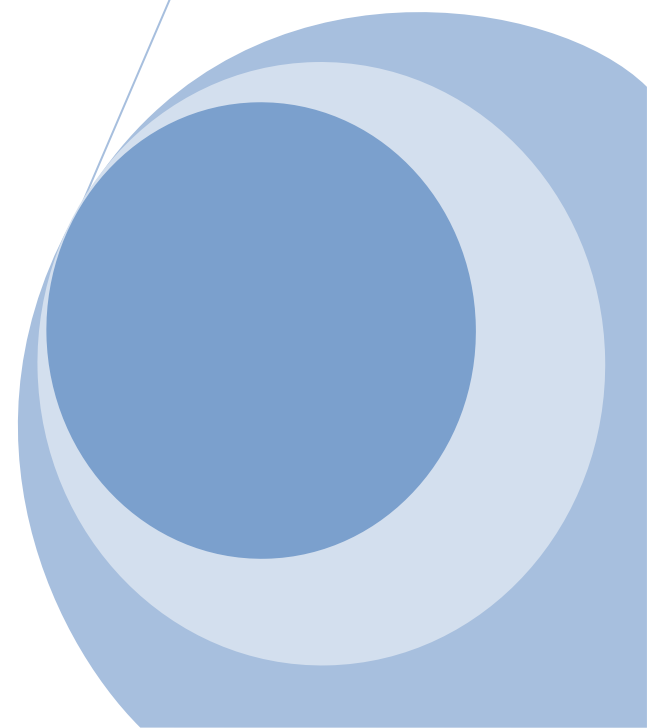
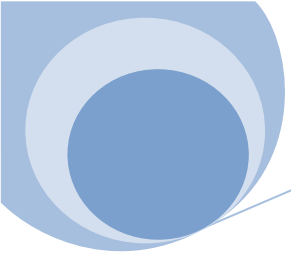




**Institutional Review Board Program**  
GUIDE

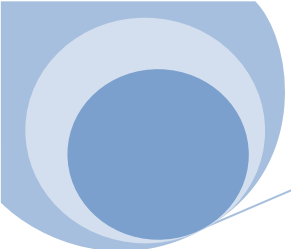
DIVISION OF RESEARCH  
Office of Research Compliance  
March 2011





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## 1. INTRODUCTION

The Boise State University (BSU) Institutional Review Board Program Guidelines for the Protection of Human Research Subjects is a reference document detailing the policies and regulations governing research involving human subjects and the requirements for submitting research proposals for review by the BSU Institutional Review Board (IRB). These policies and procedures are intended to serve as a guide for investigators and their staff who conduct human subject research.

While these policies and procedures provide a general overview of the human research protection process and the main regulatory requirements designed to protect human subjects of research, the regulations of human subject research is continually evolving. Therefore, investigators should ensure that they and their staff understand the information contained herein and follow any mandatory requirements, obtain additional information on any regulatory requirements or expectations relevant to their specific research, and contact the Office of Research Compliance (ORC) with any questions they may have.

**As BSU policy and procedures evolve and federal regulations change, this information will be updated.** Please make sure you have the latest information by checking the ORC Website: <http://www.boisestate.edu/research/compliance/>

### 1.1 Statement of Ethical Principles

Boise State University (BSU) is committed to excellence in teaching, research, and public service and will uphold the ethical principles for the protection of human subjects in research. 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.

For research projects involving human subjects, BSU will fully comply with regulations of the U.S. Department of Health and Human Services (DHHS) Office for Human Research Protections (OHRP) and implement the principles outlined in the Belmont Report. BSU has a signed compliance agreement with the Office for Human Research Protections (OHRP), a subdivision of the Department of Health and Human Services. The assurance document provides written assurance that all federally-funded research conducted at this institution which involves human subjects will be in compliance with the [Code of Federal Regulations \(CFR\) Title 45, Part 46](#).

These broad principles are the basis for BSU's policies and procedures concerning review of research involving human participants:

1. No distinctions in monitoring of research projects will be drawn between funded and unfunded projects, sponsored and unsponsored projects, or between projects carried out by students, faculty, or other University employees, on or off campus;

2. All activities involving humans as participants must ensure the safety, health and welfare of every individual. Rights, including the right of privacy, must not be unduly infringed;
3. The direct or potential benefits to the participant, and/or the importance of the knowledge gained, must outweigh the inherent risks to the individual;
4. Participation in projects must be voluntary and informed consent must be obtained from all participants, unless this requirement is waived by the IRB;
5. An individual does not abdicate any rights by consenting to be a research participant. A participant has the right to withdraw from a research project at any time or may refuse to participate without loss of benefits to which the participant would be otherwise entitled; and
6. Safeguarding information about an individual that has been obtained in the course of an investigation is a primary obligation of the investigator

The basic ethical principles on which the federal regulations for the protection of human subjects are founded are set forth in The Belmont Report. This Report was submitted in 1978 by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, which was established in 1974 under the National Research Act. The Commission was charged with identifying the basic ethical principles that should underlie the conduct of biomedical and behavioral research involving human subjects. The Report sets forth three principles that are basic to the protection of human subjects: Respect for Persons, Beneficence, and Justice.

