

# **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 the university's assurance of compliance is 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.

# Definitions

*Human Subject* means a living individual about whom an investigator (professional or student) conducts research.

*Human Subject Research* means systematic investigation involving a Human Subject and designed to contribute to generalizable knowledge or to advance understanding in a particular field by gathering and using Human Subject Research Data. This may involve

- intervention or interaction with the individual to obtain Human Subject Research Data, such as through medical procedures, surveys, or interviews; and
- obtaining, using, studying, analyzing, or generating Human Subject Research Data.

*Human Subject Research Data* means the information collected from or about a Human Subject during Human Subject Research where the Human Subject's identity can be linked to the information collected.

#### **Researcher Compliance Obligations**

To protect Human Subjects, researchers must comply with relevant domestic and international laws and regulations, as well as university policies and procedures. These include IRB requirements, university data protection practices, and university approval protocols (e.g., <u>Travel Policy</u>, <u>Out-of-State Work Policy</u>, <u>Legal Documents Policy</u>).

# **Principles of Ethical Responsibility**

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 Human 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 Human Subjects is equitable and representative of the group that will benefit from the Human Subject 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 Subject Research, regardless of the source of funding and location of the study, if one or more of the following conditions apply:

- The Human Subject Research is sponsored by university authorities
- The Human Subject Research is conducted by or under the direction of any BYU 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 for reviewing and overseeing Human Subject Research under its authority to ensure the research 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 Human 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 Subject 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 any Human Subject Research activity or any expenditure of related grant or contract funds.

### **Coordination with University Committees and University Officials**

BYU's human research protection program is in the Research Administration Office and consults and coordinates with 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 university committees serve an advisory role and are not responsible to make determinations about Human Subject Research or protections.

Human Subject 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 Human Subject Research if it has been disapproved by the IRB. A non-IRB group that disapproves a Human Subject 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 Subject Research activity conducted without IRB review and approval may not be published, and data may not be included in a thesis or dissertation.

#### **Data Requirements**

Researchers are Data Stewards for the Human Subject Research Data they process (see <u>Data</u> <u>Use, Privacy, and Security Policy</u>).

An employee or student must not disclose Human Subject Research Data owned by BYU or associated with an IRB study unless all of the following conditions have been met:

- the employee or student ensures that the disclosure complies with the consent originally obtained from the relevant Human Subjects;
- the human research protection program confirms Human Subjects have provided datasharing consent;
- the employee or student obtains approval as required by the administrative process described in the Intellectual Property Policy; and
- the associate academic vice president research and graduate studies, or his or her designee, approves and signs any necessary agreements.

**APPROVED:** 16 Dec 2024

PRIOR VERSION: 1 Jun 2020



**Official BYU Policy** 

**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:** Associate Academic Vice President – Research and Graduate Studies

**IMPLEMENTING PROCEDURES:** <u>Policies and Standard Operating Procedures for the Institutional</u> <u>Review Board</u>

**RESOURCES:** <u>The Belmont Report: Ethical Principles and Guidelines for the Protection of Human</u> <u>Subjects of Research</u>

#### **RELATED POLICIES:**

- Data Use, Privacy, and Security Policy
- Financial Conflict of Interest in Sponsored Research Policy
- Intellectual Property Policy
- <u>Research Misconduct Policy</u>
- <u>Student Disruptive Behavior Procedures</u>
- <u>Surveys Policy</u>