Collaborative IRB

USM has a unique Collaborative IRB Model where many institutions take part in the IRB. https://usm.maine.edu/orio/collaborative-institutional-review-board-irb/

AAHRPP Accreditation: ORIO has voluntarily gone through the rigor of accreditation **for** research participants. AAHRPP standards go "above and beyond" and recognize additional requirements that must be met should research be supported by other entities.

ORIO Homepage:
www.usm.maine.edu/orio

Human Research Protection Program
https://usm.maine.edu/orio/human-research-protection-program-hrpp/

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

CITI Online Training Guides:
https://usm.maine.edu/orio/irb-human-subject-research-training/

Standard Operating Procedures (SOPs): https://usm.maine.edu/orio/irb-policies-and-procedures/

Office of Research Integrity and Outreach (ORIO)

126 Bedford Street, Portland ME
Tel: (207) 780-4517
Fax: (207) 228-8405
Email: usmorio@maine.edu

Office of Research Integrity and Outreach

USM UNIVERSITY OF SOUTHERN MAINE

Guidelines for Conducting Human Subjects Research

AAHRPP

Association for the Accreditation of Human Research Protection Programs, Inc.®

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.

Acronyms:
- Office of Research Integrity and Outreach (**ORIO**)
- Human Research Protection Program (**HRPP**)
- Institutional Review Board (**IRB**)
- Human Subject Research (**HSR**)
- Research Compliance Administrator (**RCA**) or Human Protections Administrator (**HPA**)
- Standard Operating Procedure (**SOP**)
- Collaborative Institutional Training Initiative (**CITI**)

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.

Human Research Protection Program (HRPP)

- Request for Determination of Research Involving Human Subjects: ORIO must determine whether any data collection activities meet either the DHHS definitions of research with human subjects or the FDA definitions of clinical investigation with human subjects.
- Exempt: Research activities are exempt from the human research protection regulations when the only involvement of human subjects falls within one or more categories. Only the IRB can make this determination.
- Expedited: Expedited review procedures allow the IRB to review and approve studies that meet the categories adopted by the U.S. DHHS or the FDA that involve no greater than minimal risk without convening a meeting of the full IRB.
- Full Board: Greater than minimal risk, research is classified, or research category does not appear as eligible for expedited review.

Policies and Procedures
https://usm.maine.edu/orio/irb-policies-and-procedures/

Required Training before Submitting HSR Protocol

Collaborative Institutional Training Initiative (**CITI**)

In order to receive approval for human subject research, all Investigators are **required** to complete the applicable Collaborative Institutional Training Initiative (**CITI**) Training Module.
Social & Behavioral Basic/Refresher or ***Biomedical Research Basic/Refresher.***

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

Investigators and research staff cannot have human subject research protocols approved without completing this educational requirement.

Visual Guides for new and returning CITI users:
https://usm.maine.edu/orio/irb-human-subject-research-training/
Affiliate with **University of Maine System**

Human Subject Research!

IRB Review of Human Subject Research using Cayuse

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

- If you are not already in Cayuse, request a User ID.
- New Protocols:
https://usm.maine.edu/orio/irb-submission-process/
- Upload relevant attachments: resumes/CV, questionnaires, consent forms, support letters, tests, recruitment samples, and any other pertinent information related to your research should be submitted with your application.
- Review will be delayed when revisions are required. Plan to submit 30 days prior to collecting data.
- Research cannot begin until the IRB has approved the submission.

Additional Resources:
https://usm.maine.edu/orio/irb-guidance-and-resources/

Consent

Consent checklist: https://usm.maine.edu/orio/wp-content/uploads/sites/361/2022/08/IRB-Informed-consent-checklist.pdf

Types of Informed Consent/Assent/ Parental Permission:

- **Informed Consent**: subjects completely informed of all aspects and signature required
- **Waiver of Documentation of Informed Consent**: subjects completely informed of all aspects but no signature required
- **Alteration of Informed Consent:** one or more required elements are altered or not included, including a signature requirement
- **Waiver of Informed Consent**: subjects are not informed of the research

Mandatory statement:
If you have any questions or concerns about your rights as a research subject, you may contact the USM Research Compliance Administrator at (207) 780-4517 and/or email usmorio@maine.edu.
Information for Participants: https://usm.maine.edu/orio/irb-information-for-research-participants/