**INSTITUTIONAL REVIEW BOARD FOR THE**

**UNIVERSITY OF MARY WASHINGTON**

**APPLICATION FOR RESEARCH INVOLVING THE USE OF HUMAN SUBJECTS**

**Effective 1/1/2022**

**Please note this form should be used for all IRB Applications. There is an opportunity on the form to indicate if you believe the research is Exempt, Expedited, or needs Full Board Review.**

**Prior to completing this form, read and follow the** ***IRB Instructions and Definitions*** <https://provost.umw.edu/irb/instructions-and-forms/> and review the *Manual of Policies and Procedures for the Institutional Review Board at the University of Mary Washington* at the same location.

ALL APPLICATIONS MUST BE ACCOMPANIED BY PROOF OF ETHICS TRAINING FOR EACH INVESTIGATOR INVOLVED IN THE RESEARCH

<https://provost.umw.edu/irb/irb-training/>

**This is an official form; do not alter or remove any questions or instructions on this form. To avoid delays, all questions must be answered completely. Incomplete forms will be returned to the applicant.**

**Type of Review**

What type of Review do you believe this Research falls under?

 \_\_\_\_ Exempt, please indicate category number here \_\_\_\_\_\_\_\_\_\_

 \_\_\_\_ Expedited

 \_\_\_\_ Full Board

Note: please see the Exempt Status Instructions & Definitions document for the descriptions of different research categories that fall under Exempt Status (<https://provost.umw.edu/irb/instructions-and-forms/>) . If you are unsure about the category under which your research project falls, contact the IRB Board Member from your Department (<https://provost.umw.edu/irb/board-members/> ).

**A. Project and Primary Investigator**

The individuals named below are the main contacts for communication between the IRB and the research team. List additional researchers on the Signatures page.

**1.** Title of proposal:

**2.**  Proposal abstract (Describe your study in 150 words or less):

**3**. Faculty/staff primary investigator or faculty supervisor for student research.

 Name: Email:

 Department: Phone:

 Student: Email:

**4.** Is this a revision of an application for the same study that was previously approved by the IRB?

 Yes No

**5.** Is this research being funded in whole or part with federal dollars? Yes \_\_\_ No \_\_\_

**B. Description of Research**

Briefly describe the proposed research, consistent with the *Instructions and Definitions* (<https://provost.umw.edu/irb/instructions-and-forms/>).

**1.** **Rationale for and goals of the research** *Provide a brief literature review that identifies key research in this area and what the research project seeks to examine, how the project contributes to a broader understanding of the topic identified, and whether or how the project will benefit society.*

**2.** **Method of Data collection and identification of procedures and interventions** *Describe exactly what participants will do in the study, from the moment they begin participation to the end. Describe and attach all data collection instruments, including research questions asked of participants. Indicate if any voice, video, digital or image recordings will be used and include requisite consent forms*.

**3.** **Privacy and confidentiality measures to protect participants** S*pecify how the privacy of*

*participants will be protected during the research process, in any reports or presentations, and when*

*the research is completed, including what will happen with the data when the study ends. In*

*addition, specify how any personally identifying information of participants will be protected, and*

*whether the identity of participants will be anonymous or confidential. See*

<http://www.umw.edu/documents/document/irb-expedited-instructions/> *that identifies differences*

*between participant privacy, anonymity, and confidentiality.)*

**4.** **Foreseeable risks to participants** *Identify possible risks to the participant and specify how they plan to minimize each risk. Note that the idea of risk is defined as* *exposure to danger, harm, or loss and may be physical, psychological, economic or social in nature. The goal of the* *researchers should be to specify how risk to participants, even if minimal, will be minimized.*

**5.** **Direct benefits to participants** *Specify whether the research provides tangible or direct benefits to participants, such as incentives or compensation. Specify how benefits of project outweigh any risks identified in item 4 above.*

**C. Characteristics of Research Participants**

**1. Age range of participants \_\_\_\_** Are any participants under age 18? (Y/N)

If YES, list age range of minor child participants and specify how parental or guardian consent will be obtained. Examples of Assent (if applicable) and Consent forms must be included with this application.

**2. Demographic details of participants** *(In this section researchers should provide demographic details about participants, such as race, ethnicity, sex, gender, or sexuality if that information is relevant to the study and will be collected. Researchers should only ask about participants’ sex, gender, or sexuality when it is necessary. If researchers must ask this information, they should specify why the data is being collected, how it will be used, and how that information will be protected. It is important for researchers to recognize that identity information is routinely used to target LGBTQ2S+ people and therefore make clear that the collection of such information will not be used for discriminatory purposes.)*

(\_\_ Check if applicable) Demographic information of participants will not be collected as it is not pertinent to the study.

