**Investigator Responsibilities**

The MSOE **Institutional Review Board (IRB)** is an administrative body established to protect the rights and well-being of human subjects recruited to participate in research activities. MSOE complies with requirements set forth in Title 45, Part 46 of the code of Federal Regulations (45 CFR 46), known as the “Common Rule,” as well as Wisconsin State laws and MSOE policies.

All students, staff, and faculty at MSOE planning to conduct research involving human subjects must submit an IRB protocol application packet for review by the IRB. Investigators must obtain approval from the MSOE IRB before human subject recruitment and research begins. See MSOE’s IRBNet Document Library for necessary forms at [http://www.irbnet.org](http://www.irbnet.org).

The purpose of the IRB is to ensure adequacy of the research plan, to minimize risks, and to maximize benefits for human subjects who participate in research activities. If the investigator is a student, the research must be performed under supervision of an MSOE faculty or staff member who, by his or her signature, assumes responsibility for the conduct of the research with respect to proper safeguards of the rights of human subjects (participants).

Research is defined (45 CFR 46.102(d)) as “a systematic investigation, including methodology, development, testing and evaluation, designed to develop or contribute to generalizable knowledge.” This definition includes formal investigations from which the results will be publicly disseminated, pilot projects, exploratory research, and educational research.

IRB approval is required before research is undertaken by students for classroom work, independent study, senior design, nursing professional practice projects, surveys, master’s degree theses, or any purpose not specifically listed. This includes research with human subjects (participants) conducted for non-academic purposes, as well.

Human subjects are defined (45 CFR 46.102(f)) as “a living individual about whom an investigator conducting research obtains data through intervention or interaction with the individual or the collection of identifiable private information.” Human subjects give consent prior to and during their participation in the research project and may stop their involvement at any time without consequence.

Intervention includes both physical procedures by which data is gathered (blood pressure readings, exercising, equipment design, etc.) and manipulations of the participant or the participant’s environment (light, temperature, etc.).

Interaction includes communication and interpersonal contact between the investigator and participant (interviews, focus groups, surveys, etc.). Private information includes academic, financial, medical, and other documents about behavior that occurs in a context in which the participant can reasonably expect that no recording is taking place, or information the participant has provided for a specific purpose with reasonable expectation that the information will not be made public.

**Submission to IRB**

A proposal for research to be conducted at MSOE, using MSOE faculty, staff, students, or affiliates, must be submitted to the MSOE IRB, even if the PI is from another institution. If the planned research is a multi-site investigation, the PI should contact the IRB Administrator at [IRB@msoe.edu](mailto:IRB@msoe.edu) to discuss multi-site approval processes.

Proposals for research projects conducted as classroom activities need to be submitted to the MSOE IRB if the intention is to share results of the project in a public forum or through publication. Data collection by students or faculty/staff for assessment purposes does not need MSOE IRB approval.
Class projects in which results will only be presented to students enrolled in the course and instructor(s) assigned to the course do not need IRB approval. It is the instructor’s responsibility to ensure that there are minimal risks for both the student researchers and their participants. “Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves that those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.” (45 CFR 46.102(i)).

It should also be noted, however, if the instructor assumes that the project could lead to further presentation of results, either through publication or public forum, those projects will need to be reviewed by the IRB. Results of research projects conducted in the classroom cannot be presented outside of the classroom without IRB approval; retroactive IRB approval is never granted.

Documentation of Consent

Investigators obtain data through intervention or interaction with an individual, or identifiable private information (45 CFR 46.102(f)). With informed consent, investigators protect the rights and welfare of their participants using clear explanations of what information will be gathered from participants and how those data will be protected.

Privacy (having control over the extent to which a person shares details about self) and confidentiality (the treatment of information disclosed by an individual in a relationship of trust) are essential elements for respectful interactions between researchers and participants. Considerations on privacy and confidentiality must be present throughout the research project protocol from beginning to end (e.g., participant recruitment, disseminating final analyses of findings, follow-up, maintenance of research records, etc.).

Appropriate and reliable mechanisms to protect data must be clearly defined and followed via research protocol. MSOE IRB expects PIs and associated investigators to be familiar with discipline-specific privacy and confidentiality rules and guidelines. Clear elaboration within the research protocol and informed consent document will safeguard privacy and confidentiality of human participants.

PIs are responsible for obtaining and documenting the informed consent of research participants, or their legally authorized representative, unless the IRB approves a waiver of informed consent, or a waiver of documentation of informed consent (45 CFR 46.116; 45 CFR 46.117).

Therefore, once IRB approval is obtained, it is the PIs responsibility to ensure that consent is obtained in accordance with the approved research protocol. During the consent process, participants, or their representatives, must be given sufficient time to understand the research project and their prospective role within it. Each participant must be allowed to make the personal decision on whether or not the provisions for privacy and confidentiality are adequate. Coercion or undue influence by the researcher is strictly prohibited.

Consent materials must be conveyed in a way that participants understand, which means a minimal use of technical terms or jargon. In the case that a research participant cannot give consent on their own (legally a minor, cognitive impairment, inability to communicate, etc.), a legally-authorized representative will need to provide consent and research participants should be given the opportunity to assent, if they are able. In the situation where providing specific aims of the study in consent documents would influence the participants, justification must be provided to the IRB to waive particular elements of consent.

Compliance with IRB Approved Protocol

Research must be conducted in alignment with the IRB approved protocol, except in life-threatening situations. If an unanticipated event occurs, the PI is required to submit an “Unanticipated Events” form to the IRB within 5 days of occurrence. PIs are expected to report the progress of their study to the IRB at least once a year, or more often, if requested by the IRB Administrator. Proposed changes (amendments) to an approved protocol must be reviewed and approved by MSOE IRB prior to execution. Upon completion of the research project, the PI must submit a final form to communicate to MSOE IRB that the study is finished and may be officially closed. Consult MSOE’s IRBNet Document Library at http://www.irbnet.org for necessary forms. Refer questions to MSOE’s IRB Administrator via email to IRB@msoe.edu.