



1. INTRODUCTION

The University of Notre Dame is committed to compassionate care for the whole person. In all its activities, the University will promote the physical, psychological, spiritual, and social wellbeing of those we serve.

The University 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. In the review and conduct of research, actions by the University 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. The actions of the University will also conform to all applicable federal, state, and local laws and regulations.

2. POLICY STATEMENT

2.1. Human Subjects Research Review

The University of Notre Dame shall require all research involving human subjects under the scope of this policy to be reviewed by an Institutional Review Board (IRB) prior to project initiation and without respect to funding or the source of funding.

2.1.1. Institutional Review Board

The University of Notre Dame shall, at the recommendation of the Vice President of Research, appoint individuals to the IRB. The IRB shall be responsible for establishing policies and procedures that ensure researcher compliance with all applicable laws, regulations, and policies governing human subjects research.

2.1.2. Institutional Review Board Approval

Research involving human subjects must receive approval from the IRB prior to project initiation.

2.2. Collaborative Human Subjects Research

Human subjects research may be conducted by University faculty, staff, and students in collaboration with investigators at external institutions. Requirements at section 2.1 above may be satisfied either by University of Notre Dame IRB review, or review at an officially appointed IRB registered with the Office of Human Research Protections, prior to project initiation. Projects may receive IRB review at external institutions only where

an agreement is completed between the University and the external institution before University investigators engage in human subjects research in the proposed project.

2.2.1. Multi-Site Human Subjects Research Funded by National Institutes of Health

Human subjects research projects receiving funding from the National Institutes of Health (NIH) to support the completion of a single protocol at multiple institutions are required by NIH Policy to receive IRB review at a single site, with all non-reviewing sites relying on that review. When the University of Notre Dame is engaged in such multi-site research, the University IRB shall either rely on the review of another institution engaged in the same research protocol, or provide review on behalf of all other institutions engaged in the same research protocol. The University will not enter into an agreement under this provision where any part of the proposed research protocol violates this or any other University policy.

2.3. Prohibited Research

The University recognizes and upholds the sanctity of human life from conception to natural death, as described in the Institutional Statement Supporting the Choice for Life, and consistent with the teaching of the Catholic Church. Research contrary to these beliefs is prohibited.

3. SCOPE

The Policy applies to all University faculty, students, and staff.

The Policy applies to all human subjects research conducted under the auspices of the University. This includes research conducted:

1. At any University facility;
2. By or under the direction of any employee or agent of this organization (including students) in connection with his or her institutional responsibilities;
3. By or under the direction of any employee or agent (including students) of this institution using any property or facility of this institution; or
4. Involving the use of this institution's non-public information to identify, contact, or study human subjects.

4. DEFINITIONS

Human Subject	Living individual about whom an investigator conducting research (i) obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or (ii) obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.
----------------------	---

Research	Systematic investigation, including research development, testing,
-----------------	--

	and evaluation, designed to develop or contribute to generalizable knowledge.
Institutional Review Board	Board defined by the Department of Health and Human Services and appointed by the Vice President of Research for the purposes expressed in that policy.

5. POLICY ENFORCEMENT

Violations	It is an explicit violation to fail to meet the requirements of this policy in the conduct of human subjects research.
Enforcement	The University Institutional Review Board will require any researcher suspected to have violated this policy to submit information about suspected violations, and may recommend disciplinary action in accordance with University codes of conduct, policies, or applicable laws. Sanctions may include one or more of the following: <ul style="list-style-type: none"> • suspension or termination of research; • compelled destruction of data collected in research.
Reporting Violations	Suspected violations may be reported to Notre Dame Research Compliance at compliance@nd.edu or 574-631-1461.

6. CONTACTS

Includes the office or position (not individual name) to contact for policy clarification, along with others who can provide information about the subject matter of the policy.

Subject	Office or Position	Telephone Number	Office Email or URL
Policy Clarification	Notre Dame Research Compliance	(574) 631-1461	compliance@nd.edu