BOISE STATE UNIVERSITY

University Policy 5050

Use of Human Subjects

Effective Date

July 1986

Last Revision Date

June 28, 2021

Responsible Party

Vice President for Research and Economic Development, (208) 426-5732
Office of Research Compliance, (208) 426-5401

Additional Authority

- Federal Policy for the Protection of Human Subjects (Common Rule)
- 45 CFR 46 including subparts B, C, and D
- 21 CFR 50, 56, 312 and 812

Scope and Audience

This policy applies to sponsored and unsponsored research involving human subjects when using University facilities or equipment or when conducted by, or on the behalf of, University employees, students, affiliates, volunteers, or visitors.

1. Policy Purpose

To protect the rights, well-being, privacy and confidentiality of individuals and their information by establishing the authority and responsibilities of the University, Institutional Review Boards, and Principal Investigators conducting sponsored and unsponsored human subjects research.

To establish processes and procedures to protect the rights, well-being, and personal privacy and confidentiality of individuals, to assure a favorable climate for the conduct of scientific inquiry, observations, collection of historical data, surveys, questionnaires and to protect the interests of Boise State University when conducting research involving human subjects.

2. Policy Statement

The use of human subjects and their data and biospecimens at Boise State University is essential to the University's research enterprise. Therefore, the University is committed to the ethical principles for the protection of human subjects in research set forth in the Belmont Report of the National Commission for the Protection of Human Subjects in Biomedical and Behavioral Research and the Common Rule. The University recognizes and accepts responsibility, which it shares with its Principal Investigators and other researchers, for determining that research involving human subjects fulfills these ethical principles.

3. Definitions

3.1 Federal Wide Assurance (FWA)

An FWA is an assurance of compliance required and approved by the Department of Health and Human Services (DHHS) Office for Human Research Protections (OHRP) for an institution engaged in human subjects research that is funded or conducted by DHHS. Other federal agencies and departments following the Common Rule may rely on the FWA.

3.2 Human Subject

A human subject is a living individual about whom an investigator (professional or student) conducting research obtains data or biospecimens through intervention or interaction with the individual or collects identifiable private information. Human subject under United States Food and Drug Administration ("FDA") regulations includes an individual who is or becomes a participant in research, either as a recipient of a test article or as a control.

3.3 Research

Research is defined as a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalized knowledge. Research includes surveys and interviews, behavioral investigations, retrospective reviews of medical information, experiments with blood and tissue, and demonstration and service programs and clinical trials. In addition, FDA includes under the definition of reviewable research, any use of an FDA-regulated product except for use of a marketed product in the practice of medicine. Under this definition of Research, the University includes the collections of historical data and reviewing

records, observations, and questionnaires that will be used, shared, or published outside the University's campus.

4. Responsibilities and Procedures

4.1 University

The University uses the Common Rule and its subparts along with FDA requirements, when applicable, as guidance for its human subjects research program. The University also uses guidance published by DHHS for conducting certain types of research.

Under federal regulations as prescribed by the Common Rule, the FWA, and the Office for Human Research Protections (OHRP), the University has established an Institutional Review Board (IRB) charged with reviewing all human subjects research for Boise State University involving human subjects. The IRB under law is required to review all human subject research before it may begin and may approve only that research that meets the established regulatory and ethical criteria.

4.2 Vice President for Research and Economic Development

The President of Boise State University has delegated the Vice President for Research and Economic Development as the University's official signatory and Institutional Official (IO) who is responsible and has oversight for all human subject research activity. The IO has delegated certain responsibilities to the IRB to ensure compliance with these requirements and to the Office of Research Compliance for support and oversight of the IRB. The IO appoints the IRB members annually to ensure appropriate composition and representation according to federal guidelines and committee effectiveness.

4.3 Institutional Review Board

The IRB has the following authority and responsibilities:

a. Review all research projects that will involve human subjects prior to contact of subjects or involvement of human subjects and to determine the appropriate level of review to be exempt, expedited, or full board depending on the risk, confidentiality, and identifiable information required for the research project;

b. Approve, disapprove, or require changes in all research (including the protocol, consent document, etc.) and will notify the principal investigator in writing of this status. Should the IRB disapprove or terminate a research project, the principal investigator may request to present more information either in person or in writing to the IRB explaining why they believe the project should be approved or continued. However, a final IRB decision to

require modifications in, disapprove, suspend, or terminate a project is incontrovertible. No other committee or official, either University or federal, can override these IRB's decision. Further, no committee or person can approve an investigator to conduct any research that an IRB has not approved;

c. Notify federal government agencies and sponsors of approvals and disapprovals or forward such notifications to investigators for submission as applicable;

d. Ensure prompt reporting by investigators to the OHRP as well as any sponsoring agency of unanticipated problems involving risk to subjects or others;

e. Ensure prompt reporting to the IRB by investigators of compliance with the IRB or federal policies or regulations, and report serious or continuing noncompliance to appropriate federal agencies;

f. Suspend or terminate a previously approved project and notify applicable agencies;

g. Conduct continuing reviews of ongoing research as well as any other monitoring such research may require; and

h. Review and monitor the treatment use of investigational drugs, biologicals, and devices outside of the context of research.

- Advise the Vice President for Research and Economic Development and the Office for Research Compliance Director on program, guidelines, procedures, training, and education for human subjects research.

4.4 Office of Research Compliance

The Office of Research Compliance provides administrative support and oversight of the IRB and its program, which includes maintaining official records and developing program guidance, forms, and procedures.

4.5 Principal Investigator

The Principal Investigator serves as the lead person with responsibility and authority over activities involving human subjects research and has the responsibility to:

a. Adhere to federal and state regulations and University policy for human subjects research;

b. Sufficiently complete and submit applicable forms to the IRB for activities requiring review;

c. Abstain from performing activities requiring IRB approval where approval is not granted; and

d. Ensure activities under their direction adhere to the scope and procedures approved by the IRB.

5. Related Information

IRB Program Guidance
boisestate.edu/research-compliance/irb/

University Policy 5020 (Principal Investigator Eligibility)

Revision History

August 2007; June 28, 2021

Last Review Date

June 18, 2024