



RESEARCH PROTECTIONS OFFICE

Determine if the Project Requires IRB Review

[RPO](#) | [Human Subjects Research](#) | [Electronic Submission Guide](#)

Introduction

You need to answer the following three questions to determine if your project requires IRB review and approval.

1. IS UVM or UVMMC engaged in the activity?

An organization is considered engaged in human research when its employees or agents, for the purposes of the nonexempt research project, obtain:

1. Data about the subjects of the research through intervention or interaction with them;
2. Identifiable private information about the subjects of the research;
3. The informed consent of human subjects for the research; or
4. When the institution receives a direct federal award to conduct human subjects research, even when all activities involving human subjects are carried out by a subcontractor (that is, employees or agents of another institution).

See section [3.7 of the IRB Policies and Procedures Manual](#) for more information about engagement.

2. Is the activity in which you will be engaged RESEARCH?

Research is defined as a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. Whereas quality improvement projects or program evaluation projects systematically collect data for administrative, clerical, or reporting purposes.

See section [3.6 of the IRB Policies and Procedures Manual](#) for more information about not research determinations.

The IRB does not review projects that are not considered research.

Please use our [Self-Determination Tool](#) to assist you in making your own determination if the project is research or not research.

3. Will the activity involve HUMAN SUBJECTS?

Human subject means a living individual about whom an investigator (whether professional or student) conducting in 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 or identifiable biospecimens.

See our [Assessing whether there are "Human Subjects" in research page](#) for more detailed information.

If YES to all of the above, then this is considered HUMAN SUBJECTS RESEARCH and thus requires submission of applicable materials for appropriate level of IRB review or exempt determination.

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Grant Proposals Lacking Definite Plans for Involvement of Human Subjects

See section [14.3 of the IRB Policies and Procedures Manual](#).



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