

## University of Notre Dame

### Institutional Human Research Protections Program Policy

As a Catholic Institution, the University of Notre Dame is committed to compassionate care for the whole person. Thus, in all of its activities, the University of Notre Dame will promote the physical, psychological, spiritual, and social well-being of those we serve. The University of Notre Dame is dedicated to defending and promoting human dignity, health, and well-being.

The University of Notre Dame fosters a research environment that promotes the respect for the rights and welfare of individuals recruited for, or participating in, research conducted by or under the auspices of the University of Notre Dame. In the review and conduct of research, actions by the University of Notre Dame will be guided by the principles (i.e., respect for persons, beneficence, and justice) set forth in the ***Ethical Principles and Guidelines for the Protection of Human Subjects of Research*** (often referred to as the [Belmont Report](#)). The actions of the University of Notre Dame will also conform to all applicable federal, state, and local laws and regulations.

In order to fulfill this mission, the University of Notre Dame has established a human research protections program (HRPP). The mission of the HRPP is to:

- Safeguard and promote the health and welfare of human research subjects by ensuring that their rights, safety, and well-being are protected;
- Provide guidance and support to the research community in the conduct of research with human subjects;
- Assist the research community in ensuring compliance with relevant regulations;
- To provide timely and high quality education and review of human research projects; and
- To facilitate excellence in human subjects research.

The University of Notre Dame will designate an Institutional Official who has overall responsibility for the University of Notre Dame's HRPP. The duties of the Institutional Official are as follows:

- Fostering, supporting, and maintaining an organizational culture that supports the ethical conduct of all research involving human subjects and the adherence to regulations and organizational policies;

- Ensuring that the Institutional Review Board (IRB) functions independently by, among other mechanisms, being directly accessible to the IRB Chair(s) and members if they experience undue influence or if they have concerns about the function of the IRB;
- Oversight of the IRB;
- Oversight over the conduct of research conducted by all University of Notre Dame investigators;
- Ensuring the IRB members are appropriately knowledgeable to review research in accordance with ethical standards and applicable regulations;
- Ensuring that all investigators are appropriately knowledgeable to conduct research in accordance with ethical standards and applicable regulations;
- Oversight of the development and implementation of an educational plan for IRB members, staff, and investigators;
- Ensuring compliance with institutional policies and all applicable regulations for the protection of human subjects;
- Serving as the signatory authority and ensuring compliance with the terms of the Federal-wide Assurance to the Office of Human Research Protections; and
- Providing support to the human research protections program, by ensuring that the HRPP has the sufficient staff and resources to fulfill its mission and obligations.

In the performance of these duties, the Institutional Official has the authority to delegate such activities as may be necessary in order to fulfill these duties.

To conduct its responsibility effectively, the University of Notre Dame maintains an IRB to review research protocols involving human subjects. The IRB is an autonomous administrative body established to protect the rights and welfare of human research subjects recruited to participate in research activities conducted under the auspices of the University of Notre Dame. The IRB has the following authority with respect to all research involving human subjects:

- To approve, require modifications to secure approval, or disapprove all research activities involving human subjects overseen and conducted under the auspices of the University of Notre Dame, regardless of location of the research activities;
- To require that informed consent be obtained and documented in accordance with regulatory requirements unless the criteria for the waiver or alteration of such requirements has been satisfied and approved by the IRB. The IRB may require that information, in addition to that specifically mentioned in the regulations, be given to the

subjects when in the IRB's judgment the information would meaningfully add to the protection of the rights and welfare of subjects;

- To conduct continuing review of research at intervals appropriate to the degree of risk of the research, but not less than once per year;
- To suspend or terminate approval of research not being conducted in accordance with the IRB's requirements or that has been associated with unexpected serious harm to subjects;
- To observe, or have a third party observe, the consent process; and
- To observe, or have a third party observe, the conduct of the research.

All IRB-approved research studies are subject to ongoing review, which must be conducted at least once annually by the IRB. If approval by the IRB lapses, all research activity must stop unless it is determined to be in the best interest of already enrolled subjects to continue participating in the research. The investigator can petition the IRB to continue an individual subject's research intervention/interaction during a period of lapsed IRB approval if the investigator believes there is a safety concern or ethical issue such that it is in the best interests of the individual participant to do so.

The IRB has jurisdiction over all human subject research conducted under the auspices of the University of Notre Dame, regardless of funding source or performance site. Research under the auspices of the institution includes research:

- Conducted at this organization;
- Conducted by or under the direction of any employee or agent of this organization (including students) in connection with his or her organization responsibilities;
- Conducted by or under the direction of any employee or agent (including students) of this organization using any property or facility of this organization; or
- Involving the use of this organization's non-public information to identify, contact, or study human subjects.

No research involving human subjects may be conducted without IRB approval and no research may commence until all required Institutional approvals (including IRB) are obtained. Exempt research is subject to review for determination of exemption status. At the University of Notre Dame, exemptions are reviewed and granted by the HRPP Director.

All institutional and non-institutional performance sites for the University of Notre Dame, domestic or foreign, will be obligated by this policy to conform to ethical principles which are at least equivalent to those of this institution or as may be determined by the Department of Health and Human Services (DHHS) Secretary.

The Institutional Official and the IRB shall adopt operating procedures to implement this policy. These procedures shall serve as the governing procedures for the conduct and review of all human research conducted under the auspices of the University of Notre Dame.