

## Responsible Conduct of Research – Student

### Purpose

The purpose of these procedures are to clarify the implementation of the Responsible Conduct of Research Student Research Policy at Mayville State University (MSU). This includes the types of student research at MSU and to define which if any class projects would require approval from MSU's Institutional Review Board (IRB).

Student research projects have potential value as published literature and could advance a field of knowledge. All student research projects have scholastic value to the student researcher(s) and MSU supports such research. Student Research at MSU follows two distinct routes: faculty research using students as research assistants, and/or students as researchers (includes in classroom and independent study projects). The purpose of these procedures are to define and clarify which class projects require review and approval from MSU's IRB. These procedures also defines the responsibilities of MSU affiliated individuals (e.g., faculty and students) who are overseeing or conducting classroom activities that do not require IRB.

### General Research Definitions

*Class Projects or Activities.* Course assignments/projects conducted by students for training and education to fulfill a course requirement, which may use particular methods (e.g., qualitative research methods), devices or equipment with no intent to contribute to generalizable knowledge.

*Generalizable.* Activities designed to develop or contribute to generalizable knowledge are those designed to draw general conclusions (i.e., knowledge gained from a study may be applied to populations outside of the specific study population), inform policy, or generalize findings.

*Human Subject or Participant.* A living individual about whom an investigator (whether professional or student) conducting research obtains: (1) data through intervention or interaction with the individual, or (2) identifiable private information. Title 45, Part 46 - Protection of Human Subjects (Department of Health and Human Services policy for Protection of Human Research Subjects)

*Human Subjects Research.* A systematic investigation designed to develop or contribute to generalizable knowledge that involves gathering/obtaining data about living individuals through intervention or interaction with the individual or by obtaining identifiable private information about the living individual. Interaction. Includes communication or interpersonal contact between an investigator and a subject.

*Internal Review Board.* Entity that ensures protection of human subject's research and sets institutional policy and procedure to ensure that protection.

*Laboratory Safety.* Protocols necessary to maintain a safe lab for student and researcher use. Any person who works in a laboratory must receive training to become knowledgeable about potential hazards in the laboratory. Student researchers must participate in a laboratory safety training session and receive additional, more specific training as dictated by project specific needs.

*Minimal Risk.* As defined by HHS policy for the Protection of Human Research Subjects at Title 45, Part 46 (i) - Protection of Human Subjects: 45 CFR 46.102i, means that "the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests."

*Responsible Conduct:* Responsible Conduct is while acting for/or on behalf of MSU, conducting research in a fair and ethical manner, beyond reproach, exemplifying the principles of professionalism and scholar integrity, honesty, trustworthiness, respect and accountability. Responsible conduct and training on such conduct is mandated by certain grant awards from the National Institutes of Health and the National Science Foundation prior to the start of a project. Training at MSU may provided by CITI and MSU Faculty/Principal Investigator's/Project Director's and the grants office. All researchers are required to provide assurance of responsible conduct.

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

*Systematic Investigation.* For the purposes of this policy, a systematic investigation is an activity that involves a prospective study plan which incorporates data collection, both quantitative and qualitative, and data analysis to answer a study question or prove/disprove a hypothesis.

### **Faculty/Principal Investigator/Project Director Responsibilities**

Faculty/Principal Investigator's/Project Director's must ensure and document students engaged in research have been instructed in data management, conflict of Interest, human and/or animal subjects, research misconduct, publication practices and responsible authorship, mentor/trainee responsibilities, disputes, Faculty/Principal Investigator's/Project Director's agreements , and lab safety (as relevant to said research).