### **Respect for Persons**

Respect for persons involves the recognition of the personal autonomy and dignity of individuals, and the need for special protection of individuals with diminished autonomy. Under this principle, individuals must be given sufficient information to decide whether to participate in a study, they must be able to comprehend the information, and their consent must be voluntarily given, free from coercion and undue influence. The IRB is expected to be particularly sensitive to these factors when vulnerable subjects are involved, to ensure that extra measures are taken to protect the immature and incapacitated, and may even require that they be excluded from participating in certain research. Respect for persons also means honoring the subjects' privacy and confidentiality.

### **Beneficence**

This principle entails an obligation to protect persons from harm by maximizing anticipated benefits and minimizing possible risks of harm. This principle requires assessing the nature and scope of the risks and benefit, and systematically assessing the risks and benefits. All possible harms must be considered, not only physical and psychological injury. All possible benefits, including societal benefits that might be gained from research must also be considered. Benefits to the

subjects, or generalizable knowledge to be gained from the research, should always outweigh the risks. In assessing the risks and benefits, the appropriateness of involving vulnerable populations is considered.

### **Justice**

The principle of justice requires that the benefits and burdens of research be distributed fairly. Subjects must be fairly selected, and may not be selected either because they are favored by a researcher or held in disdain. Social justice requires an order of preference in the selection of classes of subjects, for example, adults before children. The principle cautions that researchers should not systematically select subjects because of their easy availability, their compromised position, or their social, racial, sexual, or economic position, or because of cultural biases institutionalized in society. Investigators should base inclusion criteria on those factors that most appropriately address the research problem.

## **1.2 Human Subjects Research**

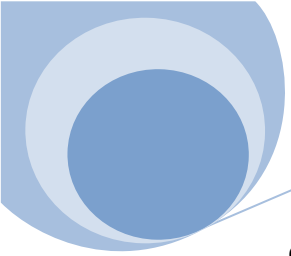
A human subject is a “living individual about whom a professional or student investigator conducting research obtains data through intervention or interaction with the individual or collects identifiable private information” 45 CFR 46.102 (f). Human subjects under United States Food and Drug Administration (“FDA”) regulations include 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 is “a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalized knowledge,” 45 CFR 46.102(d). Research includes, but is not limited to, surveys and interviews, behavioral investigations, retrospective reviews of medical information, experiments with blood and tissue, demonstration and service programs, and clinical trials. In addition, the 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.

### **Internal Evaluation**

Administrative surveys, questionnaires, and interviews designed for use in the internal management and operation of the University do not constitute “research” within the meaning of this policy if the information or conclusions of the surveys are not intended for scholarly publication or for dissemination to persons outside the administrative organization of BSU. A survey which is not “research” need not be submitted to the IRB for review. However, circumstances where there is potential in the future for scholarly publication or dissemination outside the administrative organization of the University, it is strongly encouraged to seek IRB review

Some projects assigned to students in a classroom or coursework may have a research component or constitute training in research methodology. If such projects may



contribute to generalizable knowledge (e.g., through publication or dissemination of the findings) they are participant to the regulations and must undergo IRB review and approval prior to beginning the project. Classroom projects that are exclusively for instructional purposes need not undergo review by the IRB; however, instructors and students are encouraged to follow federal and University regulations when designing and conducting class projects with human participants.

**It is always the responsibility of the principal investigator to obtain IRB approval prior to initiation of any research activity involving the use of human participants.** Failure to do so may result in restrictions on the research activities of such individuals, as well as potentially endanger all federal funding to the University.

In their review of human subject research, the IRB has jurisdiction over all aspects of research involving human subjects, including:

- methods of identifying potential subjects;
- methods proposed for contacting potential subjects;
- materials to recruit subjects and proposed remuneration;
- pilot studies if the data collected will be used solely or in combination with other data for publication purposes;
- proposals to use or provide stored blood, tissues, or confidential data;
- surveys and interview questions;
- the informed consent process and form;
- the protocol and summary of the research;
- proposed changes to the research;
- unanticipated problems involving risk to the subjects or others;
- continuing reviews; and
- use of investigational medical devices.

## **2. IRB ROLES AND RESPONSIBILITIES**

All research projects in which human participants participate, whether funded or unfunded, are subject to the federal regulations governing such research, and to the policies and procedures outlined in the [BSU Policy No. 5050](#) "USE OF HUMAN SUBJECTS" and this Program Guide. Except for cooperative research projects which may be participant to review by another institution's IRB, all projects directed or co-directed by BSU faculty, students or staff must be reviewed and approved by BSU's IRB.

### **2.1 FEDERAL**

Boise State University's Federal Wide Assurance (FWA) #00000097 issued and approved by the Office of Human Research Protection (OHRP) obligates the University to comply with federal human subject research regulations and requirements. In this assurance, BSU has agreed that it will apply these standards to all human subject research, regardless of funding. Therefore, all BSU human subjects research falls under the requirements of its FWA.

Under federal regulations and the FWA, the OHRP establishes IRBs that meet certain requirements and follow specific criteria for reviewing and approving human subject research. These IRBs are required under the law to review all human subject research before it may begin, and may approve only that research that meets the established regulatory and ethical criteria. In conducting their reviews and providing feedback to investigators on required changes, etc., the IRBs serve to educate institutions on important human subject research issues.

The following federal regulations also contain requirements for the review and conduct of human subject research:

- 45 CFR Part 46, entitled "Protection of Human Research Subjects" (DHHS 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."

