



## **INSTITUTIONAL RESEARCH PROCESS AT MCCS**

All research requests must be reviewed by the System Chief Academic Officer, who is the Institutional Official. Research meeting the following conditions must also be reviewed by the USM IRB or its designee and in some cases by the president. This procedure is intended to ensure that the College staff and students who may be affected by the research can be certain that the research is sound and does not violate board policy, college operating procedures, or federal regulations concerning the protection of human participants.

### **Research requiring only MCCS Institutional Official Review and Approval:**

Research involving human subjects conducted by **researchers who are affiliated with another educational institution** who have received approval by their institution's review board for the protection of human subjects are required to obtain permission directly from the Institutional Officer at MCCS before beginning data collection. The approval process is outlined below and must be fully completed by all outside researchers prior to implementation.

### **Research requiring MCCS and USM IRB Review and Approval:**

All research involving human subjects conducted by any employee or agent of MCCS (faculty, staff, students, etc.) must receive IRB review and approval prior to implementation. The approval process is outlined below and must be fully completed by all employee or agent researchers prior to implementation.

### **USM Institutional Review Board:**

MCCS has joined the USM Institutional Review Board which is led by the University of Southern Maine (USM). The USM IRB agrees to provide Institutional Review Board (IRB) review of human subject research covered by the Federalwide Assurance (FWA) of Maine Department of Corrections (MDOC). The USM IRB will have each protocol reviewed by at least one IRB member or designee for the Expedited protocols and at least 2 IRB members or designees plus the Fully Convened IRB for each of the Full Board protocols; review protocols in accordance with applicable human subject regulations and or guidance (such as The Common Rule 45 CFR 46, et seq.); review research design and methodologies to ensure that risk is minimized and make recommendations for any required changes; ensure that proper procedures for obtaining informed consent, data protection and confidentiality are implemented; and if the IRB or its designee approves a research protocol, issue an approval letter with an approval period

of up to 1-year; conduct appropriate protocol monitoring; and review any protocol amendments submitted to the IRB during the approval period.

### **APPROVAL PROCESS:**

#### **Approval Process for human subjects research conducted by an outside researcher who is affiliated with another educational institution:**

- Research involving human subjects must have received approval by their institution's review board.
- A request to conduct the research, including a brief description of the research, must be made in writing to the office of the Vice President in advance of implementation.
- The research tool must be submitted for review and approval prior to use.
- Copy of the IRB approval from the sponsoring institution needs to be submitted.

Please note that no course credit or any other incentive or reward connected to the grade for the course may be used. Student participation must be voluntary.

#### **Approval Process for human subjects research conducted by any employee or agent of MCCS:**

1. Submit a Research Request to the Institutional Officer at MCCS, who must sign off on the proposal.
2. Submit an application for approval of the research study, including a detailed plan for the protection of any human subjects who will be participants in the research study, as well as the full research protocol, to the USM IRB (IRB). The procedures for obtaining IRB approval are detailed on the WEB page for the USM Office of Research Integrity and Outreach <https://usm.maine.edu/orio/collaborative-institutional-review-board-irb/>. Specifically:
  - A. If you have a new protocol you would like to submit for IRB review or need to take action on an existing protocol submitted using e-Protocol, please visit the <https://usm.maine.edu/orio/irb-submission-process/> page.
3. Approval must be obtained from the USM IRB before the study can begin. All research activities involving human subjects must receive review and approval BEFORE they are initiated. Approval is documented formally, on signed letterhead. Email notification should not be construed as approval. Until approval from the USM IRB is given, subjects may not be recruited or contacted for potential participation, or any data collected. If such approval is not given, the study cannot be conducted. The Institutional Officer must approve the entire project once IRB approval has been received.
4. Please note that FERPA grants students significant rights of access to their educational records. It also protects the privacy of student records and requires the College to inform students of all their rights and safeguards. Only material classified as "directory" information

can be released without student consent. Directory information as defined by MCCS includes: the student's full name, home town, date-of-birth, fact that student is or was enrollment, enrollment status, class level and major and minor fields, dates of attendance, degree awarded, dean's list, honors, awards received, cumulative credit hours, participation in officially recognized activities and sports, certain biographical information on athletes, MCCS email address, picture, credit hour load, and periods of enrollment. Research that depends on use of non-directory information, such as students' addresses, will require FERPA review and probable alteration to the research plan in order to proceed.

5. Research that involves only passive observation or archival data (accessible to the public) does not require IRB approval. In these situations, no new information is obtained directly from human subjects and identities are not revealed. Instructors who require research (other than literature searches) as part of course requirements should see the IRB website for guidelines on whether IRB approval is required. Instructors and advisors are urged to contact the IRB office at any time for consultation about student projects.
6. If the research study involves classroom or university department time and/or assistance, in addition to USM IRB and FERPA approval, the researcher must obtain the written permission of the class instructor or department chair (as appropriate) before proceeding with the actual study. Approval by the USM IRB and FERPA clearance do not require or obligate the instructor or supervisor to give permission, as he or she retains the right to deny such permission.
7. MCCS students, faculty, or staff members have the right to refuse to participate in approved research studies. If MCCS students, faculty, or staff members are involved as research subjects, their individual permission is required before the researcher can proceed. If they refuse to participate, they cannot be penalized or inconvenienced in any manner for their refusal to participate.

#### NOTE

Applicants seeking full-board review: Submissions for IRB review must be received 30 business days prior to the next IRB meeting. Submissions that are incomplete or in need of major revisions will be reviewed at the next available IRB meeting.

Applicants please note that most applications require more than one review because the IRB often requests additional information and/or changes. Therefore, applicants should leave ample time for additional review before the anticipated research start date.

If you have any questions or would like to request assistance please contact the Office of Research Integrity and Outreach (ORIO) at: [usmorio@usm.maine.edu](mailto:usmorio@usm.maine.edu) or 207-780-4517.