [ ]  No |
| If yes, please explain the change in risks or benefits: |
|       |

**PROGRESS TO DATE**

|  |
| --- |
| Provide a descriptive summary of the progress of your study to date. The following must be addressed:1. What is the justification for continuing the study? Include, as appropriate, preliminary data, and/or references to previous research, or gaps in our knowledge.
2. If modifications to the methods in the original proposal are requested, please specify and explain.
3. If there have been any changes to the risks or benefits of the participants in the study, please specify.
4. If there have been any adverse events, withdrawals, and/or complaints about the research, please specify.

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

**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 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.  |
|  |
|  | **(*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:** |  |

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

|  |
| --- |
| **CO-INVESTIGATOR** |
|  |
| 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)**

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