**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. PROJECT TITLE:**

**III. IRB APPROVAL NUMBER:**

**III. PROPOSED CHANGES:** (Please type)

**Do not write “See Attached”**

1. Are you requesting a change to the Principal Investigator or Co-Investigator?

Yes  No

If yes, describe the reason for the change and any impact to the project.

1. Are you requesting a change to the protocol?

Yes  No

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

3. Are you requesting a change 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.

4. Are you requesting a change to 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.

**VI. 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 Change of Protocol application is accurate and complete. I will initiate change(s) to this research only after receiving notification of final IRB approval (unless necessary to eliminate apparent immediate hazards to the participants).

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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