What You Need To Know If You Plan to Conduct Research Involving Human Subjects

This brochure will provide basic information to ensure that your research complies with federal and state regulations, and University of Notre Dame guidelines.
If You Plan to Conduct Research Involving Humans.

Some examples of human subject research include, but are not limited to, surveys, observation, interviews, accessing private records, and taste testing.

According to University of Notre Dame research policy, all research conducted with human subjects must be reviewed and approved by their Institutional Review Board (IRB) before the subjects may be involved. IRB approval must be obtained whether the research is conducted by faculty, staff or students. Neither the source of funding nor the lack of funding for any research has any bearing on this requirement.

Defining Human Subject Research

1. A “human subject” is a living individual about whom an investigator indirectly or directly obtains either (1) data through intervention or interaction with the individual, or (2) identifiable private information (as per Title 45 Code of Federal Regulations, Part 46, June 18, 1991).

2. Systematic investigation includes research development, testing, and evaluation designed to develop or contribute to generalizable knowledge. Activities that meet this definition constitute research for purposes of the IRB, whether or not they are conducted or supported under a program that is considered research for other purposes. For example, some demonstration and service programs may include research activities, clinical trials, therapeutic evaluations, experimental treatments, and bodily materials, residual diagnostic specimens, cell lines or DNA samples.

Training is Required Prior to IRB Approval.

The University of Notre Dame participates in the Collaborative IRB Training Initiative (CITI) online program to provide educational courses for personnel involved in the conduct of human subjects research.

The principal investigator for each protocol is responsible for ensuring that he/she and all the key study personnel for the project complete this course, which will fulfill the basic human subject protection training requirement at the University of Notre Dame for a five-year period. This is a great resource for faculty to educate students about research involving human participants, including historical background for behavioral and biomedical research, ethical principles for human subjects research, and information on the role of an IRB.

For questions regarding submitting protocols contact the Research Compliance Office at irb@nd.edu or 574-631-1461.
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3 Types of IRB Review

An IRB application submitted for review will fall into one of the following categories listed below. The categories reflect the risks for the human subjects participating in the study.

Full Board Review. Studies that involve more than minimal risk are recommended for review by a full board. Approval for these studies requires that the proposed research be reviewed at a convened meeting with a quorum of IRB members present. IRB approvals are valid for up to one year and require submission of annual renewals and approval for amendments.

Expedited Review. Certain kinds of research involve no more than minimal risk and for minor changes in approved research. These will be reviewed by one or two members designated by the IRB chair rather than by the entire convened IRB. Approvals are valid for up to one year and require submission of annual renewals and approval for amendments.

Exemption. Any research study considered as minimal risk to human subjects can be exempt under federal regulations; however, the exempt form must be submitted to the IRB for a determination. The exempt categories include certain educational practices and tests, study of archived or existing data, public service programs and food evaluation. No renewals are required for a certified exempt project, although amendments are required to be submitted for determination of exemption by the IRB.

Studies with Vulnerable Populations

Federal, state and University of Notre Dame guidelines provide special protection for populations falling under the following categories:

- Select Native American tribes
- Substance abusers
- Non-English-speaking population(s)
- Children, prisoners, pregnant women, or fetuses

IRB must review and approve research if it involves interactions with one of these populations, either directly or indirectly.

Informed Consent

Potential subjects participating in research must be adequately informed about key aspects of the research study. This information is provided by the use of informed consent. After all the relevant details regarding the study have been provided to participants, their participation in research should be voluntary. An ideal informed consent should have the following items:

- Purpose of the research
- Benefits of research to individuals and society
- Procedures involved in research
- Alternatives available if subject decides not to participate
- Risks and discomforts to the subjects, including physical injury, possible psychological, social, or economic harm, discomfort, or inconvenience
- Length of time the subject has to participate
- Contact person in case of injury or illness resulting from study participation
- Statement that participation is voluntary
- Clarify the subject’s right to confidentiality and right to withdraw

Research with children requires parental permission and assent forms for minors.

Adverse events in all studies should be promptly reported to the University of Notre Dame IRB at irb@nd.edu or 574-631-1461.
The University of Notre Dame
Human Subjects Institutional Review Board (IRB)

### Appointed Members

<table>
<thead>
<tr>
<th>Name</th>
<th>Title and Affiliation</th>
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<tbody>
<tr>
<td>Anita Kelly, Ph.D.</td>
<td>Professor, Psychology, Chair</td>
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<tr>
<td>Darren Davis, Ph.D.</td>
<td>Professor, Political Science, Vice Chair</td>
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<tr>
<td>Michael T. McCauslin</td>
<td>Associate Professional Specialist, Alliance for Catholic Education</td>
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<tr>
<td>Rebecca Moskwinski, MD</td>
<td>Notre Dame Health Center</td>
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<tr>
<td>Margaret Pfeil, Ph.D.</td>
<td>Assistant Professor, Theology</td>
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<tr>
<td>Richard Williams, Ph.D.</td>
<td>Associate Professor, Sociology</td>
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<tr>
<td>Jeanne Romero-Severson, Ph.D.</td>
<td>Associate Professor, Biological Sciences</td>
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<tr>
<td>James Frabutt, Ph.D.</td>
<td>Associate Professional Specialist, Alliance for Catholic Education</td>
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### Public Member(s)

- George Maher, DO

### Executive Secretary

- Tracey L. Poston, Ph.D.

  Director of Research Compliance, ex officio

### Function:

The University recognizes an inherent obligation to ensure that the rights and well-being of persons who serve as subjects in research conducted under its auspice are adequately protected. In the matter of protection of human subjects, the University relies on the good judgment of its faculty and administration, augmented by a special review committee, the Human Subjects Institutional Review Board (IRB). The University calls for a posture of heightened sensitivity and special scrutiny on the part of the initiators of any project and of their immediate supervisors as the primary agents of the University in these matters.