UNIVERSITY OF MARYLAND EASTERN SHORE INSTITUTIONAL REVIEW BOARD
APPLICATION INSTRUCTIONS

Please prepare the body of your application and Informed Consent document as outlined in the following document.

1. Research Design/Methods

Include a brief description of the research and its purpose.

a. Is the approach appropriate and valid?

2. Subject Selection

a. Who are the subjects?

b. How will they be recruited? If you plan to advertise for subjects, include a copy of the notice.

c. From where will they be recruited?

d. Are the subjects being selected for any specific characteristics, e.g., age, sex, race, ethnic origin, religion, social or economic qualifications?

e. Provide assurance that there is equitable selection in terms of age, sex, race, ethnic origin, religion, social and or economic qualifications. If there is not equitable selection, provide a justification.

3. Procedures

a. What precisely will be done to the subjects? Explain in detail your methods and procedures in terms of what will be done to the subjects.

b. Where will the study be conducted? If not on campus, please explain the nature of your cooperative arrangement with those in charge of the research site and also attach the appropriate Human Subjects Research Approval forms from the cooperative site, if applicable.

4. Risks/Anticipated Benefit Analysis

Care must be taken to minimize the risks subjects are exposed to by participating in the research project.

a. What are the risks to the subjects?

b. How did you attempt to minimize the risks to the subjects?

c. What are the direct and indirect benefits of this research?

d. Are benefits distributed fairly among populations?

5. Privacy/Confidentiality

Adequate provisions must be made to protect the privacy of subjects and to maintain confidentiality of identifiable information.

a. Explain how procedures are in place to assure confidentiality of subjects' identification and information collected.

b. Explain how procedures protect subjects' privacy.

6. Informed Consent and Informed Consent & Assent

The following page outlines the information that must be in the consent form. Please use the following page as your template. Include a draft of the consent form that you will utilize as part of your IRB application.

Include a signature line, date line and page and number on each page ("1 of 2," "2 of 2"). The consent form should be written at a 3rd to 5th grade level, avoiding jargon or medical terms.

If the research involves minors, both assent of the minor and consent of their legal guardian is required. Ensure the forms are distinct and include each in your application. A minor is not to sign an assent form, ask that he/she checks a box stating that they read the form and print their name. The minor's their legal guardian must sign the consent form. All subjects must be given a copy of their signed consent and assent forms prior to their participation and the investigator must keep the original.

In the body of your application please address the following:

a. State how the subjects' informed assent and or consent will be obtained.
b. Address how and when the form will be returned to the subject and or legal guardian.
c. Provide assurance that the language in your Assent and Consent forms is appropriate.

7. Research Plan for Collection, Storage and Analysis of Data

a. Include a description of how data will be collected from subjects. If you plan to use a questionnaire or handout, include a copy of the questionnaire or handout.
b. Include a description of how the data will be stored.
c. Include a description of how the data will be analyzed.
d. Indicate who will have access to the data.
e. Indicate how long the data will be stored.
f. Indicate when data will be destroyed and the method of its destruction.

8. Conflict of Interest

a. Describe any potential conflicts of interest, individual or institutional, including how such a conflict would affect the level of risk to the study participants. Please consult the University of Maryland policy on conflict of interest as defined by the University of Maryland Policies and Procedures III-1.11 and can be viewed at: https://www.usmd.edu/regents/bylaws/SectionIII/III111.html
b. If a conflict of interest is probable or inevitable, provide a management plan to reduce bias in the research.

9. HIPAA Compliance

a. Does your research include the collection of protected health information (PHI)?
b. If the data to be collected meets the definition of identifiable PHI and are being used for purposes that fall within HIPAA's definition of research, an explicit written authorization (consent) from the data subject for research use is required, unless: a) the research involves only minimal risk to the subject; b) the data is used solely for activities preparatory to research; c) only deceased individual's information is used in the research; d) it is grandfathered research. Include a copy of the authorization form. Attach a copy of the form, if required.

INFORMED CONSENT

Project Title

Statement of Age of Subject (parental consent needed for minors AND assent from minors)
I state that I am over 18 years of age, in good physical and mental health, and wish to participate in the research being conducted by (state the PI's name) at the University of Maryland Eastern Shore in the Department of (Department PI is affiliated with).

Purpose Succinctly state the purpose of the research project. The purpose must be conveyed in language that is understandable by the research subject.

Procedure(s) State what the subject is expected to do to participate in the study.

Confidentiality Simply explain how privacy and confidentiality will be respected.

Risks Explain the risks associated with participation in research.

Benefits (Direct or Indirect) Explain the benefits, direct or indirect, to the participant and to the broader population.

Freedom to Withdraw and Ask Questions
I understand that I can ask questions at any time during my participation and that I can withdraw from the study at any time without penalty.

Where Medical Care is Available
In the event of injury resulting from participation in this is study, I understand that immediate medical treatment is available nearby at Peninsula Regional Medical Center. However, I understand that the University of Maryland Eastern Shore does not provide any medical or hospitalization insurance coverage for participants in the research study nor will the University of Maryland Eastern Shore provide any compensation for any injury sustained as a result of participation in this research study except as required by law.

Conclusion
You are making a decision whether or not you will participate in this study. If you give consent, you are agreeing to participate based on your reading and understanding of this form.
If you have questions regarding the study, please speak with (PI's name), the principal investigator, who can be reached at (PI's phone number and email).
If you have questions regarding your rights as a research subject, please contact the Chair of the Institutional Review Board at the University of Maryland Eastern Shore, Dr. Jennifer Bobenko by calling 410-651-7945 (office), 443-614-9226 (cell) or via email at JLHearne@umes.edu.

Each page of the Informed Consent must have a line for printed name, date and signature.

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Printed Name & Date Signature