

University of North Dakota Institutional Review Board (IRB)

Answers to the Most Frequently Asked Questions

What is the Institutional Review Board (IRB)?

A campus-wide committee charged with the review of research involving human participants to assure that the rights, welfare, and safety of participants are protected.

When is IRB review of research necessary?

A proposed project that requires IRB review must meet the definition of human subject research as outlined in federal regulations that govern the work of the IRB. According to the regulations:

Research is defined as “...a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.”

Systematic means that there is a research plan in place that will utilize accepted research methodologies to test a hypothesis. Generalizable knowledge means that the results of the study may be applied to a broader population beyond the study population. Plans to publish or present research findings or to use them toward fulfillment of an academic degree are some examples of creating generalizable knowledge.

Human subjects are “...living individuals about whom an investigator (whether professional or student) conducting research obtains data through intervention or interaction with the individual or identifiable private information.”

Intervention includes both physical procedures by which data are gathered (e.g., venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes (e.g, providing stimuli to gauge reaction and response).

Interaction includes communication or interpersonal contact between investigator and subject (for example, surveys and interviews).

Private information includes:

- information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place; or
- information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record).

*** If you are unsure whether your project involves research with human subjects, please consult with IRB staff who can provide guidance in making this determination. ***

Who is required to submit a research proposal to the UND IRB?

Any faculty, staff, student, or agent* of the University of North Dakota conducting research involving human participants is required to submit a proposal to the UND IRB before undertaking any research.

*Agents are defined as employees and non-employees with a faculty rank who are conducting research under that faculty status when any of the following conditions exist:

1. The researcher identifies himself/herself as a UND faculty member on any press release, promotional pieces, or recruitment materials related to the study/research.
2. The researcher intends to publish and/or present at public/professional events or in professional publications and represent himself/herself as a faculty member of UND.
3. The research is personally compensated by UND in any manner for this specific research, or receives UND funds in support of the specific research project.
4. The researcher pursues and receives external funding for the specific research project using his or her faculty status as support in securing the funding.

5. The researcher is provided general salary support from UND at a level where the research project would be an expectation within the job description.
6. The researcher intends to use the research project as an element of the promotion and tenure relationship within UND.

What is the purpose of IRB review?

In fulfillment of the terms of UND's federalwide assurance with the DHHS Office of Human Research Protections, the IRB is required to prospectively review human subject research to ensure that the rights, welfare, and safety of participants will be protected. Specifically, participants should have the right to:

- be told everything they need to know about the research before being asked to participate;
- freely choose whether or not to participate in a research project;
- be aware of any available alternatives;
- be free to quit participating at any time;
- have their privacy and confidentiality of their information respected;
- know that their safety and welfare come first;
- keep all the legal rights they already have; and
- ask questions or voice concerns to the investigator or the IRB.

These rights are extended to participants of all UND human subject research projects, including those projects that may involve little or no risk, or may be eligible under one of the exempt categories. Through the protocol review process, the IRB obtains the necessary information to verify that the project will be conducted so that participants are afforded these rights.

Projects involving a vulnerable population (children, pregnant women and fetuses, or prisoners), and/or some level of risk (e.g., physical, psychological, social, legal, privacy, employability, etc.) require a higher level of review and have more stringent requirements.

By reviewing all materials that will be shown to subjects (recruitment messages, invitations, consent forms), the IRB is able to verify that participants will be fully informed of the nature of the research, what is being asked of them, as well as any potential risks, harms and benefits.

How is the review category determined?

There are three categories of IRB review: exempt, expedited, and full board. Exempt and expedited proposals must meet the definition of minimal risk: *"...probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinary encountered in daily life or during the performance of routine physical or psychological tests."* Exempt and expedited proposals are reviewed by a single board member. Proposals that must go before the full board have risks that are greater than minimal. These proposals are reviewed by the full board to determine if the increased risks to subjects are acceptable.

- Exempt does not mean that you do not have to submit an application to the IRB. It means you do not have to submit an annual review of approved research.
- Expedited does not mean that the application turnaround time is really fast. It means that a single board member can review the proposal, instead of it having to go before the full board.

How long does approval of an IRB application take?

Various factors influence the length of time necessary to approve an IRB application, including the quality of the application, current volume of applications submitted and under review, and type of review. Upon submission of a *complete* IRB application:

- Exempt protocols typically require up to 5 business days to process, review, and approve.
- Expedited protocols typically take 2-3 weeks to process, review, and approve.
- Full board applications may take up to a month to approve – the IRB meets only once per month, so a full board application that is time sensitive should be submitted as far in advance as possible to ensure approval by the researcher's anticipated start date.

What are common reasons that an IRB approval may be delayed?

- Required IRB training is not current.
- Plan for protecting privacy of participants and maintaining confidentiality of their data is inadequate.
- Consent document lacks required elements.
- Protocol lacks some or all required signatures.
- Missing or incomplete responses on protocol.
- Insufficient detail in description of procedures.
- Information on the protocol and/or consent form is inconsistent.
- Missing attachments or permission letter(s).
- Funding proposal not attached.
- Misunderstanding of eligibility for exempt status.

What happens if a human subject research project is conducted without IRB approval?

The implications of engaging in activities that qualify as research subject to IRB review without obtaining such review are significant. This is a serious violation of UND policies and federal regulations. Data generated from research conducted without IRB approval cannot be used in publications or presentations or to satisfy requirements toward a degree.

Visit the IRB website for more information about policies and procedures and to obtain current IRB forms:

<http://UND.edu/research/resources/human-subjects/>