**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[ ]  OtherSpecify: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_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. STUDY SUMMARY**

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.

**VI. SCREENING QUESTIONS**

1. Will the research expose participants to discomfort or distress beyond that normally encountered in daily life?

[ ]  Yes [ ]  No

1. Does the research involve direct recruitment of prisoners/inmates?

[ ]  Yes [ ]  No

**If you checked YES to any of the questions above, your research is NOT EXEMPT FROM ANNUAL REVIEW. Do not complete this application. You must submit an Application for Initial Review of Human Subject Research.**

**VII. EXEMPTION CATEGORIES**

Check one or more categories of exemption for which you are applying:

[ ]  Category 1 – Educational setting

[ ]  Category 2 – Interactions involving educational tests, surveys, interviews, public behavior observation

[ ]  Category 3 – Benign behavioral interventions

[ ]  Category 4 – Secondary research with identifiable private information or biospecimens

[ ]  Category 5 – Conducted or supported by a Federal department or agency

[ ]  Category 6 – For taste, food quality and consumer acceptance studies

[ ]  Category 7 – Storage or maintenance or identifiable private information or biospecimens for secondary research

[ ]  Category 8 – Secondary research using identifiable private information or biospecimens

**VIII. EXEMPTION DETAILS (Complete the category selected in Section VII)**

|  |
| --- |
| [ ]  **CATEGORY 1 – EDUCATIONAL SETTING**1. Will the study be conducted outside of an established or commonly-accepted educational setting including, but not limited to, schools and universities?

[ ]  Yes [ ]  No 1. Will the research involve activities outside of normal educational practices (normal educational practices include research on education instructional strategies or the effectiveness of classroom instructional techniques, curricula or classroom management methods)?

[ ]  Yes [ ]  No 1. Is the research likely to adversely impact the student’s opportunity to learn the required educational content?

[ ]  Yes [ ]  No  1. Will the research adversely impact the assessment of the educator that is providing the instruction?

[ ]  Yes [ ]  No **If you checked YES to any of the questions (a-d above) in the category, your research is NOT EXEMPT. Do not complete this application, you must submit an Application for Initial Review of Human Subject Research.**  |
| [ ]  **CATEGORY 2 – INTERACTIONS INVOLVING EDUCATIONAL TESTS, SURVEYS, INTERVIEWS, PUBLIC BEHAVIOR OBSERVATION**1. Does the research involve any interventions (if yes, see category 3)?

[ ]  Yes [ ]  No  1. Will the research involve minors (under 18 years of age)?

[ ]  Yes [ ]  No **If you checked YES to either of the questions (a-b above) in the category, your research is NOT EXEMPT. Do not complete this application. You must submit an Application for Initial Review of Human Subject Research.** 1. The research must meet one of the following criteria:
	1. [ ]  The data is recorded in a non-identifiable manner (i.e., not linkable to subjects)
	2. [ ]  The data is not sensitive in nature (i.e., low risk of harm if disclosed)
	3. [ ]  The data contains identifiable information, that might be sensitive, and a limited IRB review is being requested (the current application will serve for the limited IRB review)
 |
| [ ]  **CATEGORY 3 – BENIGN BEHAVIORAL INTERVENTIONS**1. Does the research involve biomedical interventions?

[ ]  Yes [ ]  No  1. Will the research involve minors (under 18 years of age)?

[ ]  Yes [ ]  No 1. Is the intervention invasive in nature (i.e., long duration, harmful, painful, physically invasive, likely to have an adverse lasting impact, and offensive or embarrassing)?