The NIH and FDA also publicize additional guidelines for the conduct of certain types of research from time to time.

### **2.2 INSTITUTION**

Boise State University, under the FWA, has established an IRB for Human Subject Protection to review all research involving human subjects as participants. The IRB consists of individuals with various experiences and skills necessary to evaluate human research and its institutional, legal, scientific, and social implications.

In order to meet the requirements for approval of proposed research protocols, the IRB shall determine that all of the following requirements are satisfied:

1. Risks to participants are minimized by using procedures which are consistent with sound research design and which do not unnecessarily expose participants to risk, and whenever appropriate, by using procedures already being performed on the participant for diagnostic or treatment purposes.
2. Risks to participants are reasonable in relation to anticipated benefits (if any) to participants, and the importance of the knowledge that may reasonably be expected to result. In evaluating risks and benefits, the IRB shall consider only those risks and benefits that may result from the research (as distinguished from risk and benefits of therapies participants would receive even if not participating in research). The IRB shall not consider possible long-range effects of applying knowledge gained in the research (for example, the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility.
3. Selection of participants is equitable. In making this assessment the IRB shall take into account the purposes of the research and the setting in which the research will be conducted.
4. Informed consent will be sought from each prospective participant or the participant's legally authorized representative, in accordance with, and to the extent required under [45 CFR 46. 116](#).
5. Informed consent will be appropriately documented, in accordance with, and to the extent required under [45 CFR.46. 117](#).
6. Where appropriate, the research plan makes adequate provisions for monitoring the data collected to insure safety (physical and psychological) of participants.
7. Where appropriate, there are adequate provisions to protect the privacy of participants and to maintain the confidentiality of data. Where some or all of the participants are likely to be vulnerable to coercion or undue influence, such as persons with acute or severe physical or mental illness, or persons who are economically or educationally disadvantaged, appropriate additional safeguards have been included in the study to protect the rights and welfare of these participants.

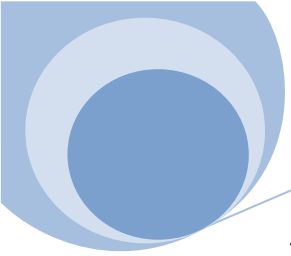
### **2.3 PRESIDENT**

The responsibility for compliance with federal, state or University regulations concerning activities involving human subjects rests with the President of Boise State University. The President has delegated this authority to the Vice President for Research as the Institutional Official (IO).

### **2.4 VICE PRESIDENT FOR RESEARCH**

The Vice President for Research is the authorized IO, delegated by the President, for human subjects research. The Vice President for Research shall:

1. Ensure compliance with all applicable laws and policies;



2. Appoint an IRB with appropriate administrative support;
3. Develop administrative procedures necessary to implement the BSU Human Research Protections Program;
4. Will, with consultation from the IRB Chair and the Director of the ORC, annually review the composition of the IRB membership to ensure efficiency and a balance of interests in regard to human subject research
5. Perform all necessary reporting requirements;
6. Report to the appropriate officials any noncompliance with laws and policies, as well as any corrective or remedial action taken;
7. Have proper administrative and operational authority to commit institutional resources to ensure compliance with the Federal Wide Assurance and other requirements;
8. Ensure that all personnel involved in human subject research are qualified to perform duties and that training and instruction in specific areas (i.e. psychological stresses of interviews, handling pressure or emotional situations) are provided to those personnel;
9. Review qualifications of personnel to ensure they can fulfill their responsibilities for the research project; and
10. Ensure that the University maintains records for at least 3 years, as required by [45 CFR 46.115\(b\)](#).

### 3. COMPOSITION AND ROLES OF IRB MEMBERS

#### 3.1 Voting Members

Federal regulations require the IRB to have no less than five voting members, including the Chair. The IRB will include at least one member whose primary concerns are in scientific areas, one whose primary concerns are in nonscientific areas, and at least one member from the community.

The Vice President for Research will ensure appointed members are sufficiently qualified through the experience and expertise of its membership and the diversity of its members, including consideration of race, gender, and cultural backgrounds and sensitivity to such issues as community attitudes, to promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects. Further, the University affiliated IRB members will be able to ascertain the acceptability of proposed research in terms of institutional commitments.

**Scientific members.** The IRB must include a practicing scientist experienced in research involving human subjects, whose primary concerns are in a scientific area. Scientific members of the IRB will be recruited from among active members of the faculty of BSU academic units as appropriate. The principle role of the scientist is to ensure that the interests of scientific colleagues are being fairly represented in the review process and to aid in the IRB's assessment of relevance, validity and technical aspects of the protocol submitted for approval. This individual can also bring a better understanding of the selection, use and limitations of human models, instruments, and tools for evaluation of methods and certain aspects of experimental design.

**Nonscientific members.** Nonscientific members will possess a primary focus in non-scientific area, such as law, ethics, human or patient rights, etc. Nonscientific members of the IRB will be recruited from among active members of the faculty of BSU academic units as appropriate.

**Community members.** Individuals serving in this capacity should represent the community and have no obvious connections to the University. The community members will be knowledgeable about the local community and willing to discuss issues and research from that perspective. They are usually chosen from the Boise vicinity. An informed community member can bring significant value to the committee by bringing a non-institutional perspective to the research endeavor. This member has equal status to every other committee member and should be provided the opportunity to participate in all aspects of IRB functions.

