**I. INVESTIGATORS**

|  |  |
| --- | --- |
| Principal Investigator | Co-Investigator \* |
| Name:  | Name:  |
| Department:  | Department:  |
| Address**\*\***:  | Address**\*\***:  |
| Phone:  | Phone:  |
| Fax:  | Fax:  |
| Email:  | Email:  |
| Position:[ ]  Faculty[ ]  Graduate student[ ]  Undergraduate student[ ]  Other | Position:[ ]  Faculty[ ]  Graduate student[ ]  Undergraduate student[ ]  Other |
| Funding Status: [ ]  Pending [ ]  Awarded [ ]  Non-applicable | **\***Submit the names of additional co-investigators on a separate piece of paper, including all the information requested above.**\*\***For address, include your preferred contact address. |
| If the Principal Investigator is a student include the following:Faculty Advisor: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Department: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Office Address: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_­­­­\_\_\_\_ Phone/email: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |

**II. REQUIRED CITI TRAINING**

Verify that all Faculty, Staff, Students and External Researcher(s) have active certification in the CITI Course in Human Subjects Research (initial or continuing). Protocols submitted to IRB are not considered complete until this training is up-to-date.

**III. PROJECT TITLE:**

**IV: IRB APPROVAL NUMBER:**

**V. DURATION OF PROJECT:** From (MM/DD/YYYY) to (MM/DD/YYYY)

**VI. RESEARCH STATUS:** (Please type)

**Do not write “See Attached”**

1. Include a brief summary of the results of the research to date. If applicable, describe the progress in obtaining your sample, retention of subjects, missing data and any preliminary analysis.

1. Are any changes to the protocol proposed?

[ ]  Yes [ ]  No

If yes, describe the changes and also discuss the impact to the risk on subjects.

3. Number of subjects have been accrued to date:

Number of subject to be recruited in the future:

4. Have any adverse events or problem occurred during the project?

[ ]  Yes [ ]  No

If yes, describe the adverse events or problems and also discuss the impact to the risk on subjects.

5. Have any research subjects withdrawn from the project?

[ ]  Yes [ ]  No

If yes, summarize the reason for the subject withdrawal.

6. Have there been any complaints received about the research/project?

[ ]  Yes [ ]  No

If yes, describe the complaints.

7. Are there any conflicts of interest to report?

[ ]  Yes [ ]  No

If yes, describe the conflicts of interest.

8. Have there been any changes to the originally approved consent and/or assent forms?

[ ]  Yes [ ]  No

If yes, describe the changes to the consent and/or assent forms and attached the revised documents.

9. Have there been any revisions to any project materials (materials given to subjects, recruitment materials, data collection forms, verbal scripts, and project information)?

[ ]  Yes [ ]  No

If yes, describe the changes to the project materials and attached the revised documents.

**VII. CONFLICT OF INTEREST**

Federal Guideline require assurances that there are no conflicts of interest in research projects that could affect the welfare of human subjects. If this study presents a potential conflict of interest, additional information will need to be provided to the IRB.

Examples of potential conflicts of interest in research involving human subjects may include, but are not limited to:

* An investigator or family member participates in research on a technology, process, or product owned by a business in which the faculty member holds a financial interest. Any interest should be disclosed to the IRB, regardless of whether it meets the threshold of a “significant financial interest,” as defined by the Public Health Service (PHS).
* An investigator or family member has a financial or other business interest in an entity that is supplying funding, materials, products, equipment, research subjects, or the site of data collection for the current research project.
* An investigator or family member serves on the Board of Directors of a business that is supplying funding, materials, products, equipment, research subjects, or the site of data collection for the current research project.
* An investigator or family member is employed by the organization under study.
* An investigator receives consulting income from an entity that is funding the current research project.
* An investigator participates in research on technology, process, or project development for which the investigator has intellectual property rights (e.g., copyrights, trademarks, patents, or trade secrets) or receives royalties.

**Do any members of the study team, or any of their family members, have a financial or other non-research interest in the source(s) of funding, materials, equipment, data, research subjects, or site of research related to this study?**

[ ]  Yes [ ]  No

If yes, please describe the interest.

**VIII. PRINCIPAL INVESTIGATOR/CO-INVESTIGATOR ASSURANCES**

I agree to follow all applicable policies and procedures of Walsh University and federal, state, and local laws and guidance regarding the protection of human subjects in research, as well as professional practice standards and generally accepted good research practice guidelines for investigators.

I verify that the information provided in this Continuing Review application is accurate and complete.

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Principal Investigator Co-Investigator

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Date Date

**ADVISOR ASSURANCES**

By my signature below, as advisor to the student(s) preforming research with human subjects, I agree:

* To consult with the student investigator on a regular basis to monitor study progress;
* To be available to assist the student investigator should problems arise with the study;
* To forward to the IRB in writing any information related to an adverse event immediately upon my knowledge of the event;
* To complete the CITI Course in Human Subjects Research prior to submitting this IRB application.

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Faculty Advisor

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Date