Stockton University

**INSTITUTIONAL REVIEW BOARD**

**APPLICATION FOR PROTOCOL REVIEW**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **1.Date submitted:** |  | **2. Project Duration–Start Date:** |  | **End Date:** |  |
|  |
| **3. Title of Project:** |  |
|  |  |  |  |
| **4. Project Director/Faculty Sponsor:** |  | **School:** |  |
|  |  |  |  |
| **5. Funding Agency – is review required for outside funding?** | [ ]  *YES* | [ ]   *NO* |
|  |  |  |  |
| ***As the principal investigator, my signature testifies that I pledge to conform to the following:*** |
| * *As one engaged in study utilizing human participants, I acknowledge the rights and welfare of the human participant involved.*
* *I acknowledge my responsibility as an investigator to secure the informed consent of the participant by explaining the procedures, in so far as possible, and by describing the risks as weighed against the potential benefits of the investigation.*
* *I assure the Review Board that all procedures performed under the project will be conducted in accordance with those Federal regulations and University policies which govern research involving human participants. Any deviation from the project (e.g., change in principal investigator, research methodology, participant recruitment procedures, and so on) will be submitted to the IRB using the Change in Research Form for IRB approval prior to implementation.*
* *As the faculty sponsor, my signature testifies that I will oversee the research to its entirety, through to its termination. I understand that I am subject to random document checks. I will complete the CITI training and submit my certificates with the IRB application. If my data collection continues past the expiration date, I will renew my application.*
 |
| **Project Director/Faculty Sponsor** |
|    |  |  |
| (typed/printed name) |  | (signature) |  | (date) |  |
|  |  |  |  |  |  |
| **Co-Investigators** |
|    |  |  |
| (typed/printed name) |  | (signature) |  | (date) |  |
|  |  |  |
| (typed/printed name) |  | (signature) |  | (date) |  |
|    |  |  |
| (typed/printed name) |  | (signature) |  | (date) |  |
|  |  |  |
| (typed/printed name) |  | (signature) |  | (date) |  |
|  |  |  |
| (typed/printed name) |  | (signature) |  | (date) |  |
|  |
| **6. Review***This protocol for the use of human participants has been reviewed and approved by Stockton University Institutional Review Board for the Protection of Human Participants.* |
| Exempt Review [ ]   | Expedited Review [ ] Citi Training Completed [ ] ***\* Citi Training is Required \**** | Full Review [ ] Citi Training Completed [ ] ***\* Citi Training is Required \**** | Renewal [ ] **\***\*are there any changes to original project? Yes [ ]  No [ ]  |
|  |  |  | **If yes**, include description of changes |