#### 3.1.1 Selection and Appointment

The IO will appoint all members to serve on the board for a three year term. The IO, in consultation with the IRB Chair and IRB Coordinator, will annually review

the IRB membership. Appointments to the committee begin June 1<sup>st</sup> of the year appointed and end May 31<sup>st</sup> the following year. Appointments may begin at other times, but all appointments will end on May 31<sup>st</sup> of the following year. Annual review may include but not limited to, the attendance, timely submission of comments and participation in scheduled meetings. IRB members may be removed or replaced by the IO prior to their three-year term if deemed necessary.

At the conclusion of their three-year term, a committee member may (or may not) be appointed to an additional term and/or year of service. There is no limit to the number of terms a member may serve on the IRB.

### **3.1.2 Duties**

IRB members are responsible for protecting the rights and welfare of human research subjects by reviewing, approving and monitoring human subject research in a manner consistent with federal regulations, state and local laws, and Institutional guidelines and policies. Committee members are also required to complete the IRB Committee Member CITI training modules.

Serving as an IRB member is considered to be an important role as well as an honor. It is recognized and appreciated that faculty and community members serve in addition to their regular profession, teaching, research, and other service.

## **3.2 IRB Chair**

### **3.2.1 Selection and Appointment**

Each IRB committee will have a Chair. The IO shall appoint one member of the IRB to serve as the Chair for a term of three years. Chairs may be reappointed for additional one year appointments. There is no limit to the number of terms a member may serve on the IRB.

### **3.2.2 Duties**

The Chair works closely with the IRB members, the Director of the ORC, the IRB Coordinator, Institutional officials, and investigators to ensure the rights and welfare of research participants are protected. The Chair has the authority to sign for the IRB and conducts all IRB meetings. The Chair designates the reviewers for expedited applications and may delegate in writing the ability to assign reviewers to the IRB Coordinator. The Chair also designates the IRB Coordinator to send official letters, email approval notifications and other IRB related correspondence on behalf of the Chair. Whenever possible, the Chair is encouraged to attend regional and/or national IRB conferences for additional education and certification.

Broad responsibilities include:

1. The review and approval of exempt protocol applications;
2. Ensuring proper conduct and review of all expedited and full board applications;
3. Conducting each of the monthly convened meetings;
4. Request special meetings when necessary;
5. Initial review of adverse events, unanticipated events, and assisting in investigating and resolving complaints;
6. With IO consultation, making decisions in emergency situations to protect subjects and remain in compliance with regulations;
7. Reviewing institutional policies, procedures and forms on an ongoing basis;
8. In consultation with IO, reviewing the make-up and performance of current committee members;
9. Relating concerns to administration regarding issues in human research review; and
10. Signing the Notification of Approval and other formal acknowledgment letters.

## **4. MANAGEMENT OF THE IRB**

### **4.1 Administrative Support**

Administrative and operational support for the IRB is provided by the IRB Coordinator.

The following duties are responsibilities of the IRB Coordinator:

1. Take minutes of the meetings and maintain appropriate records;
2. Advise faculty, staff and students in preparation of applications for research involving human subjects and consent documents;
3. Provide education to the BSU campus about the human subjects protection process;
4. Receive all protocol submissions, including new, modified and renewed protocols;
5. Ensure each member receives agenda and protocol applications with sufficient time for review prior to meetings;
6. Prepare adverse events reports to the Director;
7. Maintains a database of IRB approved protocols, annual reviews and disapproved protocol;
8. Maintains the IRB membership roster and update roster information under the Federal Wide Assurance;
9. Complete all CITI program modules on human subjects research;
10. Attend regional and/or national IRB conferences when possible for continuing education;
11. Communicate reviewer's requests to investigators for additional information and revisions and review responses.

## 5. LEVELS OF IRB REVIEW

It is the policy of Boise State University that the IRB will utilize the **Common Rule** criteria for all projects involving human participants in research when evaluating proposed research protocols.

### 5.1 EXEMPT REVIEW (criteria from 45 CFR 46.101)

Research activities in which the only involvement of human subjects will be in one or more of the following categories will qualify for an exempt review:

1. Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as:
  - a. research on regular and special education instructional strategies, or
  - b. research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.
2. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless:
  - a. information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and
  - b. any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.
3. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under category 2 above, if:
  - a. the human subjects are elected or appointed public officials or candidates for public office; or
  - b. federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.
4. Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.
5. Research and demonstration projects which are conducted by or subject to the approval of department or agency heads, and which are designed to study, evaluate, or otherwise examine:

- a. public benefit or service programs; or
  - b. procedures for obtaining benefits or services under those programs; or
  - c. possible changes in or alternatives to those programs or procedures; or
  - d. possible changes in methods or levels of payment for benefits or services under those programs.
6. Taste and food quality evaluation and consumer acceptance studies:
- a. if wholesome foods without additives are consumed; or
  - b. if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

#### **5.1.1 LIMITATIONS ON EXEMPTIONS**

Research involving prisoners may not be exempted. Research involving minor children may be exempt only as it applies to categories 1, 3, 4, 5 and 6 above. Research involving minors which falls under category 2 may be exempt for educational tests and observation (when the investigator does not participate in the activities being observed). Research involving survey or interview procedures may not be exempted for minors.

