

James Madison University Office of Research Integrity and Institutional Review Board Standard Operating Procedures			
TITLE: Students & Research Assistants as Participants			
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OBJECTIVE

To address research that involves the dual role students as research assistants that also wish to serve as participants in their own research, excluding research on themselves.

GENERAL DESCRIPTION

A student's decision about research participation may not affect (favorably or unfavorably) grants, potential letters of recommendation, or other opportunities or decisions made by teacher-investigators. Recruitment of students as research participants must be designed to minimize the possibility of coercion or undue influence. Students (individuals or groups) should not be selected solely on the basis of convenience when they would not otherwise be appropriate for inclusion. Additionally, potential participants should be solicited from a "broad base" of individuals meeting the conditions for study, rather than by personal solicitation of specific students when possible.

DEFINITIONS

Coercion occurs when an overt threat of harm is intentionally presented by one person to another in order to obtain compliance.

Perceived coercion is an internalized sense of pressure related to participants as a research subject in a teacher-investigator's research protocol.

Undue influence occurs through an offer of an excessive, unwarranted, inappropriate, or improper reward or other overture in order to obtain compliance.

For IRB Purposes:

1. **Investigators** are defined as all persons who contribute significantly to the design and implementation of a study protocol. Investigators do not participate in the research as participants.
2. **Research Assistants** are all persons who contribute to the implementation of the study, including interaction with subjects and/or access to data, but do not participate in the design and development of the study protocol. Research assistants may participate in feasibility studies and pilot testing. However, that data gathered from the use of research assistants as participants from either of these endeavors cannot contribute to the final analysis. **Research assistants do not participate in the research as participants, unless it is external pilot data.**

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- a. **External pilot studies** are defined as a rehearsal of the main study where the outcome data are not included as part of the main trial outcome data set.

Some exceptions to this are the research assistants are part of a demographic that is unable to be obtained outside of the laboratory. In this case, through Full Board review, it will be determined how the environment can be the least coercive. The IRB has the final decision on all exceptions and will review each exception on an individual basis.

RESPONSIBILITY

Execution of SOP: Principal Investigator (PI)/ Study Personnel, IRB Chair, IRB, ORI, Provost and Senior Vice President for Academic Affairs, Vice Provost for Research, Economic Development and Innovation (VPREDI)

REVISION HISTORY

Version No.	Brief Description of Changes	Created on Date
00	Creation of SOP	11/7/2022
01	Updated title of Vice Provost for Research, Economic Development and Innovation (VPREDI)	9/22/2023

SIGNATURE HISTORY

Name and Title	Signature	Date

REFERENCES

[The Belmont Report](#)