

## Note to Faculty

All student research, whether reviewed or not, must be supervised by a faculty member who is responsible for the student's research conduct; this includes adherence to USM Policy and Procedures for Human Subject Research and research ethics.

Refer to: THE ROLE AND RESPONSIBILITIES OF THE FACULTY ADVISOR: USM IRB GUIDANCE

## Useful Web Pages

### ORIO Homepage:

<https://usm.maine.edu/orio/>

### Human Research Protection Program

[www.usm.maine.edu/orio/institutional-review-board-irb](http://www.usm.maine.edu/orio/institutional-review-board-irb)

### Resources:

<https://usm.maine.edu/orio/human-research-protection-program-hrpp>

### CITI Online Training:

<https://usm.maine.edu/orio/irb-human-subject-research-training/>

### Office of Research Integrity and Outreach (ORIO)

126 Bedford Street, Portland ME  
Tel: (207) 780-4517  
Email: [usmorio@maine.edu](mailto:usmorio@maine.edu)

## Office of Research Integrity and Outreach



## Guidelines for Conducting Human Subjects Research

## Definitions 45 CFR §46

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

**Human Subject Research** is defined as a living individual about whom an investigator conducting research obtains (1) data through intervention or interaction with the individual, or (2) identifiable private.

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

Common acronyms:

- Human Research Protection Program (HRPP)
- Institutional Review Board (IRB)
- Human Subject Research (HSR)

## Special Populations

- Minors (under 18 years of age)
- Prisoners
- Individuals with a diminished capacity to give informed consent
- Pregnant women (in studies that may influence maternal health)
- Fetuses or products of labor and delivery

## Categories of Sensitive Information

- Information relating to sexual attitudes, preferences, or practices.
- Information relating to the use of alcohol, drugs or other addictive products.
- Information pertaining to illegal conduct.
- Information that if released could reasonably damage an individual's financial standing, employability, or reputation within the community.
- Information that would normally be recorded in a patient's medical record and the disclosure of which could reasonably lead to social stigmatization or discrimination.
- Information pertaining to an individual's psychological well-being or mental health.
- Genetic information.

## Things You Will Need to Know Before You Submit Your Research Protocol

- Handwritten submissions are not accepted. Submit online.
- Online submission provides a copy of your protocol submission to you and your Faculty Advisor.
- CITI training certificates are required for anyone conducting research at USM and Faculty Advisors overseeing student research.
- All resumes, consent forms, surveys, support letters, recruitment scripts, and any other pertinent information related to your research should be submitted with your application.
- Protocol submissions are reviewed in the order in which they are received.
- Review will be delayed when revisions are required.
- You cannot begin your research until you receive IRB or ORIO approval.
- Submit early to avoid delay of your research project.
- Call or email the Office of Research Integrity and Outreach (ORIO) with your questions.

### Human Subject Research?

#### Request for Determination of Human Subject Research

If you are not sure your research is human subject research, submit the **Request for Determination of Human Subject Research** form.

In the form, please provide a **thorough** paragraph of your research objectives for the reviewer.

You will receive written notification and instructions as to how to proceed.

<https://usm.maine.edu/orio/human-research-protection-program-hrpp/>

### Required Training before Submitting HSR Protocol

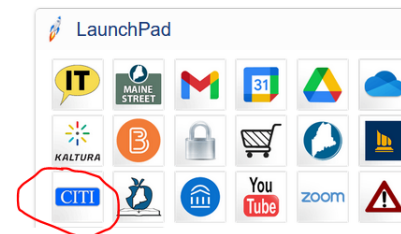
#### Complete the CITI Training Module

In order to receive approval for human subject research, all Investigators and Faculty Advisors overseeing student research are **required** to complete the Collaborative Institutional Training Initiative (**CITI**) Training Module. **Social & Behavioral Basic/Refresher.**

Upon completion, maintain a copy of your completion report. CITI Training must be renewed every four years.

Investigators cannot have protocols approved without completing this educational requirement.

<https://usm.maine.edu/orio/irb-human-subject-research-training/>



### Human Subject Research!

#### IRB Review of Human Subject Research using eProtocol

If your research is deemed Human Subject Research, initiate an electronic protocol using eProtocol online.

- If you are not already in eProtocol, request a User ID. Your Faculty Advisor as well;
- <https://usm.maine.edu/orio/irb-submission-process/>
- Thoroughly and thoughtfully answer all the questions;
- Upload relevant attachments: resumes, questionnaires, consent forms, support letters, tests, recruitment samples, etc;
- Your Faculty Advisor reviews and submits the protocol.

If any of the above are missing or not answered thoughtfully, the protocol may be returned, delaying approval.

Guidance and Resources:  
<https://usm.maine.edu/orio/irb-guidance-and-resources/>