#### **5.2 EXPEDITED REVIEW**

Expedited research activities involve no more than "minimal risk" to participants. Expedited review procedures are described in the DHHS regulations at [45 CFR 46.110](#). The list of categories that may be reviewed by the IRB through an expedited review are listed below:

1. Clinical studies of drugs and medical devices only when condition (a) or (b) is met:
  1. Research on drugs for which an investigational new drug application (21 CFR Part 312) is not required. (Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review).
  2. Research on medical devices for which (i) an investigational device exemption application (21 CFR Part 812) is not required; or (ii) the medical device cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.
2. Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:
  1. from healthy, nonpregnant adults who weigh at least 110 pounds. For these participants, the amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week; or

2. from other adults and children considering the age, weight, and health of the participants, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these participants, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week.
3. Prospective collection of biological specimens for research purposes by noninvasive means.  
Examples: (a) hair and nail clippings in a nondisfiguring manner; (b) deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction; (c) permanent teeth if routine patient care indicates a need for extraction; (d) excreta and external secretions (including sweat); (e) uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gumbase or wax or by applying a dilute citric solution to the tongue; (f) placenta removed at delivery; (g) amniotic fluid obtained at the time of rupture of the membrane prior to or during labor; (h) supra- and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques; (i) mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings; (j) sputum collected after saline mist nebulization.
4. Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.)  
Examples: (a) physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject's privacy; (b) weighing or testing sensory acuity; (c) magnetic resonance imaging; (d) electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography; (e) moderate exercise, muscular strength testing where appropriate given the age, weight, and health of the individual.
5. Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis).

(NOTE: Some research in this category may be exempt from the U.S. Department of Health and Human Services regulations for the protection of human participants. 45 CFR 46.101(b)(4). This listing refers only to research that is not exempt.)

6. Collection of data from voice, video, digital, or image recordings made for research purposes.
7. Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.

(NOTE: Some research in this category may be exempt from the DHHS regulations for the protection of human participants. 45 CFR 46.101(b)(2) and (b)(3). This listing refers only to research that is not exempt.)

8. Continuing review of research previously approved by the convened IRB as follows:
  1. where (i) the research is permanently closed to the enrollment of new participants; (ii) all participants have completed all research-related interventions; and (iii) the research remains active only for long-term follow-up participants; *or*
  2. where no participants have been enrolled and no additional risks have been identified; *or*
  3. where the remaining research activities are limited to data analysis.
9. Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where categories two (2) through eight (8) do not apply but the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.

### **5.3 FULL BOARD REVIEW**

Any research or training project involving the use of human participants which does not fall into an exempt or expedited review category must be submitted for full board IRB review. Research projects involving more than minimal risk and the use of human participants under the age of 18 years of age or other protected populations may fall into this category.

## 6. IRB PROTOCOL APPLICATION SUBMISSION PROCESS

Investigators do not have authority to begin their research until notification of approval from the IRB has been received.

### 6.1 Requirements for All Protocol Submissions

#### 6.1.1 CITI Training

The IRB requires that all principal and co-principal investigators listed on IRB protocol applications must successfully complete the Collaborative Institutional Training Initiative (CITI) online training program (<https://www.citiprogram.org>) prior to submitting a protocol for consideration. You will need to create a password and login in order to access the tutorial.

#### REQUIRED MODULES

If you are conducting Social & Behavioral Research (Psychology, Sociology, Education, etc.) choose “**Social Behavioral Research**” under Question 1 when selecting your curriculum on the CITI webpage.

If you are conducting Biomedical Research (Nursing, Kinesiology), choose “**Biomedical Research**” under Question 1 when selecting your curriculum on the CITI webpage.

The modules on Responsible Conduct of Research (RCR) are optional and not required for IRB protocol application submissions. If you have questions about which modules you should complete to submit an IRB protocol application, please contact the Coordinator in the Office of Research Compliance at 208.426.5401 or [HumanSubjects@boisestate.edu](mailto:HumanSubjects@boisestate.edu).

#### 6.1.2. Principal Investigator Eligibility

The IRB requires principal investigators to be a Boise State University full, assistant, or associate professor, or director. Visiting faculty, adjuncts, instructors, and staff may be listed as a principal investigator as long as a BSU full, assistant, or associate professor or director is listed as the co-principal investigator.

If you are not affiliated with BSU, the IRB will review your research for approval, but you may be charged. Please contact the Office of Research Compliance for additional information. If this protocol application is part of a grant requesting federal money, the PI must fall under the BSU PI eligibility policy #5020.

#### 6.1.3 Student Investigator Eligibility

The IRB does not permit students to serve as principal investigators on protocol applications except in the cases of thesis and dissertation research activities. Graduate students working on their thesis or dissertation may be designated as

the PI as long as their advisor is identified as the Co-PI. In all other circumstances, a faculty member must be designated as the PI and the student as the Co-PI.

### **6.1.3. Signatures**

The application must be signed by the PI before the protocol will be approved. If the principal investigator is a graduate student, the faculty advisor must also sign the application. The faculty advisor's signature must be received before the protocol application will move forward to the IRB for review.

If there are multiple individuals listed as the PI, each individual must sign the protocol application. Co-PIs are not required to sign, unless the PI is a graduate student.

