

**AUTHORITY AND PURPOSE**

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<b>THIS POLICY PERTAINS TO:</b>		<b>ALL ACTIVITIES OF THE IRB</b>					
<b>RESPONSIBILITY FOR EXECUTING POLICY:</b>		<b>IRB STAFF, IRB CHAIRPERSON, IRB MEMBERS, AND INSTITUTIONAL OFFICIALS</b>					
<b>LAST REVIEWED ON:</b>		<b>/ /</b>		<b>RESULTS:</b>	<b>REVISED</b>		
<b>APPROVAL AUTHORITY:</b>		<b>Associate Vice President for Research and Economic Development</b>					
<b>APPROVED BY:</b>						<b>DATE:</b>	<b>/ /</b>

**1. POLICY**

**1.1 Statement of Institutional Authority**

The University of North Dakota’s Institutional Review Board (IRB) is under the authority of the Vice President for Research and Economic Development. The University of North Dakota requires that all research projects involving humans as subjects, or which use human material, be reviewed and approved by the University of North Dakota IRB prior to initiation of any research using human participants, including recruitment and screening activities.

**1.2 Purpose of the IRB**

The purpose of the IRB is to protect the rights and welfare of human subjects participating in biomedical and behavioral research. The IRB reviews and oversees such research to assure that it meets ethical principles and that it complies with federal regulations that pertain to human subject protection at 45 CFR 46 and 21 CFR 50 and 56, and other pertinent regulations, guidance, state and local laws.

**1.3 Governing Principles**

The IRB is guided by the ethical principles regarding all research involving humans as subjects as set forth in the report of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, entitled: Ethical Principles and Guidelines for the Protections of Human Subjects of Research (the “Belmont Report”). These principles are defined in the Belmont Report as follows:

- **Respect for Persons** - Recognition of the personal dignity and autonomy of individuals and special protection of those persons with diminished autonomy.
- **Beneficence** - The benefits to the subject and the importance of the knowledge to be gained must outweigh the risks to the subject.
- **Justice** - The selection of subjects is equitable and is representative of the group that will benefit from the research.

## **1.4 IRB Authority and Jurisdiction**

1.4.1 The IRB has the authority to review all research involving human subjects regardless of the source funding and location of study if:

- The research is sponsored by the University of North Dakota and/or;
- The research is conducted by the University of North Dakota agents, staff and/or students.

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 (inclusion of the fact of such appointment on the researcher's CV is allowed, but narrative within grant application which uses his/her faculty position to bolster the argument for funding is not).
  5. The researcher is provided general salary support from the 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.
- The research is conducted by or under the direction of any employee, faculty, staff, student, or agent of the University of North Dakota using any property or facility of the University of North Dakota; and/or
  - The research is conducted by Investigators at the Grand Forks Human Nutrition Research Center and/or the Neuropsychiatric Research Institute; and/or
  - The research is conducted by Investigators at institutions in which the IRB has an IRB Authorization Agreement in place; and/or
  - The research involves the use of the University of North Dakota's nonpublic information to identify or contact human research subjects.

1.4.2 The IRB has the authority to ensure that research conducted under its jurisdiction is designed and conducted in such a manner that protects the rights and welfare and privacy of research subjects. Specifically:

- The IRB may disapprove, require modifications to, or approve studies based upon consideration of human subject protection aspects.
- The IRB reviews, and has the authority to approve, require modification in, or disapprove all research activities that fall within its jurisdiction.

- The IRB has the authority to conduct continuing reviews as it deems necessary to protect the rights, welfare and privacy of research subjects, including requiring progress reports from Investigators and review of the conduct of the study, and to observe or have a third party observe the informed consent process and/or audit the progress of any study in its jurisdiction as it deems necessary to protect the rights and welfare of human subjects.
- The IRB may suspend or terminate approval of a study.
- The IRB may place restrictions on a study.

### **1.5 Independence of the IRB**

The IRB is the final authority for all decisions regarding the protection and welfare of human subjects in research, and these decisions are not subject to reversal by any governing individual or body of the University. Institutional Officials may not approve the research if it has not been approved by the IRB.

