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. It is important that you view the document that you prepare as a contract with the University. You are required to state exactly what you will do in the study and what will be done with the data and its analysis.**

**Title of the Study:**

1. **Research Design/Methods**
   a. Describe the principal investigator's (PI's) qualifications to conduct this study. The PI is the faculty member overseeing the study.
   b. Describe the experiences of the student investigator (SI) that will contribute to this study. The SI is the graduate/professional/undergraduate student(s) assisting the PI in the study.
   c. Include a brief description of the research and its goals. In this description include a relevant historical literature summary and the gaps in this literature that this study will address.
   d. Describe the methodology that will be used to achieve the study's goals.

2. **Subject Selection**
   a. Who are the subjects? Are you recruiting adults (18 years of age and above) or children (less than 18 years old)?
   b. Will you recruit federally protected populations such as children, pregnant women, prisoners, persons with diminished autonomy, or other conditionally vulnerable populations?
   c. Please state how many subjects you must recruit and the range of subjects that will ideally be recruited.
   d. How will you recruit subjects?
      - Will you use a QR code on a flyer, a post on social media with a link or QR code, email? If you plan to use a flyer, please include the flyer with your application and be sure to indicate the PI's name, UMES phone and email, and position at UMES as well as the IRB determination/approval number once it is issued.
      - If you plan to post on social media, please include the platforms on which you will post as well as a draft post. In your post, please indicate the PI's name, UMES phone and email, and position at UMES as well as the IRB determination/approval number once it is issued.
      - If you plan to send an email, please include the draft of the email and indicate how you will obtain the email addresses of the subjects. In your email, please indicate the PI's name, UMES phone and email, and position at UMES as well as the IRB determination/approval number once it is issued.
      - If you are using a QR code or link, include the link or QR code.
   e. From where will the subjects be recruited? Are you recruiting subjects from a particular location (school district, university, community center, etc)?
   f. Are the subjects being selected for any specific characteristics, e.g., age, sex, race, ethnic origin, religion, social or economic qualifications?

- Some studies require subject selection based on specific characteristics. If you study does so, please justify.
- Please state inclusion and exclusion criteria.

g. 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. Here you will list the exact steps you will engage the subjects in and how you will engage them.

- What is the overall timeline for your study?
- Will you utilize a survey, interview, focus group or some combination?
- Please provide a copy of the instrument that will be used to collect data. If using an online survey, please type your survey into the IRB application and include a link to the survey.
- How will you deliver the instrument?
- What platform will you use?
- Will this study be confidential or anonymous?
- If hardcopy survey is utilized, where will you distribute and collect?
- If you are conducting an interview or focus group, will you record the session or take notes? How will you record the session?
- How much time will the subject need to participate in your study?

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.

- If you are working with a school district, you must provide the UMES IRB approval to the school district and seek approval through their IRB/ERB, if they have one. Approvals from school districts must be submitted to the UMES IRB.
- If you are working with another university, please submit your UMES IRB determination/approval to the other institution's IRB. They may require a review in addition to the review UMES conducted.
- If you are working with a community organization, please submit a letter of cooperation with your application. For instance, if you plan to recruit subjects from a nursing home, please include a letter from the nursing home indicating that they are aware of your study and approve. It may be that the cooperating site will want to review your IRB determination prior to issuing a letter of cooperation to you.

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?

- All research has risks. Think about the risks that your subjects will encounter, uncomfortable feelings, breach of confidentiality.

b. How did you attempt to minimize the risks to the subjects?
- Will you code your study? Is your study anonymous? Are you collecting identifiable information?

c. What are the direct and indirect benefits of this research?
- What are the direct benefits of the study to the subjects?
- What are the indirect benefits of the study?

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.
- How will you protect the identity of your subjects?
- If you are using a focus group, how will you insure the privacy and confidentiality of your subjects?

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. 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.
- If you are conducting an anonymous online survey, it is best to embed the consent form at the beginning of your survey and request for the subject to take a picture or screenshot. For anonymous studies, have two options for subjects to select from: 1) Yes, I consent; and 2) I do not wish to participate in the study at this time. Only allow access to the survey if the subject selects "Yes, I consent."
- If you are conducting an online study in which the subjects' identities are confidential, please have the subjects sign the consent form electronically. State how you will return the consent form to the subject. In this option it is acceptable

to collect the email addresses of the subjects and return the consent form to them via email.
- If you hand the informed consent in hard copy to potential subjects, please state where you will interact with the subjects, how the forms will be collected and how much time you will allow for the subjects to review the consent form. Please indicate how you will return a copy of the consent form to the subject.

b. How and when will informed consent be returned to subjects?
c. Provide assurance that the language in your Assent and Consent forms is appropriate for the intended subjects. (In Microsoft Office, select Review -> Editor ->Document stats) Report the Flesch Reading Ease Score.
0-10 Professional
10-30 College graduate
30-50 college
50-60 $10^{th}$-$12^{th}$ grade
60-70 $8^{th}$ – $9^{th}$ grade
70-80 $7^{th}$ grade
80-90 $6^{th}$ grade
90-100 $5^{th}$ grade

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

a. How data will be collected from subjects?
b. How will the data be stored? Will the PI store the data in a GoogleDrive folder and share the folder with the SI? Will the PI store the data on their UMES laptop? Please do not store data on a flash/thumb drive.
c. Include a description of how the data will be analyzed. Please note the programs/methods used for analysis.
d. Indicate who will have access to the data. Only members of the study should have access to the raw data.
e. Indicate how long the data will be stored. Data must be stored for at least three years post completion of the study. The PI must retain the data for at least this period of time.
f. Indicate when data will be destroyed and the method of its destruction.
g. What will you do with the analysis? Will it be distributed as a presentation, paper, bulletin, thesis/dissertation?

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.

Please state if there is a financial conflict of interest.
If there is any other type of conflict of interest, please address in the procedures section.

**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**

**UMES Protocol ID#**

**Statement of Age of Subject**
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**
State what the subject is expected to do to participate in the study. State the expected duration of the study and how much time the subject will realistically need to dedicate to the study. If any procedures are experimental, clearly state such. State the number of anticipated subjects involved in the study. If necessary, a statement/disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject.
State the circumstances, if relevant, under which the subject's participation may be terminated by the investigator without regard to the subject's consent.

**Confidentiality**
Simply explain how privacy and confidentiality will be respected.

**Risks**
Explain the risks and or discomforts 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. Include a statement of the consequences of the

subject's decision to withdraw from the study and procedures for orderly termination of participation by the subject.

**Statement of Profit (if relevant)**
Include a statement that the subject's biospecimens (identified or deidentified) may be used for commercial profit and whether the subject will or will not share in the commercial profit.

**Statement of Compensation (if relevant)**
For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained.

**Statement of Costs to the Subject**
State any additional costs to the subject that may result from participation in the study, if applicable.

**Statement of Participation**
Your participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which you are otherwise entitled. You may discontinue participation at any time without penalty or loss of benefits to which you are otherwise entitled.

**Statement of Disclosure (if relevant)**
Include a statement regarding whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions and for research involving biospecimens whether the research will (if known) or might include whole genome sequencing)

**Statement Regarding the Collection of Identifiable Private Information or Identifiable Biospecimens (select one of the following statements and delete the other, if relevant)**
Identifiers might be removed from the identifiable private information or identifiable biospecimens and that after such removal, the information or biospecimens could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from you. ***Broad Consent required – please include the elements listed at the end of this document here.***
OR
Your identifiable private information or biospecimens collected as part of this research, even if identifiers are removed, will not be used or distributed for future studies.

**Where Medical Care is Available**
In the event of injury resulting from participation in this study, immediate medical treatment is available nearby at TidalHealth - Peninsula Regional Medical Center. However, 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 because of participation in this research study except as required by law.

**Conclusion**
You are deciding whether you will participate in this study. If you give consent, you agree to participate in the research study 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 JCBobenko@umes.edu.

| | |
|---|---|
| _____ | _____ |
| Subject's Printed Name & Date | Subject's Signature |
| _____ | _____ |
| Witness's Printed Name & Date | Witness's Signature |

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

**Broad Consent Elements:**
If broad consent is required, the following elements must be included in the consent document.
1. A general description of the types of research that may be conducted with the identifiable private information or identifiable biospecimens.
2. A description of the identifiable private information or identifiable biospecimens that might be used in research, whether sharing of identifiable private information or identifiable biospecimens might occur, and the types of institutions or researchers that might conduct research with the identifiable private information or identifiable biospecimens.
3. A description of the period of time that the identifiable private information or identifiable biospecimens may be stored and maintained (definite or indefinite), and a description of time that the identifiable private information or identifiable biospecimens may be used for research purposes (definite or indefinite).
4. Statement regarding the sharing or not of details about research studies.
5. Unless it is known that clinically relevant research results, including individual research results, will be disclosed to the subject in all circumstances, a statement that such results may not be disclosed to the subject.