

## **Research Approval Procedures for Human and Animal (Live Vertebrate) Subjects**

Mayville State University (MSU) collaborates with North Dakota State University (NDSU) for human and animal subject research requiring IRB and IACUC review and approval. Due to this direct relationship, several of the following definitions, protocols, and procedures are from NDSU's standard operating procedures, frequently asked questions and other related resources.

### **Human Subjects**

Mayville State University requires NDSU IRB review (or certification of exempt status) when faculty, staff, students, or other representatives of the institution become engaged in research that will involve human subjects/participants. IRB review is required regardless of funding source. Collaborative projects also require IRB review when an agent or employee of MSU will be involved *“(e.g., receiving funding, project planning/design, participant recruitment, obtaining informed consent, data collection, or handling of identifiable human data)”*. *“In addition, it is important to note that IRB review would also be required if a project or activity conducted for other purposes (e.g., program evaluation, quality improvement, education), will also involve a research component.”* **IRB approval must be obtained prior to initiating any research involving human subjects.**

*“It is important to consider the definition of three terms in order to classify a project or activity as human subject's research that requires review by NDSU IRB: 'research', 'human subject/participant' and 'engagement'.”*

MSU via our Memorandum of Understanding with NDSU defines research through Federal Policy 45 CFR 46. *“45 CFR 46.102 (d) Definitions. Research means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities which meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program which is considered research for other purposes. For example, some demonstration and service programs may include research activities. In general, a contribution to generalizable knowledge could include a journal publication, conference presentation, or dissertation, although this is not the sole factor in making the determination. “*

*“If there is also an intent to contribute to “generalizable knowledge”, the activity would also be considered research, and require IRB review.”*

*“Course assignment projects that collect information about individuals are not normally considered to be 'research' and would not normally require IRB review. In these instances, the*

*project should be clearly represented to individuals as a course assignment, and not as a MSU research project, to avoid confusion about the need for IRB review.” As outlined in MSU’s Student Research Policy, course instructors are responsible for the conduct of these course assignments. Faculty and staff should familiarize themselves with this Policy and Procedures prior to undertaking any human subject research project”.*

If a student or instructor wants to utilize human research data as a part of their thesis/dissertation, or for a publication this would constitute a contribution to generalizable knowledge, therefore 'research'. *“In these cases, IRB review must be sought prior to contacting or collecting any data from participants; the IRB may not grant retroactive approval.”*

### **Animal (Live Vertebrate) Subjects**

The use of live vertebrate animals in any research, teaching, testing, or exhibition conducted by any MSU faculty, staff, students, visiting faculty or other representatives of MSU; or conducted at any NDSU facilities (including satellite facilities), must be reviewed and approved by the NDSU IACUC prior to the project's initiation. Mayville State University requires NDSU IACUC review (or certification of exempt status) when faculty, staff, students, or other representatives of the institution become engaged in research, teaching, or testing that will involve live vertebrate animals. IACUC review is required regardless of funding source.

### **IRB/IACUC Determination Protocol**

To assist faculty and staff in the determination of IRB or IACUC approvals, the Office of Institutional Effectiveness has developed a “Do I need IRB/IACUC Approval?” form to assist in determining the need for such approval. The intent of this form is to assist in determining if IRB/IACUC is required and if so, what type of protocol is necessary and to provide documentation of these actions, thus providing further protections for the institution, faculty, staff and students and participants whether animal or human. This form is to remain on file at the Office of Institutional Effectiveness for any/all research on MSU’s campus.

### **After Determination is made**

IRB determination documentation and subsequent changes/updates from NDSU are maintained in the Office of Institutional Effectiveness main files. IRB/IACUC research that does not include grant or other financial funding remains for three (3) years all other remains on file for at least five (5) years.

It is the faculty/staff member’s responsibility to follow IRB/IACUC Protocol and update this status as required in their approved research project.

NDSU makes all final IRB/IACUC determinations. MSU Office of Institutional Effectiveness may require and assist faculty/staff with protocols for their proposals that do not require IRB approval.

Materials referenced within this policy and procedure include and are available online at NDSU Research and Creative Activity website:

[https://www.ndsu.edu/research/integrity\\_compliance/irb/faqs/#c333768](https://www.ndsu.edu/research/integrity_compliance/irb/faqs/#c333768),  
[https://www.ndsu.edu/research/integrity\\_compliance/irb/forms/](https://www.ndsu.edu/research/integrity_compliance/irb/forms/),  
[https://www.ndsu.edu/research/integrity\\_compliance/iacuc/forms/](https://www.ndsu.edu/research/integrity_compliance/iacuc/forms/)  
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