|  |
| --- |
| **7.** **The research will be carried out in cooperation with the following institution(s): *(the box below expands as needed)*** |
|  |  |
|  |
| **8a.** **Categories of Human Subjects to be studied:**  |
|  | Proposed Age Group of Subjects (range): |  | Proposed # of Subjects: |  | # Males: |  |
| **8b. Is your research study targeting any of the following?:** |
|  | Minors (If so, include Informed Consent Form for the guardian and an Assent Form for the child.) | Yes [ ]  | No [ ]  |
|  |
|  | Non-English Speaking (If so, include all documents including the Informed Consent Form, survey, questionnaire, recruitment flyer and any other materials in English and the second language). | Yes[ ]  | No[ ]  |
|  |  |  |  |
|  | Your Own Students (If so, you’ll need to be very clear about the benefits, risks, and inducements that will be given to students). | Yes[ ]  | No[ ]  |
|  |  |  |  |
|  | Individuals with Impaired Decision-Making (Be sure to discuss how these participants will be protected. Include an Informed Consent form for the guardian if the participant is not considered his or her own guardian). | Yes[ ]  | No[ ]  |
|  |  |  |  |
|  | Individuals who are Economically or Educationally Disadvantaged (Explain why you will target a specific group.) | Yes[ ]  | No[ ]  |
|  |  |  |  |
|  | Prisoners (If so, you’ll need to be very clear about the benefits, risks, and inducements that will be given.) | Yes[ ]  | No[ ]  |
| ***\*****Note: If any of these populations will be included in your study, fully explain the rationale for including these vulnerable populations and the ways in which they will be protected in section #13 below.* |
|  |  |
| **9. Conflict of Interest Statement:** |
| Do any of the investigators have a direct or indirect personal financial interest or advisory relationship to the sponsor, manufacturer; or to the owner of the test materials? |
|  | Yes [ ]  | No [ ]  | Not Applicable [ ]  |
|  |  |  |  |
| **10. Type of Research Activity** |
|  |  |
|  | At what location will this research be conducted? |  |
|  |
| - | Will there be an advertisement for subject recruitment? | Yes [ ]  | No [ ]  |
|  |  | If yes, it must also be submitted for approval in English and any other languages needed. |  |  |
| - | Is there a survey/questionnaire? | Yes [ ]  | No [ ]  |
|  |  | If yes, attach document(s):  |  |  |
| - | Will data banks, data archives or medical record be used? | Yes [ ]  | No [ ]  |
|  |  | If yes, please indicate in #15 where the data will be stored behind two sets of lock and key. |  |  |
| - | Will there be filming or video recording of subjects: | Yes [ ]  | No [ ]  |
|  |  | If yes, please indicate in #15 where the data will be stored behind two sets of lock and key. |  |  |
| - | Will there be audio or voice recording of subjects? | Yes [ ]  | No [ ]  |
|  |  | If yes, please indicate in #15 where the data will be stored behind two sets of lock and key. |  |  |
| - | Will there be a subject inducement/payment? | Yes [ ]   | No [ ]  |
|  |  | If yes, dollar ($) amount:  |  |  |  |
| - | Does the study include biospecimens or identifiable primate information?  If so, are safeguards are in place to protect these data and are those safeguards in the ICF? | Yes [ ]  | No [ ]  |
| - | Is this project a clinical trial or behavioral health intervention?  If so, it needs a project description for external posting. | Yes [ ]  | No [ ]  |
|  |  |  |  |  |
|  |  |  |

|  |
| --- |
|  **STUDY DESIGN** |
|  |
| ***In order to review applications in an adequate and timely way, the Committee wishes to see the highlights of your proposal. We encourage you to use bullet formatting whenever possible, while providing complete and accurate information.*** **Note:** *IRB review focuses on the scientific merit and adequacy of experimental design as well as on issues of safety and protection of anonymity or confidentiality.* |
| ***\*\*Please note all boxes below expand as needed\*\**** |
| **11.** **Background and Purpose of Proposed Study:** State briefly the reason for doing the study. What question(s) is it designed to answer and why is the question being asked? Please include some current literature and references to support this project. Please limit this to no more than 3 pages. Please **do not** attach research proposals, grant applications or any other documents in lieu of a brief literature review in the box below. |
|  |  |
|  |
| **12.** **Outline of Proposed Study:** State briefly but precisely what is to be done, and the methods to be used. If the study involves the use of a questionnaire or structured interview, attach the text of such instruments as an appendix and upload it as a separate document. |
|  |  |
|  |
| **13. Participants:** Explain your rationale for including vulnerable populations, if any, and ways they will be protected. The exclusion of women and minorities in research studies must be specifically justified. If certain populations are intentionally excluded in your study, this needs to be well-documented. Indicate on the rationale which justifies their exclusion. Indicate also the composition of control groups. |
|  |  |
|  |
| **14.** **Safety:** State in adequate detail any anticipated physical, mental, or emotional risk to the subjects of this research activity and the degree of likelihood that it may occur. If no such risk is anticipated, state why this is so. If risk is anticipated, provide appropriate resources on the Informed Consent or Debriefing forms. |
|  |  |
|  |
| **15. Confidentiality:** Please indicate in adequate detail what measures will be taken to protect the confidentiality of the data to be obtained and the participant’s rights to privacy. You are required to store all data behind two (2) sets of lock and key. One set may be a password protected computer or locked cabinet. Please specify the location where your data will be securely stored. |
|  |  |
|  |
| **16. Informed Consent:** Complete and attach an appropriate consent form in 6th grade language utilizing the checklist on the web. Identify where (building and room #) the records containing the signed consent forms will be located. |
| Name those responsible for obtaining informed consent and their role in this project. |
|  |  |
|  |  |