



Human Research Protection Policy

Brigham Young University's human research protection program and Institutional Review Board (IRB) are established and empowered by the university and its assurance of compliance filed with the U.S. Department of Health and Human Services' Office for Human Research Protections. BYU is committed to its ethical and legal responsibilities to safeguard the rights and welfare of human subjects in all research sponsored by BYU or occurring on campus.

Principles of Ethical Responsibility

Human subjects research involves the collection of data through intervention or interaction with a living individual or through identifiable private information regarding a living individual. The university's ethical responsibility for human subjects involved in research is guided by the principles outlined in the Belmont Report, written by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. The three principles identified in the Belmont Report include respect for persons, beneficence, and justice.

Respect requires autonomy, which includes the responsibility to obtain legally effective informed consent, unless the requirements for waiver of informed consent are met by adequate and appropriate methods in accordance with the provisions of applicable regulations. Beneficence necessitates that the sum of the benefits to the subject and the importance of the knowledge to be gained so outweigh the risks to the subjects as to warrant a decision to allow the subject to accept these risks. Justice mandates that the selection of subjects is equitable and representative of the group that will benefit from the research.

IRB Authority over Human Subjects Research

As part of the university's human research protection program, the IRB has authority to review BYU human subjects research, regardless of the source of funding and location of the study, if one or more of the following conditions apply:

- The research is sponsored by university authorities
- The research is conducted by or under the direction of any BYU administrative or staff employee, agent, faculty member, or student in connection with his or her institutional responsibilities

IRB Responsibilities for Human Subjects Research

The IRB is responsible for protecting the rights and welfare of human subjects and reviewing and overseeing research under its authority to ensure that it meets established ethical principles and complies with regulations that pertain to human subject protection. Specifically, the IRB may do any of the following:



- Approve, disapprove, or modify studies under its authority based on the consideration of human subject protection
- Conduct continuing review as it deems necessary to protect the rights and welfare of research subjects, including requiring progress reports from investigators, auditing the conduct of studies, and observing the informed consent process
- Suspend or terminate study approval
- Place restrictions on studies and the role of investigators
- Make determinations as to the definition of “research” or “human subjects” and the resulting implications for IRB authority under this policy

IRB review and approval must be obtained prior to initiating any research-related activities, including recruitment and screening activities. If a human subjects research project is part of an application for externally funded research to a sponsoring agency, then it must be reviewed and approved by the IRB prior to initiating any human subjects research or any expenditure of related grant or contract funds.

IRB Relationship with Other University Committees and with University Officials

The IRB consults and coordinates with other university committees (e.g., Academic Safety, Health, and Environmental Committee; Executive Risk Management and Compliance Committee; Radiation and Laser Safety Committee; Faculty Advisory Council) for advice on policies and practices, but it functions independently from them. These other university committees serve an advisory role and are not responsible to make determinations about human subjects research or protections.

Research that has been reviewed and approved by the IRB may be subject to review and disapproval by institutional officials or other committees for reasons other than protecting human subjects. However, those officials or committees may not approve research if it has been disapproved by the IRB. A non-IRB group that disapproves a research project should define whether any data or other information that may have already been gathered are eligible for publication.

Failure to Submit a Project for IRB Review

The results of human subjects research activity conducted without IRB review and approval may not be published and data may not be included in a thesis or dissertation.

APPROVED: 1 Jun 2020 [Revised 2 Nov 2021]

PRIOR VERSION: 1 Mar 1991



APPLICABILITY: This policy applies to all research involving human subjects that is sponsored by BYU or occurs on campus.

POLICY OWNER: Academic Vice President

RESPONSIBLE OFFICE: Research Administration Office

IMPLEMENTING PROCEDURES: [Policies and Standard Operating Procedures for the Institutional Review Board](#)

RESOURCES: [The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research](#)

RELATED POLICIES:

- [Disruptive Student Conduct Procedures](#)
- [Financial Conflict of Interest in Sponsored Research Policy](#)
- [Information Use, Privacy, and Security Policy](#)
- [Research Misconduct Policy](#)
- [Surveys Policy](#)