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## USE OF HUMAN SUBJECTS

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### Purpose:

To establish policies and procedures to protect the rights, well-being, and personal privacy 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.

### Additional Reference:

IRB Program Guide for Human Subject Research, <http://www.boisestate.edu/research>

### Scope:

Applies to all research projects involving human subjects.

### Responsible Party:

Division of Research, Office of Research Compliance, [www.boisestate.edu/research](http://www.boisestate.edu/research)  
Contact Information: Division of Research 208-426-5732

### Definitions:

Federal Wide Assurance (FWA) - Under the Department of Health and Human Services (DHHS) human subjects protection regulations (at 45 C.F.R. 46.103), every institution engaged in human subjects research that is funded or conducted by DHHS must obtain an Assurance Of Compliance approved by the Office for Human Research Protections (OHRP). NOTE: Boise State University assumes responsibility and obligations to ensure all research activity involving Human Subjects will be regulated under this Assurance, regardless if activity is funded or unfunded.

Human subject - means a living individual about whom a professional or student investigator conducting research obtains data through intervention or interaction with the individual or collects identifiable private information, 45 CFR 46.102 ( F ) , Code of Federal Regulations (CFR.), 46.102(f). 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. A "subject" may be a healthy human or a patient, 21 CFR 56.102(e).

Research - "a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalized knowledge." 45 CFR 46.102(d). 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 a FDA regulated product except for use of a marketed product in the practice of medicine. Under this definition of Research, Boise State University includes the collections of historical data and reviewing records,

observations, and questionnaires that will be used, shared or published outside the BSU campus.

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## POLICY

### I. Policy Statement

Boise State University (BSU) 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 Federal Common Rule 45 CFR 46.101. The University recognizes and accepts responsibility, which it shares with its investigators and other researchers for determining that research involving human subjects fulfills these ethical principles. The following general guidelines apply equally to all research involving human subjects, whether carried out solely with University resources or with assistance of outside funds. The University assumes responsibility for communicating and explaining these policies and guidelines to all University personnel and for providing procedural guidelines to effect their observance.

### II. Human Subjects Research

- A. For research involving human subjects, the University uses as its guide the Federal Common Rule (45 CFR 46) entitled "Federal Policy for the Protection of Human subjects Code," Federal Register, June 18, 1991. Also those regulations include in 45 CFR. Part 46, entitled "Protection of Human Research Subjects" (HHS regulation), 21 CFR Part 50, entitled "Protection of Human Subjects" (FDA regulation), and 21 CFR Part 56, entitled "Institutional Review Boards" (FDA regulation). Other applicable FDA regulations, which the IRB and the investigator must follow, depending on the study, include 21 CFR Part 312, "Investigational Drugs" and 21 CFR Part 812, "Investigational Devices." Importantly, the NIH and FDA publicize additional guidelines for the conduct of certain types of research from time to time.
  
- B. 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 research at Boise State University that involves 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.

### III. Authority and Jurisdiction

- A. The President of BSU has delegated the Vice President for Research as BSU's official signatory and Institutional Official (IO), which is responsible and has oversight for all human subject research activity. The IO has delegated the following responsibilities to the IRB Committee to full fill BSU's federal obligations to ensure compliance. The IRB Committee also been charged with the responsibility to update and change procedures as deemed necessary to meet federal, state and University regulations. The IO appoints the IRB members annually to ensure appropriate composition and representation, according to federal guidelines. The Office of Research Compliance provides for the day to day oversight.
- B. The IRB Committee has the following authority and responsibilities:
1. 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.
  2. Approve, disapprove, or require changes in all research (including the protocol, consent document, etc.) and will notify the researcher 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 he or she believes 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 decisions. Further, no committee or person can approve an investigator to conduct any research that an IRB has not approved. 45 CFR 46.112.
  3. Notify federal government agencies and sponsors of approvals and disapprovals, or forward such notifications to investigators for submission as applicable;
  4. Ensure prompt reporting by investigators to the OHRP as well as any sponsoring agency of unanticipated problems involving risk to subjects or others;
  5. 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;
  6. Suspend or terminate a previously approved project and notify applicable agencies;

7. Conduct continuing reviews of ongoing research as well as any other monitoring such research may require; and
8. Review and monitor the treatment use of investigational drugs, biologicals and devices outside of the context of research.