**3.** **Are participants either mentally incompetent, or legally restricted** (e.g., institutionalized)? (Y/N)

If yes, please specify and explain the necessity for using this particular group how. In addition, researchers must identify how consent for participation will be obtained and documented.

**4.** **Participant identification and recruitment** *Specify how and by whom participants will be identified and recruited. Provide exact statements that will be used to recruit participants.*

**D. Informed Consent**

In most cases, research involving humans requires informed consent of participants. Before completing this section, **carefully read each item below and follow the *Instructions for Informed Consent*** (<https://provost.umw.edu/irb/instructions-and-forms/>) and templates provided. Under limited circumstances, the IRB may waive aspects of informed consent (see Subsections 3 and 4 below).

**1. Types of Consent** Place an X in the space provided to indicate the type(s) of informed consent that you plan to obtain from participants in your research. Select all that apply. **Attach copies of the consent form(s).**

 Informed consent of adult participants

 Informed consent of legal representative (parent or guardian)

 Assent of child participants

 \_\_\_\_\_ Broad consent (applies only to Exempt Categories 4, 7, and 8)

 \_\_\_\_\_ Participants younger than 18 years old who have a guardian consent form on file will have informed consent serve as assent

 **2.** **Translation:** Informed consent must be obtained using language the participants will understand. Place an X in the space provided to indicate if informed consent will be obtained using a language other than English, and follow instructions for obtaining translations on the *Instructions for Informed Consent.* Attach both the English version and the translation(s).

**3.** **Waiver of Signatures on Consent Forms:** Under limited conditions such as with online or telephone surveys, the IRB may waive the requirement for obtaining participants’ signatures on informed consent forms. Place an X in the space provided if you want the IRB to waive the requirement for participants’ signatures, and **explain** your reasons below, based on those instructions. **Attach the consent form(s) you plan to use**.

**4.** **General Waiver of Consent**: Under limited conditions, the IRB may waive the requirement for informed consent, as explained on the *Instructions for Informed Consent.* Place an X in the space provided if you want the IRB to waive the requirement for participants’ signatures, and **explain** your reasons below, based on those instructions.

**E. Attachments**

Place an X in the space provided for each item that accompanies this IRB application:

 Data collection instruments (all tests, surveys, interview questions, observation forms, etc.)

 Consent form(s)

 Assent forms for research with children (and a parent or guardian)

 \_\_\_\_\_ Broad consent (applies only to Exempt Categories 4, 7, and 8)

 Debriefing form

 Certificates of ethics training for each researcher, including faculty supervisor (**Required**)

 Other:

**Complete the “Signatures” page below.**

**Submit the completed IRB Application to your department’s IRB reviewer or the IRB Chair,**

**as listed on the IRB website:** <https://provost.umw.edu/irb/board-members/>

**Signatures**

**Primary Investigator or Faculty Supervisor**

If the proposed research is to be conducted by one or more UMW students, this part must be signed by the faculty member supervising the student research. Otherwise, this part should be signed by the UMW faculty member or administrative staff member who is the primary investigator and IRB contact for the proposed study. **Authentic signatures are required**.

*My signature below certifies that I have reviewed the information on this form and the attachments, and believe it is complete and accurate according to all instructions and IRB policies.* *I certify that I and, if applicable, the students I am supervising, are qualified to conduct this research and have completed the ethics training required by the UMW IRB. I will take full responsibility for the conduct of the research according to the version of this application form approved by the UMW IRB, including responsibility for notifying the IRB in case of any unanticipated problems or adverse events occurring during the research.*

 Name: Email:

 Department: Phone:

 Signature: Date:

**Additional Researchers**

All individuals involved in the collection, recording, and/or analysis of data for the proposed research must sign and provide the information below. All researchers should sign and submit certificates of ethics training. **Authentic signatures are required**.

*My signature below indicates that I understand and will follow the procedures for the conduct of the proposed research according to the Application for Expedited Status approved by the UMW IRB.*

**Researcher 1**

Indicate if you are: UMW student Faculty/Staff

 Name: Email:

 Signature: Date:

**Researcher 2**

Indicate if you are: UMW student Faculty/Staff

 Name: Email:

 Signature: Date:

**Researcher 3**

Indicate if you are: UMW student Faculty/Staff

 Name: Email:

 Signature: Date:

**Additional signature pages may be attached as needed.**