IRB Institutional Authority, Purpose, and Principles

Table of Contents: IRB Institutional Authority, Purpose, and Principles

Policy Statement

The University of the Incarnate Word (UIW) Institutional Review Board (IRB) reviews all human subjects research conducted by UIW faculty, staff, and students, regardless of the location of the research activity or source of funding.

Federal regulation PL 93-348, National Research Service Award Act of 1974, requires that the UIW IRB assure protection of human subjects involved in all research conducted by faculty, students, and others employed at UIW.

The IRB process is consistent with the UIW Mission to hold the dignity and well-being of all persons in the highest regard. This ethical stance as regards the IRB process is founded on the three key ethical principles of the Belmont Report: respect for persons, beneficence, and justice.

The intent of this institutional policy is to foster high standards in the conduct of research and to assure uniform criteria are applied to protect the human subjects who take part in research.

Description and Procedures

A. Regulatory Compliance and Review Criteria

The IRB reviews research in accordance with current Department of Health and Human Services (DHHS) regulations (for all research) and Food and Drug Administration (FDA) regulations (for FDA regulated research only). The purpose of the IRB is to protect the rights and welfare of human subjects who take part in research. More specifically, the IRB assures that:

1. risks to subjects are minimized (e.g., by evaluating whether procedures to be performed on subjects are consistent with sound research design and do not unnecessarily expose subjects to risk);

2. risks to subjects are reasonable in relation to any benefits that might be expected from taking part in a research study and to the importance of the knowledge that may result;

3. selection of subjects is fair and equitable (e.g., by determining that no eligible individuals are denied the opportunity to take part in any study, particularly those from which they may benefit, based on an arbitrary criterion such as gender or because they do not speak English);

4. participation is voluntary and informed consent is obtained from each prospective subject or where appropriate, from the subject's legally authorized representative;

5. the research plan provides for monitoring the data collected to ensure the safety of subjects;

6. there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data; and

7. safeguards are included to protect the rights of vulnerable subjects.

B. The IRB's Authority

Granted by Federal Law, the IRB holds the following authority relative to human subjects research conducted by faculty, staff, and students, regardless of the location of the research activity or source of funding, for the protection of human subjects:

1. to approve, require modifications to secure approval, or disapprove all research activities overseen and conducted by the faculty, staff, and students of UIW involving human subjects based on its consideration of the risks and potential benefits of the research and whether the rights and welfare of the subjects are adequately protected;

2. to require reports for protocol continuing review;

3. to continuously monitor the conduct of research with human subjects;

4. to suspend or terminate approval of research that is not being conducted in accordance with IRB requirements or that has been associated with unexpected serious risk to subjects;

5. to place restrictions on a study, if necessary to protect human research subjects;

6. to observe, or have a third party observe, the consent process;

7. to observe, or have a third party observe, the conduct of the research; and

8. to report acts of non-compliance to supervising faculty (student non-compliance), university officials, federal regulatory bodies, funding agencies, and research sites as needed.

No official within the organization may approve a protocol for human subjects research activity that has not been approved by the IRB.

Effective Date

August 24, 2020

Revision History

References

45 CFR 46
21 CFR 50
21 CFR 56
PL 93-348
Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research