4.8.202 Research with Human Participants

Subject	Research with Human Participants
Effective Date	2015-16 Academic Year
Revision Date	April 13, 2020, for 2020-21 Academic Year
Approvals	EEC
Responsible Office	MSOE Institutional Review Board
Creator(s)	Kristin Shebesta, IRB Administrator

I. PURPOSE and SCOPE

MSOE's Institutional Review Board (MSOE IRB) has jurisdiction over human subject research activities conducted at MSOE, human subject research activities conducted by MSOE employees, students, or agents at any location, and human subject research activities that use MSOE resources.

The purpose of IRB oversight 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 their signature, assumes responsibility for the conduct of the research with respect to proper safeguards of the rights of human subjects (participants).

II. DEFINITIONS:

Element	Definition
MSOE Institutional Review Board (IRB)	An administrative body established to protect the rights and well-being of human subjects recruited to participate in research activities.
Research	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.
Human Subjects	Human subjects are defined (45 CFR 46.102(f)) as "a living individual about whom an investigator conducting research obtains data through

Element	Definition
	intervention or interaction with the individual or the collection of identifiable private information."
Intervention	**Intervention** includes both physical procedures by which data is gathered (blood pressure readings, exercising, equipment design, etc.) and manipulations of the subject or the subject's environment (heat, light, temperature, etc.).
Interaction	**Interaction** includes communication or interpersonal contact between the investigator and subject (interviews, focus groups, surveys, etc.). Private information includes academic, financial, medical, and other documents about behavior that occurs in a context in which the subject can reasonably expect that no recording is taking place, or information the subject has provided for a specific purpose that can reasonably expect will not be made public.

III. POLICY STATEMENT

All students, staff, and faculty at MSOE planning to conduct research involving human participants must submit an IRB protocol application package for review by MSOE IRB including proof of relevant training certification. Investigators must obtain written approval from MSOE IRB before human subject recruitment and research may begin.

Federally funded multi-site studies requiring single IRB (sIRB) review involve coordinated local oversight by and advanced planning with the MSOE IRB office. In any study, if investigators intend to recruit study participants from locations outside of the United States must first secure written approval from MSOE IRB prior to contacting research officials in other countries.

MSOE IRB approval is required before human subject 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. Data collection by students or faculty/staff for assessment purposes only does not need MSOE IRB approval.

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. 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. 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 prior to the activity. Results of classroom activities cannot be presented

outside of the classroom without IRB approval; retroactive IRB approval is never granted.

IV. PROCEDURE

In accordance with regulatory standards, MSOE IRB is comprised of qualified board members that include at least one non-scientist and one community representative. MSOE's vice president of academics serves as the institutional official for MSOE IRB.

V. EXCEPTIONS/APPEALS

Retroactive IRB approval is never granted.

VI. ASSOCIATED LEGISLATION/REGULATIONS/ACCREDITATION STANDARD

Human subject researchers (e.g. investigators) at MSOE comply with requirements set forth in the code of Federal Regulations known as the "Common Rule" as well as Wisconsin State laws and MSOE policies.

VII. LIFECYCLE

As needed or annually as part of catalog policy review.

VIII. APPENDICES

For further information, please see the IRB Guidelines at https://libguides.msoe.edu/irb.

This section to be completed by the Records Manager		
Related Policies	Faculty Research Misconduct; FERPA	
Date Due for Review	Yearly with catalog review	
Public Location(s)	MSOE Policy Library and academic catalogs; IRB libguide	
Record Manager	Dr. Melodie Fox, Coordinator of Academic Documents & Publications	
University Archivist	Denise Gergetz, Librarian	
Version History		
Date approved	**Amendment Summary**	**Date(s) cross locations updated and past version provided to University Archivist**
EEC: April 13, 2020 for 20-21 AY	Added provision about Federally funded multi-site studies (sIRB). Added "at least" one non-scientist must be on the board.	
	Policy library template and added definitions for research, human subjects, intervention, and interaction for non-catalog version	June 4. 2020
4/30/18 EEC	Significantly rewritten to remove definitions and add more conditions under which IRB approval is needed.	N/A: catalog policy
2015-16 AY	First available version in Academic catalog	N/A: catalog policy