

James Madison University Office of Research Integrity and Institutional Review Board Standard Operating Procedures			
TITLE: Blanket/Umbrella Protocol			
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OBJECTIVE

To provide guidance blanket or umbrella protocols.

GENERAL DESCRIPTION

Some student projects conducted to fulfill course requirements involve activities that meet the definition of human subjects. Therefore, for classroom projects only, faculty members may request a blanket/umbrella protocol application to cover one-time research projects (i.e., projects that are not longitudinal and only exist during the semester in which the course is taught) for students enrolled in a given undergraduate or graduate course. In such cases, the faculty member will have the primary responsibility for submitting the IRB blanket/umbrella protocol and to supervise the work of the students in that course.

Requirements:

Topics must be listed on the protocol ahead of time with a one-sentence purpose statement and **may not** include:

- 1) more than minimal risk
- 2) vulnerable populations
- 3) externally funded projects
- 4) sensitive personal questions are included (e.g., alcohol/drug use, sexual behavior/attitudes, criminal activity, medical history, grades/test scores, etc.), that are not asked anonymously
- 5) data that is archived/saved for future use

Blanket/Umbrella protocols may not be used for collaborations external to JMU, funded research, doctoral dissertations, master's theses, or honor's theses.

Faculty Responsibilities

- 1) Assume responsibility for the projects and assure that the guidelines are met.
- 2) Provide clear framework and parameters for the topic(s) that will be explored in the classroom research.
- 3) Provide all survey instruments and interview questions while also knowing that amendments may need to be made as goals change throughout the semester.
- 4) Every student in the class must be listed on the protocol.
- 5) Provide final details of each project in the IRB Final Report form. **This form must be completed within four weeks of the end of the semester.**

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All faculty must submit a summary of the classroom projects completed under the blanket/umbrella protocol within the protocol application. The faculty member must maintain all documentation, including all consent forms and research protocols, associated with the sub-projects completed under the blanket/umbrella protocol. The documentation should be kept by the faculty member for a period of 3 years after completion of the research project and must be provided to the IRB upon request. **All students listed on the protocol must have passed the IRB Social/Behavioral Research Course through CITI.**

RESPONSIBILITY

Execution of SOP: Principal Investigator (PI)/ Study Personnel, IRB Chair, IRB, ORI Staff, ORI Director, 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	6/24/2022
01	Updated title of Vice Provost for Research, Economic Development and Innovation (VPREDI)	9/22/2023

SIGNATURE HISTORY

Name and Title	Signature	Date