### **6.1.4. Complete Protocol**

The protocol application must include all relevant materials for review and approval by the IRB. These materials include but are not limited to:

1. Grant Proposal
2. Recruitment Materials
  - i. Flyers, scripts, emails, letters
3. Consent Documents
  - i. Consent Form, Assent Form, Parent Permission Form, Cover Letter, Verbal Consent Script, Debriefing Statement
4. Research Tools
  - i. Questionnaires, surveys, interview questions and scripts, focus group questions and scripts, permission/acknowledgement letters

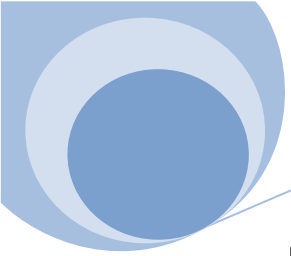
## **6.2 Initial Review**

The ORC is the administrative office responsible for oversight of the human subjects review process. The IRB Coordinator will screen new applications within one to two days of submission. If the application is complete, it will be assigned to a review committee. Incomplete or handwritten protocols will be returned to the investigator for resubmission.

## **6.3 Exempt Protocol Application Submissions**

Investigators must submit a completed exempt application and all relevant materials to [HumanSubjects@boisestate.edu](mailto:HumanSubjects@boisestate.edu). The signature page can be faxed, mailed, or brought to the IRB Coordinator in person.

Complete applications will be forwarded to the designated IRB representative for review. Exempt protocols are reviewed electronically by the Chair. The Chair is responsible for reviewing the protocol application. The Office of Research Compliance will notify the PI if additional information or clarification about the research project is



needed. The Chair also has the authority to request that an application submitted as exempt undergo expedited or full board review as appropriate.

After the chair has approved the protocol application as exempt, the Office of Research Compliance will send a Notification of Approval letter via e-mail to the principal investigator. Exempt review and approval may take up to two weeks.

Annual renewals are not required for exempt protocols. The exemption covers any research and data collected under the protocol once the protocol application is approved, unless terminated in writing by the principal investigator or the Boise State University IRB. All amendments or changes (including personnel changes) to the approved protocol must be brought to the attention of the IRB for review and approval before they occur, as these modifications may change the exempt status.

When the research project is completed, the PI must submit a “Final Report Form.” The exempt status expires when the research project is completed (closed) or when the review category changes as described above.

#### **6.4 Expedited Protocol Application Submissions**

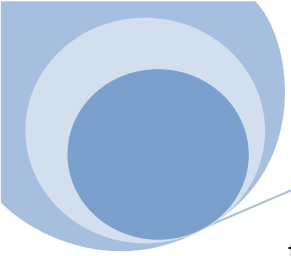
Expedited and full board protocol applications utilize the same form, “Expedited or Full Board Protocol Application.”

Investigators must submit a completed expedited protocol application and all relevant materials to [HumanSubjects@boisestate.edu](mailto:HumanSubjects@boisestate.edu). The signature page can be faxed, mailed, or brought to the IRB Coordinator in person.

Complete applications will be forwarded to the designated IRB members for review. Expedited protocols are reviewed electronically by the Chair and one IRB member. The IRB reviewers are responsible for reviewing the protocol application. The IRB Coordinator will notify the PI if additional information or clarification about the research project is needed. The IRB reviewers also have the authority to request that an application submitted as expedited undergo full board review.

After the reviewers have approved the protocol application, the Office of Research Compliance will send a Notification of Approval letter via e-mail to the principal investigator. Expedited review and approval may take up to four weeks.

The approval is effective for 12 months unless terminated in writing by the principal investigator or the Boise State University IRB. The IRB may also require continuing review at intervals appropriate to the degree of risk, but not less than once per year. If the research is not finished within the allotted year, the protocol must be renewed before its expiration date. The Office of Research Compliance will send a reminder notice approximately 60 and 30 days prior to the expiration date. The principal investigator has the primary responsibility to ensure a renewal form is submitted in a



timely manner. If the protocol is not renewed before the expiration date, a new protocol application must be submitted for IRB review and approval.

Each expedited protocol has a three-year life cycle and is allowed to be renewed within those three years. If the research is not complete by the third year a new protocol application must be submitted.

All amendments or changes (including personnel changes) to the approved protocol must be brought to the attention of the IRB for review and approval before they occur.

When the research is completed, the PI must submit a Final Report Form.

### **6.5 Full Board Protocol Application Submissions**

Expedited and full board protocol applications utilize the same form, "Expedited or Full Board Protocol Application."

Investigators must submit a completed full board protocol application and all relevant materials to [HumanSubjects@boisestate.edu](mailto:HumanSubjects@boisestate.edu). The signature page can be faxed, mailed, or brought to the IRB Coordinator in person.

Complete applications will be forwarded to the IRB committee for review. Full board protocol applications are reviewed by the full committee at their monthly convened meetings. Full board protocol applications, therefore, must be submitted no later than two weeks before the monthly scheduled meeting. An updated schedule of full board IRB meetings is on the ORC website.

After the meeting, the IRB Coordinator will notify the PI if additional information or clarification about the research project is needed. If the IRB determines that a Full Board protocol is approvable contingent upon receipt of specific minor modifications (confirming: debriefing will take place with faculty advisor, or student has been trained to conduct interviews) or clarification of a specific point, the IRB will consider these as administrative follow up of details and once clarified, will consider the protocol approved as earlier designated by a full board majority vote.