Inappropriate attempts to influence the IRB process, individual IRB members, or IRB office staff will be reported to the Vice President for Research and Economic Development. The Vice President for Research and Economic Development will respond to and stop any attempt at inappropriate influence, and has the authority to limit or remove an Investigator's privilege to conduct research.

## **2. SPECIFIC POLICY**

### **2.1 Externally Funded Research**

If the study is part of an application to a sponsoring agency, the protocol must be reviewed and approved by the IRB prior to expenditure of any grant funds. A copy of the contract (minus any budgetary information) must be included in the IRB application to ensure that the protocol, consent and contract language is consistent.

### **2.2 Relationship of the IRB to University officials and other committees**

2.2.1 Review of research by officials and other committees: Research that has been reviewed and approved by the IRB may be subject to review and disapproval by officials or other committees. However, those officials or committees may not approve research if it has been disapproved by the IRB.

As appropriate to the type of research proposed, the following committee approvals are required before the IRB will grant approval. The IRB may grant approval, but the approval letter will not be sent to the Investigator until approval from the appropriate committee(s) has been received.

- **Radiation Safety Committee:** The primary concern of the Radiation Safety Committee is radiation safety and control. The Radiation Safety Officer (RSO) will receive and perform the initial review of all applications for the use of radioactive materials and radiation producing machines at the University. If the application meets the criteria allowing for temporary review, the application will be reviewed by the Application Review Subcommittee. Final review of all applications is performed by the full Committee. Approval by the committee is noted on the University of North Dakota Proposal Transmittal Form. The Proposal Transmittal Form is submitted to the Associate Vice

President for Research and Economic Development who determines that all appropriate committees have reviewed and approved the research. The IRB may grant final approval of the study, but the researcher will be notified and told that the research cannot commence until the IRB receives notice that the project has approval of the Radiation Safety Committee. The Investigator is responsible for providing the IRB with the approval before the start of the study.

- **Institutional Biosafety Committee (IBC):** The Institutional Biosafety Committee (IBC) requires that any research, teaching, or other activities which utilize recombinant DNA or involve the use of biohazardous research material be subject to a University Review Process, and that these activities must be approved by the IBC prior to their initiation. The IBC is the only authorized University committee which can give approval to projects and activities involving recombinant DNA and biohazardous research material. The IBC follows the NIH guidelines for recombinant DNA and biohazardous material research in determining the suitability of projects and activities, and will provide an explanation of any decision not to approve a project or activity. Any project or activity not approved can be revised and resubmitted to the IBC for consideration. Approval by the committee is noted on the University of North Dakota Proposal Transmittal Form. The Proposal Transmittal Form is submitted to the Associate Vice President for Research and Economic Development who determines that all appropriate committees have reviewed and approved the research. The IRB may grant final approval of the study, but the researcher will be notified and told that the research cannot commence until the IRB receives notice that the project has approval of the Institutional Biosafety Committee. The Investigator is responsible for providing the IRB with the approval before the start of the study.

- **Conflict of Interest Committee (CoIC):** The Conflict of Interest Committee serves as both an advisory and decision-making body regarding conflict of interest issues. Administrative services are provided by Research Development and Compliance (RD&C). The Principal Investigator and any other person responsible for the design, conduct, or reporting of the research must submit copies of a completed Certification of Filing of Financial Interests Disclosure Statement form to RD&C at the time that the proposal, grant, or contract is submitted for review, including initial review, continuing review, and when there are changes in financial circumstances. The Associate Vice President for Research and Economic Development reviews the grant proposal and verifies that the appropriate paperwork has been received. The CoIC will receive the appropriate paperwork if the researcher or department head believes there may be a conflict of interest. The IRB will be notified of the CoIC's management strategies. IRB approval will be contingent upon IRB receipt and approval of the strategy by the convened IRB, and the acceptance of the management strategy by the P.I.

- **Graduate Committee and Adviser Review:** The Graduate Committee and/or the adviser must review all proposals by graduate students at UND prior to the submission of the proposal to the IRB. The Graduate Committee and/or adviser review the proposal for scientific merit and will make recommendations regarding the research question and design, as well as other areas. These changes must be incorporated into the proposal prior to IRB review. The Human Subjects Review Form requires, if applicable, the signature of the student's adviser or committee member prior to the submission of the proposal.

