**APPENDIX B**

**INSTITUTIONAL REVIEW BOARD FOR THE**

**UNIVERSITY OF MARY WASHINGTON**

**APPLICATION FOR EXPEDITED REVIEW OF RESEARCH INVOLVING**

**THE USE OF HUMAN SUBJECTS**

**Cover Sheet**

(NOTE: This cover sheet **must** be filed with all applications. For applications needing full Board approval, only one copy of this cover sheet needs to be filed. (Throughout the application, applicants are referred to relevant sections of the *Manual of Policies and Procedures for the Institutional Review Board at the University of Mary Washington.* Any person conducting research with human subjects should be familiar with the *Manual.*) **ALL APPLICATIONS MUST BE ACCOMPANIED BY PROOF OF ETHICS TRAINING FOR EACH INVESTIGATOR INVOLVED IN THE RESEARCH.**

**TITLE OF RESEARCH:**

**SUBMITTED BY:**

Name e-mail

Dept phone

Sponsoring Faculty member (for student proposals \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**BRIEF ABSTRACT (Describe your study in less than 150 words):**

Check (🗸) as appropriate:

\_\_\_ All questions on the application have been answered.

\_\_\_ The application has been signed by the investigator and, if necessary, the advisor.

\_\_\_ If appropriate, a copy of the written or oral consent script has been enclosed.

\_\_\_ If appropriate, a copy of the written or oral debriefing script has been enclosed.

\_\_\_ I HAVE ATTACHED A CERTIFICATE OF ETHICS TRAINING

Is the research currently being funded, in whole or in part, with federal dollars? \_\_\_ yes \_\_\_ no

Has the research been reviewed by the IRB?

\_\_\_ yes (If “yes”, please give the date of the review \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_) \_\_\_ no

Do you believe that this research meets expedited review criteria?

\_\_\_ yes \_\_\_ no

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**For IRB staff use only:**

date received \_\_\_\_\_\_\_\_\_\_\_\_\_\_ IRB nbr. \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**PLEASE READ INSTRUCTIONS BEFORE COMPLETING THIS FORM**

To avoid delays, all questions must be answered. Incomplete forms will be returned to the investigator for additional information.

1. **Summary of proposal**

**a. Rationale** - Describe the specific aims of the study, hypothesis or research question, and relevant literature. A reference list can be appended if thought to be of value in the evaluation of the research. The IRB needs to understand how this study adds to the knowledge on this topic in order to weigh the risks and benefits of the proposed research. Researchers who are working with sensitive topics or special populations should include a summary of any previous research experience or relevant training.

**b. Methods** - Describe what subjects will be required to do, again explaining any technical terms or procedures. Please include any information on the validity and reliability of the instruments you propose to use. If you are giving a written test or survey, please attach a copy.

**2. Characteristics of subjects**

**a.** Sex M \_\_\_\_\_ F \_\_\_\_\_ Both \_\_\_\_\_

**b.** Potential Age Range\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ **Any** subjects under age 18? Yes\_\_\_No\_\_\_\_

**c.** Are subjects either (a) mentally incompetent, or (b) legally restricted (i.e. institutionalized)? If yes, please explain the necessity for using this particular group.

 Yes \_\_\_\_\_ No \_\_\_\_\_

**d.** Describe in detail how subjects will be identified and recruited. Provide explicit detail about how and by whom subjects will be recruited. Do NOT merely state “Volunteers.” If you will be using a specific ethnic group, please describe.

**3. Type of consent to be obtained**

**a.** Oral Consent \_\_\_\_\_ Written Consent \_\_\_\_\_

If a written informed consent form is appropriate or an oral statement of consent will be read to participants, please attach.

**b**. An ASSENT statement is required for subjects who cannot legally give consent themselves. If appropriate, please attach.

Assent statement YES\_\_\_\_\_ NO\_\_\_\_\_

**4. Confidentiality**

**a.** Indicate what precautions will be taken to ensure the privacy of the subjects.

**b.** Indicate what precautions will be taken to ensure the confidentiality of the data, both what remains in the investigator’s possession and that which is contained in reports and publications.

**c.** Will audio, video or film recording of subjects be used? Yes\_\_\_\_\_\_ No\_\_\_\_\_\_

 (If yes, specific permission must be sought in the consent letter).

**d.** What will happen to the data records when the research is completed?

**5. Risks and Benefits to Participants**

**a.** Risk to participants used in research may be minimal but is never totally absent. Given this, describe in detail any possible physical, psychological, social, political, legal, economic, or other risks to the subjects, either immediate or long range.

**b.** Describe what procedures will be used to minimize each risk you have stated above. If subjects need to be debriefed at the end of the study, a copy of the debriefing statement should be attached.

**c.** Please describe the benefits of the research to the participants in the study and to

society at large. If the subject will not benefit directly from the research, this should be so stated.

**d.** Explain how the benefits outweigh the risks involved.

**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 Exempt Status approved by the UMW IRB.*

**Researcher**

Indicate if you are: Faculty/Staff UMW student

Name: Email:

Department: Phone:

Signature: Date:

**Researcher**

Indicate if you are: Faculty/Staff UMW student

Name: Email:

Department: Phone:

Signature: Date: