UMES INSTITUTIONAL REVIEW BOARD APPLICATION FOR INITIAL REVIEW OF HUMAN SUBJECTS RESEARCH
November 2019

Name of Principal Investigator (PI) _____ Phone_____
(Faculty/Staff)
Department of PI_____

Email of PI_____

Campus Address of PI_____

Name of Co-Investigator _____ Phone_____
(Faculty/Staff)
Email of Co-Investigator_____

Student Investigator(s): Student(s), Fellow, Post-Doctoral Fellow
Name_____Phone_____Student ID #_____

UMES Sponsor for Non-UMES Investigators
Name and position_____
Department Address_____
Phone_____
Email_____

_____Inclusion of all investigators' RCR and Human Subjects Research CITI certificates and IRB approvals from other institutions (if applicable)

Project Title_____
Project Duration_____
Funding Agency _____

Please suggest whether this research may be exempt from a full IRB review by indicating all of the relevant exemption categories. Your notation is simply a suggestion to the IRB._____

Principal Investigator _____ Date_____
Signature
Co-Investigator _____ Date_____
Signature
Student Investigator _____ Date_____
Signature
Student Investigator _____ Date_____
Signature
UMES Sponsor _____ Date_____
Signature

UNIVERSITY OF MARYLAND EASTERN SHORE INSTITUTIONAL REVIEW BOARD
APPLICATION INSTRUCTIONS

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 pages outline the information that must be in the consent form. Include a final draft of the consent form that you will utilize. Consent forms should be limited to two pages, whether letter or legal size. 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.

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 FORM

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 their privacy and confidentiality of data will be maintained.

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 From 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 sign the consent form, 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).
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) or 443-614-9226 (cell).

UNIVERSITY OF MARYLAND EASTERN SHORE EXEMPTION REASONS FOR RESEARCH INVOLVING HUMAN SUBJECTS
Revised to comply with the Common Rule, January 2019
(eCFR: www.ecfr.gov)

1. **Research conducted in established or commonly accepted educational settings**, that specifically involves normal educational practices that are not likely to adversely impact students' opportunity to learn required educational content or the assessment of educators who provide instruction. This includes **most research on regular and special education instructional strategies, and research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.**

2. **Research that only includes interactions involving education tests** (cognitive, diagnostic, aptitude, achievement), survey procedure, interview procedures, or observation of public behavior (including visual and auditory recording) if at least one of the following criteria is met:
    i. The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot be readily ascertained, directly or through identifiers linked to the subjects;
    ii. Any disclosure of the human subjects' responses outside the research would not reasonably place the subject at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or
    iii. The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can be readily ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by §46.111(a)(7).

3. (i) **Research involving benign behavioral interventions in conjunction with the collection of information from an adult subject through verbal or written responses** (including data entry) or audiovisual recording if the subject prospectively agrees to the intervention and information collection and at least one of the following criteria is met:
    i. The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;
    ii. Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or
    iii. The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained , directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by §46.111(a)(7).

(ii) For the purpose of this provision, benign behavioral interventions are brief in duration, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the subjects, and the investigator has no reason to think the subjects will find the interventions

offensive or embarrassing. Provided all such criteria are met, examples of such benign behavior interventions would include having the subjects paly an online game, having them solve puzzles under various noise conditions, or having them decide how to allocate a nominal amount of received cash between themselves and someone else.

(iii) If the research involves deceiving the subjects regarding the nature or purpose of the research, this exemption is not applicable unless the subject authorized the deception through a prospective agreement to participate in research in circumstances in which the subject is informed that he or she will be unaware of or misled regarding the nature or purpose of the research.

4. **Secondary research for which consent is not required**: Secondary research uses of identifiable private information or identifiable biospecimens, if at least one of the following criteria is met:
    i. The identifiable private information or identifiable biospecimens are publicly available;
    ii. Information, which may include information about biospecimens, is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained directly or through identifiers linked to the subjects, the investigator does not contact the subjects, and the investigator will not re-identify subjects;
    iii. The research involves only information collection and analysis involving the investigator's use of identifiable health information when that use is regulated under 45 CFR parts 160 and 164, subparts A and E, for the purposes of "health care operations" or "research" as those terms are defined in 45 CFR 164.501 or for "public health activities and purposes" as described un 45 CFR 164.512(b); or
    iv. The research is conducted by, or on behalf of, a Federal department or agency using governmental-generated or governmental-collected information obtained for nonresearch activities, if the research generates identifiable private information that is or will be maintained on information technology that is subject to and in compliance with section 208(b) of the E-Government Act of 2002, 44 U.S.C. 3501 note, if all of the identifiable private information collected, used, or generated as part of the activity will be maintained in systems of records subject to the Privacy Act of 1974, 5 U.S.C. 552a, and, if applicable, the information used in the research was collected subject to the Paperwork Reduction Act of 1995, 44 U.S.C. 3501 *et seq*.

5. **Research and demonstration projects that are conducted or supported by a Federal department or agency**, or otherwise subject to the approval of department or agency heads (or the approval of the heads of bureaus or other subordinate agencies that have been delegated authority to conduct the research and demonstration projects(s), and that are designed to study evaluate, improve or otherwise examine public benefit or service programs, including procedures for obtaining benefits or services under those programs, possible changes in or alternatives to those programs or procedures, or possible changes in methods or levels of payment for benefits or services under those program. Such projects include, but are not limited to, internal studies by Federal employees, and studies under contracts or consulting arrangements, cooperative agreements, or grants. Exempt projects also include

waivers of otherwise mandatory requirements using authorities such as suctions 1115 and 1115A of the Social Security Act, as amended.

i. Each Federal department or agency conducting or supporting the research and demonstration projects must establish, on a publicly accessible Federal Web site or in such other manner as the department or agency head my determine, a list of the research and demonstration projections that the Federal department or agency conducts or supports under this provision. The research or demonstration project must be published on this list prior to commencing the research involving human subjects.

ii. [Reserved]

6. **Taste and food quality evaluation and consumer acceptance studies**:
   i. If wholesome foods without additives are consumed, or
   ii. If a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

7. **Storage or maintenance for secondary research for which broad consent is required**: Storage or maintenance of identifiable biospecimens for potential secondary research use if an IRB conducts a limited IRB review and make the determination required by §46.111(a)(8).

8. **Secondary research for which broad consent is required**: Research involving the use of identifiable private information or identifiable biospecimens was obtains in accordance with §46.116(a)(1) through (4), (a)(6), and (d);
   i. Broad consent for the storage, maintenance, and secondary research use of the identifiable private information or identifiable biospecimens was obtained in accordance with §46.116(a)(1) through (4), (a)(6), and (d);
   ii. Documentation of informed consent or waiver of documentation of consent was obtained in accordance with §46.117;
   iii. An IRB conducts a limited IRB review and makes the determination required by §46.111(a)(7) and makes the determination that the research to be conducted is within the scope of the broad consent referenced in paragraph (d)(8)(i) of this section; and (iv) The investigator does not include returning individual research results to subjects as part of the study plan. This provision does not prevent an investigator from abiding by any legal requirements to return individual research results.