

STEP ONE: Complete the [CITI Basic Human Subjects Research Course](https://about.citiprogram.org/en/homepage/) and attach a .pdf of your results with your application. *Note: Some research projects may require you to take additional modules*.

STEP TWO: Complete the all applicable sections of the application below.

STEP THREE: Generate all applicable supporting documents including: recruitment letters, informed consent forms, questionnaire/interview questions, etc.

STEP FOUR: Submit all materials to faculty advisor (students) or co-researchers (faculty) for feedback on revisions.

STEP FIVE: Faculty advisor (for student research) or principal investigator (faculty research) must submit all materials to the following in a single email including:

* ONLY for use by PIs with protocols approved prior to Fall 2023 using paper forms AND for instructional purposes



# Principal Investigator Information (must be NMU faculty or staff)

* 1. Name of Principal Investigator:
  2. Department:
  3. Phone:
  4. Email:

1. **Co-PI Information** 
   1. Name of co-PI:
   2. Department:
   3. Phone:
   4. Email:

# Co-Researchers’ Information (name and email)

**a.**

**b.**

**c.**

# Research Type: Is this research primarily:

# Faculty Research

# Graduate Student Research

# Undergraduate Student Research

# Project Title:

# Project Dates: Format: MM/DD/YYYY – MM/DD/YYYY

1. **Funding**

Pending funding decision

Currently funded

Not funded

List source of funding (if applicable):

# Type of Review

* 1. **Limited IRB Review** (Benign behavioral interventions that are brief in duration, harmless, painless, not physically invasive, not likely to have significant adverse lasting impact on subjects, and investigator has no reason to think subjects will find the interventions offensive or embarrassing.)

Check one and provide a short justification in the text box below for how it applies to your project:

Instructional setting practices/educational methods not likely to adversely affect instructional time or student performance. [*Note: in K-12 settings an approval letter from a school administrator is required but not informed consent from the students*]

Educational testing or interviews outside of normal instructional setting practices, provided that any recorded information is completely de-identified or disclosure outside of the research would not put subjects at risk of harm.

Surveys/Questionnaires

Observations

Research Conducted Cooperatively with another Institution (be sure the NMU researcher’s and graduate dean’s contact information is included on all consent forms).

Provide a short explanation for why your project fits the category you selected:

* 1. **Expedited IRB Review** (Research that does not qualify for Limited IRB Review but poses no more than minimal risks to participants and does not involve vulnerable populations.)

Common examples include, but are not limited to the following[1](https://ohsr.od.nih.gov/public/SOP_7A_v4_2-16-17.pdf). Check one and provide a short justification in the text box below if it applies to your project:

Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture

Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves.

Collection of data through normal exertional physical tasks, such as running, jumping, lifting weights etc., under proper supervision

Collection of data from video or image recordings made for research purposes.

Research conducted on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior), which typically includes interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.

Other

Provide a short explanation for why your project fits the category you selected:

* 1. **Convened IRB Review** (Research involving more than minimal risk to participants or includes one or more of the following vulnerable populations as participants.)

Check one or more of the following if it applies to your project:

More than minimal risk to participants

Children (not in standard classroom settings)

Prisoners

Individuals with impaired decision-making capacity

Economically disadvantaged persons

Educationally disadvantaged persons

**Note**: Convened IRB Review projects are approved for one year. Applicants must submit a Project Extension Form if their research will last longer than one year.

# Study Objectives (Explain what you seek to determine by conducting your study)

1. **Study Procedures (Explain what you will do and what your participants will do)**
2. **Participant Recruitment**
   1. **Who will you recruit to participate in your study?**
   2. **Age range of subjects:**
   3. **How specifically will you recruit participants?**
   4. **How many participants will you recruit?**
   5. **How many participants need to participate in your study for you to accomplish your objectives stated in #7 above?**

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* 1. **Attach a sample of your recruitment documents (email text, posters, announcement scripts, etc.)**

1. **Assurance of Voluntary Participation**

Describe how you will ensure subject participation is voluntary (with the exception of studies involving classroom practices/educational methods). A copy of the consent form must be included in your application materials.

# Risk

Describe all reasonably expected risks, harms, and/or discomforts that may apply to the research. Discuss severity and likelihood of occurrence. As applicable, include potential risks to an embryo or fetus if a woman is or may become pregnant. ***Consider the range of risks, including physical, psychological, social, legal, and economic***.

# Benefits

Describe the anticipated benefit to the participants and/or to society as a result of this research.

# Data Confidentiality and Storage

Federal regulations require IRBs to determine the adequacy of provisions to protect the privacy of subjects and to maintain the confidentiality of their data. To meet this requirement, federal regulations require researchers to provide a plan to protect the confidentiality of research data. Today, the majority of data is at some point collected, transmitted, or stored electronically. The Principal Investigator (PI) is responsible for ensuring that research data is secure when it is collected, stored, transmitted, or shared. All members of the research team should receive appropriate training about securing and safeguarding research data.

Describe how you plan to protect the confidentiality of the data collected. Include a description of where the data will be stored and who will have access to it. If the data will be coded to protect subject identity, this should be explained.

Upon approval from the IRB, you will be issued a project number. You must list this project number on all materials distributed to your participants.

At any point, should you wish to make changes to your protocol, you must submit a Project Modification Form before initiating the changes.

If any unanticipated problems arise involving human subjects, you must immediately notify the IRB chair and NMU’s IRB administrator and must submit an Unanticipated Problem/Adverse Event form.