[ ]  Yes [ ]  No **If you checked YES to any of the questions (a-c above) in the category, your research is NOT EXEMPT. Do not complete this application. You must submit an Application for Initial Review of Human Subject Research.**  1. The research must meet one of the following criteria:
	1. [ ]  The data is recorded in a non-identifiable manner (i.e., not linkable to subjects)
	2. [ ]  The data is not sensitive in nature (i.e., low risk of harm if disclosed)
	3. [ ]  The data contains identifiable information, that might be sensitive, and a limited IRB review is being requested (the current application will serve for the limited IRB review)
 |
| [ ]  **CATEGORY 4 – SECONDARY RESEARCH WITH IDENTIFIABLE PRIVATE INFORMATION OR BIOSPECIMENS**

|  |
| --- |
| Notes:* The information or specimens no longer need to be “existing”
* Secondary research containing only non-identifiable private information or specimens is not considered to be human subjects research
 |

1. The research must meet one of the following criteria:
	1. [ ]  The identifiable materials are publicly available
	2. [ ]  The data does not contain directly or indirectly identifiable information and the investigator does not plan to contact the subjects or re-identify subjects
	3. [ ]  The investigator’s use is regulated under HIPAA and “health care operations,” “research,” or “public health”
	4. [ ]  Research is conducted by, or on behalf of, a Federal agency using data collected or generated by the government for non-research purposes, and the information is protected by federal privacy standards
 |
| [ ]  **CATEGORY 5 – CONDUCTED OR SUPPORTED (FUNDED) BY A FEDERAL DEPARTMENT OR AGENCY**1. Is the project conducted by or subject to the approval of someone other than a federal department or agency?

[ ]  Yes [ ]  No 1. Is the research designed to study, evaluate or improve anything besides public benefit or service programs?

[ ]  Yes [ ]  No **If you checked YES to either of the questions (a-b above) in the category, your research is NOT EXEMPT. Do not complete this application. You must submit an Application for Initial Review of Human Subject Research.** ***If this exemption category is utilized, the project eligibility must be posted on the federal website.***  |
| [ ]  **CATEGORY 6 – FOR TASTE, FOOD QUALITY AND CONSUMER ACCEPTANCE STUDIES**1. Will the research involve taste and food quality evaluation or a food consumer acceptance study in which non-wholesome foods with additives will be consumed?

[ ]  Yes [ ]  No 1. Will the research involve taste and food quality evaluation or a food consumer acceptance study in which a food ingredient, agricultural chemical or environmental contaminant, will be above the level found safe by the Food and Drug Administration?

[ ]  Yes [ ]  No **If you checked YES to either of the questions (a-b above) in the category, your research is NOT EXEMPT. Do not complete this application. You must submit an Application for Initial Review of Human Subject Research.**  |
| [ ]  **CATEGORY 7 – STORAGE OR MAINTENANCE OF IDENTIFIABLE PRIVATE INFORMATION OR BIOSPECIMENS FOR SECONDARY RESEARCH**1. The research must meet both criteria below:
	1. [ ]  A Broad Consent form was previously completed at the time of the primary research or data collection
	2. [ ]  The data contains identifiable information, that might be sensitive, and a limited IRB review is being requested (the current application will serve for the limited IRB review)
 |
| [ ]  **CATEGORY 8 – SECONDARY RESEARCH USING IDENTIFIABLE PRIVATE INFORMATION OR BIOSPECIMENS** 1. The research must meet both criteria below:
	1. [ ]  A Broad Consent form was previously completed at the time of the primary research or data collection
	2. [ ]  The data contains identifiable information, that might be sensitive, and a limited IRB review is being requested (the current application will serve for the limited IRB review)
 |

**IX. LOCATION OF THE RESEARCH**

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)** |
|  |  |
|  |  |
|  |  |
|  |  |

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.

X. INCENTIVES TO PARTICIPATE

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.

XI. DOCUMENTATION INCLUDED

 Include a copy of the following:

[ ]  Statement of Informed Consent and/or Cover Letter

[ ]  Broad Consent, if applicable

[ ]  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

**XII. 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.

**XII. 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 under the direction of the Principal Investigator (or Advisor) by appropriately trained and qualified personnel with adequate resources;
* Understand that the parameters of the research cannot be modified without approval by the IRB (except where necessary to eliminate apparent immediate hazards to participants);
* Agree to 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;
* Will 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;
* Will 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);
* Agree to 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.

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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