2.2.2 IRB relationship to University officials and other committees: The IRB functions independently of, but in coordination with, University officials and other internal or external

committees. The Associate Vice President for Research and Economic Development is the link between the IRB, and other components of the UND Human Research Protection Program.

2.2.3 IRB relationship to the Office of General Counsel: The Office of General Counsel is comprised of the General Counsel, Associate General Counsel, and Legal Counsel. As the chief legal advisors to the President, officers, faculty, and staff of the University, members of the Office of General Counsel are responsible for handling all legal matters affecting the University. In the research context, privacy issues, exculpatory language, or local and State laws with regard to consent or guardians are among the items in which an opinion may be requested from the Office of General Counsel. Normally, the IRB Chairperson, IRB Coordinator, or Investigators will work with the Associate Vice President for Research and Economic Development to request assistance from the Office of General Counsel. The Office of General Counsel will research the issue and applicable law and provide a timely response.

### **2.3 Use of Policies and Procedures**

The IRB must maintain and follow all written policies and procedures consistent with federal regulations, good clinical practices, and biomedical ethics when reviewing proposed research.

### **2.4 Serving as IRB of record for other institutions**

The IRB serves as the IRB of record for other institutions as listed on the University of North Dakota's Federalwide Assurance with the Office of Human Research Protections.

### **2.5 Multiple IRB approvals needed [to conduct research at another site(s)]**

Many times, a researcher conducting research at another site may need approval from that site's IRB. If the University of North Dakota has an IRB Authorization Agreement with the other site/hospital/institution, their IRB may be able to accept UND's IRB approval. For more information regarding IRB Authorization Agreements with other sites, call the Research Development and Compliance office.

If the site/hospital/institution does not have an agreement with the UND IRB, the UND researcher must secure approval from both the UND IRB and the site/hospital/institution IRB. The researcher must notify the IRB that they have submitted to another IRB. This information must be included on the UND IRB proposal forms.

### **2.6 Accepting review of another IRB**

Accepting the review of another IRB will be at the UND IRB's discretion, and will only be done when the other IRB has an FWA, and when there is an IRB Authorization in place.

## **3. RESPONSIBILITY**

The Vice President for Research and Economic Development is responsible for the oversight of the Human Research Protection Program which includes the IRB. The Associate Vice President for Research and Economic Development is responsible for the oversight of the operations of the Human Research Protections Program.

The Associate Vice President for Research and Economic Development will meet with Legal Counsel, Chairpersons of the compliance committees, and Grants & Contracts Administration

periodically to ensure that communications are maintained between all components of the Human Research Protection Program.

The IRB Coordinator is responsible for the oversight of the daily operations of the IRB.

The IRB Secretary has the responsibility of the daily operations of the IRB.

**4. APPLICABLE REGULATIONS AND GUIDELINES**

21 CFR 56.108, 56.109, 56.113  
 45 CFR 46.108 45 CFR 160 &164  
 Belmont Report  
[Engagement of Institutions in Research](#)

**5. PROCEDURES EMPLOYED TO IMPLEMENT THIS POLICY**

Who	Task
<i>Associate Vice President for Research and Economic Development, IRB Chairperson, IRB members, IRB Coordinator, and IRB Secretary</i>	Ensure compliance with federal regulations, policy and procedures to guarantee the protection of human subjects participating in research. Report to the VP for Research and Economic Development any inappropriate attempts to influence the IRB process.
<i>Vice President for Research and Economic Development</i>	Investigate and act on reports of inappropriate attempts to influence the IRB process.
<i>Vice President for Research and Economic Development, and Associate Vice President for Research and Economic Development</i>	Evaluate on an on-going basis the HRPP for adherence and compliance with federal, state, and local policy and regulations. Evaluate (at least yearly) the IRB workload in regard to timely and thorough review.
<i>Associate Vice President for Research and Economic Development</i>	Meet with Legal Counsel, Chairpersons of the compliance committees, and Grants & Contracts Administration periodically to ensure that communications are maintained between all components of the Human Research Protection Program.
<i>Associate Vice President for Research and Economic Development, IRB Coordinator, IRB Secretary</i>	Ensure communications between IRB and additional committees where approval is being sought. All copies of correspondence with the Investigator will be sent. Copies of correspondence between additional IRB and the Investigator will be requested.