The Office of Research Compliance will send a Notification of Approval letter via e-mail to the principal investigator. Full board review and approval may take up to six weeks.

The approval is effective for 12 months unless terminated in writing by the principal investigator or the Boise State University IRB. The IRB may also require continuing review at intervals appropriate to the degree of risk, but not less than once per year. If the research is not finished within the allotted year, the protocol must be renewed before its expiration date. The Office of Research Compliance will send a reminder notice approximately 60 and 30 days prior to the expiration date. The principal

investigator has the primary responsibility to ensure a renewal form is submitted in a timely manner. If the protocol is not renewed before the expiration date, a new protocol application must be submitted for IRB review and approval.

Each full board protocol has a three-year life cycle and is allowed to be renewed within those three years. If the research is not complete by the third year a new protocol application must be submitted.

All amendments or changes (including personnel changes) to the approved protocol must be brought to the attention of the IRB for review and approval before they occur.

When the research is completed, the PI must submit a “Final Report Form.”

### **6.6 Modifications**

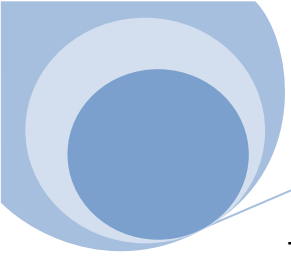
If an investigator needs to change or modify his or her research after obtaining IRB approval, a “Modification/Amendment Form” must be submitted to [HumanSubjects@boisestate.edu](mailto:HumanSubjects@boisestate.edu) for IRB review and approval. No proposed changes shall be implemented until IRB approval has been obtained. Modifications include, but are not limited to, removing or adding Principal Investigator (PI) or Co-Principal Investigator (co-PI), using a different recruitment method, recruiting a different population, adding interview questions, etc.

Some modifications may change the type of review (exempt, expedited, full board) the application originally received. For example, a previously approved exempt protocol involving anonymous surveys would be move to a full board review if an investigator wanted to include videotaping a focus group of subjects from a vulnerable population. The IRB will review the proposed changes and assess the level of risk involved and determine if the modification requires a different type of review. The ORC will notify the outcome of the review to the investigator(s) in writing.

Depending on the type of modification, approval of proposed changes can normally be returned to the investigator after one week for exempt and expedited review. Major modifications (significant change to research methods and procedures) may take up to two weeks. If the modification to a full board protocol is minor, the IRB may use the expedited review process to review and approve and can normally returned after one week. Major modifications to a full board protocol must be reviewed by the full committee at a convened meeting.

Modification forms do not need to be signed by the PI unless the PI is a graduate student conducting research for his/her thesis or dissertation.

### **6.7 Renewals/Continuing Review**



The IRB generally approves protocol applications for one year, though some research projects may require shorter renewal dates. If the research is not finished within the allotted year, the protocol must be renewed by the annual expiration date indicated on the approval letter. The ORC will send a renewal reminder notice about 60 and 30 days prior to the expiration date of the approved protocol. The principal investigator has the primary responsibility to ensure the “Annual Renewal Form” is submitted in a timely manner to [HumanSubjects@boisestate.edu](mailto:HumanSubjects@boisestate.edu).

Investigators should allow at least two weeks for expedited renewal review. Continuing reviews requiring full board review must be received at least two weeks prior to the next scheduled meeting. If the continuing review is not submitted and completed before approval expires, all research must stop and a new initial application must be submitted.

Exempt applications do not require continuing review.

Renewal forms do not need to be signed by the PI unless the PI is a graduate student conducting research for his/her thesis or dissertation.

## 7. CRITERIA FOR REVIEW AND APPROVAL

### 7.1 Criteria for IRB Approval

Federal regulations dictate the criteria the IRB must follow to approve a protocol:  
45 CFR 46.111

(a) In order to approve research covered by this policy the IRB shall determine that all of the following requirements are satisfied:

1. Risks to subjects are minimized:
  - (i) By using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk, and
  - (ii) whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.
2. Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result. In evaluating risks and benefits, the IRB should consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies subjects would receive even if not participating in the research). The IRB should not consider possible long-range effects of applying knowledge gained in the research (for example, the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility.
3. Selection of subjects is equitable. In making this assessment the IRB should take into account the purposes of the research and the setting in which the research will be conducted and should be particularly cognizant of the special problems of research involving vulnerable populations, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons.
4. Informed consent will be sought from each prospective subject or the subject's legally authorized representative, in accordance with, and to the extent required by §46.116.
5. Informed consent will be appropriately documented, in accordance with, and to the extent required by §46.117.
6. When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.
7. When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

(b) When some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons, additional safeguards have been included in the study to protect the rights and welfare of these subjects.

### 7.1.1 Risks and Benefits

The IRB is responsible for ensuring that risks to subjects are minimized and that the risks are reasonable in relation to the anticipated benefits, if any, to subjects and to the importance of the knowledge that may reasonably be expected to result.