### ***Animal/Human Rights Protection (IRB)***

It is the responsibility of the Faculty/Principal Investigator's/Project Director to determine whether an assigned project involving human and/or animal subjects can be classified as a course-related student project. Faculty should contact the Grants Office if assistance in making this determination is needed. Faculty who require students to do course-related research projects assume responsibility for the conduct of those projects and for ensuring that the rights and welfare of participants are protected. This includes discussing the general principles of ethical research with human subjects with the class prior to the initiation of the project. It also includes reviewing student research plans and monitoring research activities to ensure that human and/or animal participants are protected. At a minimum, best practices include informing participants of the voluntary nature of participation and employing measures to protect privacy and confidentiality, if applicable. The completion of the CITI on-line IRB training by the students who will conduct the projects is also highly recommended and mandatory when IRB is in place.

MSU's IRB will not review classroom projects or activities that are generally conducted for education or training solely to fulfill a course requirement. Therefore, as a rule, student class assignments do not fall under the jurisdiction of the IRB and will not require an IRB application, approval, or oversight. IRB only impacts human and/or animal subject research.

For a class project or activity to be considered research that will require a MSU IRB review, it must be designed with the intent to develop or contribute to generalizable knowledge. Class projects or activities that are intended to collect information systematically with the intent to develop or contribute to generalizable knowledge, will meet the definition of research and will fall under the jurisdiction of the IRB. The intent to publish or otherwise disseminate the results of the human and/or animal activity is one clear indication that the activity is regulated as research and requires IRB.

### ***IRB Required Disclosure to Participants***

All students conducting projects under this policy must disclose important information to the participants. An Informed Consent Document or Consent Cover Letter is required and the following information must be included:

1. The student identifies him/herself as a MSU student who is performing the activity to fulfill a course requirement, and the course is specifically identified.
2. The name and contact information for the course instructor or supervising faculty member to contact for questions is provided.
3. The person/s who have access to the individual data and/or summarized results are specified (e.g., instructor only, company/agency/organization).
4. Participants are informed that their participation is completely voluntary, that they do not have to participate in the study if they don't want to, and that they can stop participating at any time.
5. The disclosure should include MSU's IRB Stamp of approval indicating the project has been officially approved by MSU's IRB.
6. Documents must be retained by course instructor and grants office.

#### *Use of Data*

It is very important that careful consideration be given to the possibility of any publication, presentation, or use of any collected data for future research studies. Retroactive approval cannot be granted for studies conducted without IRB approval. For example, if a class project was conducted without IRB approval and resulted in unexpected but important findings or data, those findings or data may not be presented at a national meeting or used in a future project or research study. Research data that does not require IRB can be used for future studies (e.g., plant studies).

#### *Misconduct and Confidentiality*

It is the Faculty/Principal Investigator's/Project Director's responsibility to inform all student researchers of confidentiality and ethical research policies relating to their said research and/or project. This includes research misconduct and the consequences for such.

#### *Required Training and Documentation*

All MSU students involved in conducting research must receive training related to the Responsible Conduct of Research Policy. Minimum required topics include: data management, conflict of Interest, human and/or animal subjects, research misconduct, publication practices and responsible authorship, mentor/trainee responsibilities, disputes, Student and Faculty/Principal Investigator's/Project Director's agreement, and lab safety (as relevant to said research).

#### *Required Documentation*

Informed Consent Form

Conflict of Interest Disclosure Form 1 & 2

Student and Faculty/Principal Investigator's/Project Director's Agreement

Lab Safety Training Form

*Reference(s)/Related Policies & Procedures*

Protection of Human Subjects, Title 45 Code of Federal Regulations, Part 46, SubPart A  
Office of Research Integrity (ORI) US Dept. HHS  
National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research, Washington DC: HHS 1079.

M18308 Code of Conduct – Research/Grants  
M18308.1 Responsible Conduct of Research - Student  
MP18308.2b Lab Safety Procedures (Pending)  
M18611 Conflict of Interest – Research/Grants  
M18308.3 Human/Animal Subjects Internal Review Board (IRB) (Pending)  
M18308.4 Integrity in Research (Pending)  
M18308.5 Data Management (Pending)

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**Sponsors: President, Vice President for Academic Affairs and Vice President for Business Affairs,  
Director of Grants Office**