**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 |
| Type of Project:  Faculty Research  Student Research  Thesis/Dissertation  Other  Specify: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  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**

All Faculty, Staff, Students and External Researcher(s) involved in the research must complete the CITI Course in Human Subjects Research prior to submitting an IRB application. Protocols submitted to IRB are not considered complete until this training is completed. Include a copy of all CITI Training Completion Certificates with the IRB application.

**III. PROJECT TITLE:**

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

**V. PRELIMINARY REVIEW:** (Please type)

Summarize proposed project and procedures to which human subjects will be subjected. Please include any special instruments. **Do not write “See Attached”**

1. Describe the primary objective(s), purpose(s), hypothesis (es), and significance(s) of the research and supporting literature review:

1. Identify the basic research design of the study: (i.e., experimental, quasi-experimental, single-case, single-factor, multiple-factor designs or non-experimental, retrospective, prospective designs).

3. Description of Subjects: (include age range, selection criteria, recruitment procedures, and anticipated and desired sample size).

4. Research Procedures (to which human subjects will be subjected) including each variable, measurement instruments and their reliability and validity:

5. Risks and Benefits: Identify/Describe benefits and risks/or discomforts that will be experienced by the subjects. Include the risks and benefits in the informed consent form.

6. If you are conducting secondary research (secondary research contains information or specimens that were already collected by another study or for another purpose) with identifiable private information, are you requesting a waiver of informed consent?

Yes  No  N/A

If yes, address the following questions:

1. Are the risks to the subjects minimal?

Yes  No

If no, please explain.

1. Why is an informed consent waiver necessary?
2. Explain why the data must contain private, identifiable information.
3. Will the waiver of informed consent adversely affect the rights and welfare of the subjects?

Yes  No

If yes, please explain.

1. Will the subjects be debriefed (if appropriate)?

Yes  No  N/A

If yes, please explain the debriefing process.

7. Include a copy of the following:

Statement of Informed Consent and/or Cover Letter

Assent forms, if applicable

Copies of material given to the subjects and parents/guardians

Participant recruitment materials such as fliers and advertisements

Data collection forms including demographic data, questionnaires, surveys, interview questions, and so on. Copyrighted material that cannot be copied need not be submitted. The Committee may request to review the material.

Scripts of verbal instructions and project information

Supporting bibliography for literature review

CITI training completion certificates

Grant proposal, if applicable

8. Please answer the following questions:

1. Will subjects be identifiable either through records, responses, pictures, or identifiers (labels, numbers) linked to the subjects?

Yes  No  N/A

1. Will subjects be at risk of criminal or civil liability, changes in conditions of employment, undue damage to financial standing, or undue embarrassment if others than the principal investigator know the responses?

Yes  No  N/A

1. Does the research deal with sensitive aspects of subject's behavior such as illegal conduct, drug use, sexual behavior, use of alcohol, beliefs or values, and could present a possible invasion of privacy?

Yes  No  N/A

1. Will participants receive compensation for participation in the research study?

Yes  No  N/A

If yes, describe the incentive, including the amount and timing of all payments.

1. Does research involve the collection or study of existing data (documents, records, pathological specimens or diagnostic specimens) from sources not publicly available?

Yes  No  N/A

1. Will the subject be video/audio taped?

Yes  No  N/A

1. Are subjects free to withdraw at any time without penalty?

Yes  No  N/A

1. Does the research involve deception?

Yes  No  N/A

If yes, describe the rationale for deception involved in the study, its necessity, and any debriefing procedures that are to be done at the end of the study.

1. Does the research deal with special populations including minors under 18 year of age?

Yes  No  N/A

If yes, indicate the special populations included in the research:

Minors (under 18 years of age)  Prisoners/Arrestees

Pregnant Women/Fetuses/Neonates

If yes, include how you will provide special protections to these groups. They are entitled to special consideration under federal regulations: 45 CFR Part 46, Subparts B (pregnant women, fetuses and neonates), C (prisoners), and D (minors).

1. Are some or all of the subjects likely to be vulnerable to coercion or undue influence through means other than the special populations above?

Yes  No  N/A

If yes, include how you will provide special protections to these groups.

1. Will the research be conducted at other locations?

Yes  No  N/A

If yes, list the specific sites at which Walsh University research will be conducted:

|  |  |
| --- | --- |
| **Location Name (or description)** | **Address (street, city, and state or country)** |
|  |  |
|  |  |
|  |  |
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If yes, include documentation of the approval of the external site. This will minimally include a letter of support but may require another IRB’s approval.

**VI. 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.

**VII. 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, including, but not limited to, the following:

* Perform the research as approved by the IRB with appropriately trained (including the CITI course in Human Subjects Research) and qualified personnel with adequate resources;
* Initiate the research only after written notification of IRB approval has been received;
* Obtain and document (unless waived) informed consent and HIPAA research authorization from human subjects (or their legally authorized representatives) prior to their involvement in the research using the currently IRB-approved consent form(s) and process;
* Promptly report to the IRB events that may represent unanticipated problems involving risks to subjects or others;
* Provide significant new findings that may relate to the subjects willingness to continue to participate;
* Inform the IRB of any proposed changes in the research or informed consent process before changes are implemented, and agree that no changes will be made until approved by the Walsh University IRB (except where necessary to eliminate apparent immediate hazards to participants);
* If applicable, per your IRB approval letter, complete and submit a Continuing Review of Human Subjects Research application before the deadline for review at intervals determined by the IRB to be appropriate to the degree of risk to avoid expiration of IRB approval and cessation of all research activities;
* Maintain research-related records (and source documents) in a manner that documents the validity of the research and integrity of the data collected, while protecting the confidentiality of the data and privacy of participants;
* Retain research-related records for audit for a period of at least three years after the research has ended (or longer, according to sponsor or publication requirements) even if I leave the University;
* Contact the IRB for assistance in amending (to request a change in Principal Investigator) or terminating the research if I leave the University or am unavailable to conduct or supervise the research personally (e.g., sabbatical or extended leave);
* Provide a Final Study Report to the IRB when all research activities have ended (including data analysis with individually identifiable or coded private information); and
* Inform all Co-Investigators, research staff, employees, and students assisting in the conduct of the research of their obligations in meeting the above commitments.

I verify that the information provided in this Use of Human Subjects in Research application is accurate and complete.

I understand that Walsh University’s Institutional Review Board (IRB) is responsible for reviewing all human subjects research and is registered with the Office of Human Research Protection (OHRP) within the US Department of Health and Human Services.  Be advised that any research found noncompliant with IRB policies, procedures, and/or regulations may result in a research misconduct investigation and require the submission of a federal incident report, as well as University sanctions.

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Principal Investigator Co-Investigator

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

Date Date

**ADVISOR ASSURANCES**

The faculty advisor must be a member of Walsh University’s faculty.  The faculty advisor is considered a responsible party, along with the student investigator(s), for the legal and ethical performance of the project.

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

* To meet 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;
* To notify the IRB by letter if I will be unavailable, such as during a sabbatical, leave, or vacation, and I will arrange for an alternative faculty advisor to assume my oversight responsibility during my absence.

I verify that the information provided in this Use of Human Subjects in Research application is accurate and complete.

I understand that Walsh University’s Institutional Review Board (IRB) is responsible for reviewing all human subjects research and is registered with the Office of Human Research Protection (OHRP) within the US Department of Health and Human Services.  Be advised that any research found noncompliant with IRB policies, procedures, and/or regulations may result in a research misconduct investigation and require the submission of a federal incident report, as well as University sanctions.

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Faculty Advisor

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

Date