

## IRB Standard Operating Procedure

<b>SOP</b> 11	<b>Student Investigators or Research Assistants</b>	<b>Effective Date</b> 1/1/2023
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### PURPOSE

To clarify the role and responsibility of the student when conducting research.

### DEFINITIONS

**Class projects** - any collection and/or analyses of human subjects data that are assigned as an educational exercise in the context of a specific course.

**Faculty or staff advisor/sponsor** - a qualified faculty or staff member of the University who oversees and supervises the student investigator's research and serves as a co-investigator or faculty sponsor in the student's research.

**Generalizable knowledge** - information which has the potential to be expanded from the isolated circumstances in which it is acquired to any broader context.

**Human subject** - a living individual about whom an investigator (whether professional or student) conducting research: (i) Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or (ii) Obtains, uses, studies, analyzes, or generates identifiable private information.

**Identifiable private information** - private information for which the identity of the subject is or may readily be ascertained by the investigator or associated with the information.

**IRB** - an institutional review board established in accord with and for the purposes expressed in the federal regulations for the protection of human research subjects.

**Minimal risk** - the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

**Research means** - systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.

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## POLICY

### Students Conducting Research as Investigators

When students enrolled in University conduct research in the role of investigator, the students' research must be overseen by University faculty or staff members. Research conducted by undergraduate students/graduate students/postdoctoral scholars that include human subjects research as defined by the federal regulations. Such projects include, but are not limited to, honors theses, and graduate theses. Research initiated by undergraduate students, and graduate students (including staff conducting human subjects research in fulfillment of a degree program) requires a faculty or staff advisor/sponsor to serve either as a co-investigator or a faculty sponsor.

Student scholars planning to conduct a research project involving human subjects must work in collaboration with their faculty or staff advisor/sponsor, who is then responsible for ensuring the IRB application is complete and accurate. All interactions, from original submission through the termination and final report will take place between the IRB staff and the student investigator who is the Primary Investigator (PI) on his/her/their research. To the extent that student investigators will be interacting with human subjects, regardless of whether their project meets the federal regulations' definition of human subjects research, care must be taken to ensure that those subjects are treated with respect and courtesy, do not have their privacy invaded, and are not subjected to unnecessary discomfort (physical or emotional). It is important that the faculty or staff advisor/sponsor overseeing the research fully understands the scope and intent of the student investigator's research. The faculty or staff advisor/sponsor must provide clear and unambiguous guidelines to those student investigators with respect to their interactions with their subjects. It is the faculty or staff advisor/sponsor responsibility to ensure that the student's research is grounded in theory, uses the appropriate research methodology, targets the correct participants, meets all ethical and federal regulations, and contributes to existing research.

### CITI Training Necessary

The faculty or staff advisor/sponsor and the student researcher must successfully complete the online CITI training prior to initiating or conducting in human subjects research. It is the faculty or staff advisor/sponsor's responsibility to ensure that successful completion of CITI training has been achieved by the student researcher. CITI certification must not expire during the term of data collection.

## PROCEDURES:

The student investigator will complete the most current application and forms available on the IRB

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website and submit all required documents electronically. Instructions for preparing the application are available on the IRB's website. Using the University application, the student investigator must submit their IRB application to their faculty or staff advisor/sponsor for their review and approval prior to submitting to University IRB.

## REGULATIONS

[45 CFR 46.102](#)

## CONTACT INFORMATION

Please direct questions or concerns about this policy to:

<b>Contact</b>	<b>Title/Role</b>
Brett Gordon	IO IRB Chair

## DISCLAIMER

The University reserves the right to modify or amend sections of this IRB SOP at any time at its sole discretion. This IRB SOP remains in effect until such time as a suitable Institutional Official or IRB Member requests review or exception to this SOP.