
UNIVERSITY OF MARYLAND COLLEGE PARK
Institutional Review Board
Human Subject Research Determination

Principal Investigator		Email Address	
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Student/Co-Investigators		Email Address(es)	
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Department	
ORA Proposal #	

1. Project Information:

A. **Provide a brief description of the project:** Describe the specific objectives, including background information and rationale for the proposed project. This summary should be written in a way that will be intelligible to non-specialists in your specific subject area.

B. **Describe the subject population/type of data/specimens to be studied:** Identify who your subjects will be and indicate the type of data or specimens you will collect. Describe the methods in which the data or specimens will be collected, stored, and how confidentiality will be maintained.

2. Determination of *Research* – 45 CFR 46.102 (d):

Research means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge (publication, presentation, etc.)

A. For existing specimens, was the data/specimen(s) obtained in a systematic manner?

No Yes Not Applicable-does not involve the collection of existing data

B. For future data collection, will the data/specimen(s) be obtained in a systematic manner?

No Yes Not Applicable-does not involve future data collection

C. Is the project designed to develop or contribute to generalizable knowledge (publication, presentation, etc.)?

No Yes

D. Is the intent of the project to create an archive for the purpose of providing a resource for others to do research?

No Yes

E. For research only involving coded private information or specimens, was the private information or specimens collected specifically for the currently proposed research project through an interaction or intervention with living individuals?

No Yes Not Applicable-does not involve coded private information/specimens

3. **Determination of *Human Subject* – 45 CFR 46.102(f):**

Human subject means a living individual about whom an investigator (whether professional or student) conducting research obtains **(1)** Data through intervention or interaction with the individual, or **(2)** Identifiable private information.

Intervention includes both physical procedures by which data are gathered and manipulations of the subject or the subject's environment that are performed for research purposes.

Interaction includes communication or interpersonal contact between investigator and subject.

Private information includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record). Private information must be individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human subjects.

A. Does the study involve intervention or interaction with a ***human subject***?

No Yes

B. Does the study involve access to identifiable ***private information***?

No Yes

C. Are data/specimens received by the investigator with identifiable ***private information***?

No Yes

D. Are the data/specimens coded such that a link exists that could allow the data/specimen(s) to be re-identified?

No Yes

- If Yes: Is there a written agreement that prohibits the Principal Investigator, Co-Investigator, student investigator(s), and any other members of the research team from access to the link?

† No Yes

(If Yes, please explain below.)

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- Are there other legal requirements that prohibit the release of the key to the investigators, until the subjects are deceased?

No Yes

(If Yes, please explain below.)