**Risk:** The probability of harm, including:

1. Physical (for example, in biomedical studies, the risks of adverse events or the risk of randomization and not receiving the treatment that turns out to be more efficacious);
2. Psychological (for example, depression, confusion, fear, stress, loss of self-esteem); and
3. Social or economic (for example, breaches of confidentiality and privacy in research involving drug or alcohol use, sexual behavior, mental illness, or illegal activities, or in genetic research, could lead to embarrassment in a social group, prosecution, or loss of employment, insurability concerns, etc.).

Both the probability and magnitude of possible harm may vary from minimal to significant. Risks include immediate risks as well as, risks of long term effects.

**Benefit:** A valued or desired outcome. Anticipated benefits may express the probability that subjects and society may benefit from the research procedures. Research may benefit the individual, for example, by alleviating a condition or providing a better understanding of his or her disease. Research that has no therapeutic intent may still benefit society as a whole. If research will not benefit individuals, it is required to provide a reasonable likelihood of resulting in benefits to society, e.g., the advancement of important knowledge.

In reviewing the risks to ensure that they are minimized, IRB may consider whether previous studies have been done, whether the investigators serve a dual role as instructor/investigator, physician/investigator role to the subject and if so, whether safeguards are necessary, whether the research is designed to yield useful data, whether there are any monitoring mechanisms if necessary, and whether follow-up counseling or other care will be provided (for instance, with genetic research), as applicable. Thus, the IRB may consider the study design in reviewing investigators' studies, since putting subjects at any risk or even inconveniencing them with a study that is methodologically flawed such that little or no reliable information will be obtained would be unethical.

### 7.1.2 Selection of Subjects

The IRB is required to review the method for prospective identification of subjects. They will examine the means of identifying and contacting potential subjects and the methods for ensuring the subjects' privacy and confidentiality.

Investigators are required to submit plans for ensuring the privacy and confidentiality of subjects.

### **7.1.3 Privacy and Confidentiality**

Privacy refers to persons. It is the control over the extent, timing, and circumstances of sharing oneself (physically, behaviorally, or intellectually) with others. Confidentiality refers to data. It is the treatment of information already revealed and states that there is an expectation that it will not be divulged to others in ways that are inconsistent with the understanding of the original disclosure without authorization.

These issues are of particular concern in requests to review databases and medical records without patient consent, and research that will elicit potentially sensitive or damaging information (for instance, interview or genetic research) about the subject or a group to which the subject belongs. Factors that may be considered include the importance of the research, the sensitivity of the information sought to be obtained and to which the investigator will have access, whether links to identifiers will be maintained, the procedures the investigator has devised for protecting the information, and, if the review is for the purpose of identifying potential subjects, whether there are other feasible methods for recruiting subjects. Investigators should address these issues of confidentiality and privacy under the "Risk" section of their protocol package.

A Certificate of Confidentiality helps researchers protect the privacy of human research participants enrolled in biomedical, behavioral, clinical and other forms of sensitive research. These certificates are issued by the NIH. Certificates protect against compulsory legal demands, such as court orders and subpoenas, for identifying information or identifying characteristics of a research participant. Any research that collects personally identifiable, sensitive information and that has been approved by an IRB is eligible for a Certificate. Federal funding is not a prerequisite for Certificate. For more information:

<http://grants.nih.gov/grants/policy/coc/index.htm>

### **7.1.4. The Informed Consent Process**

The IRB will carefully review the proposed informed consent process and document to ensure that human subjects will be adequately informed regarding the proposed research.

### **7.1.5 Additional Monitoring or Safeguards**

The IRB may decide that a protocol application requires review more than annually or that it needs verification from other sources that no material changes have been made since the previous review, and/or that the project needs additional monitoring or procedures to ensure the safety of the subjects.

Both of these determinations generally will be based on the degree of risk in the study, taking into account any vulnerability of the subject population.

## **7.2 Additional Requirements for Special Populations**

The Office for Human Research Protections (OHRP) has identified [populations](#) in need of special protections in research. When research involves greater than minimal risk, the participant needs a reasonable enumeration of the risks in order to decide whether or not to participate. The list should not be constructed either to minimize real risks or to overstate them. Projects with risks should also list protection measures used to lower the risk potential or to ensure safety while the participant encounters the risks.

Although the regulations only specify certain special categories of subjects, the overall intent is clear. Whenever the potential subjects of research have special features or circumstances that might alter their ability to render informed and voluntary consent to participate in research, the researcher has additional responsibilities. There is no way to anticipate every situation. Therefore, researchers must use extreme care to respect the rights of potential subjects in developing the means of obtaining their informed consent and collecting data.

The regulations identify additional requirements for review and approval of research involving fetuses, pregnant women, and neonates, 45 CFR 46 Subpart B, prisoners, 45 CFR 46 Subpart C, and children, 45 CFR 46 Subpart D. In reviewing research projects involving all categories of vulnerable subjects, the IRB ascertains the use of the vulnerable population being adequately justified and that additional safeguards are implemented to minimize risks unique to each group, as appropriate. A summary of the additional requirements for review and approval of research involving children, prisoners, and pregnant women and fetuses is presented below:

### **7.2.1 Fetuses, Pregnant Women, and Neonates**

The federal regulations have specific requirements for research involving pregnant women, human fetuses, and neonates. These requirements are found in Subpart B of the DHHS regulations (45 CFR Part 46).

### **7.2.2 Prisoners**

The federal regulations have specific requirements for research involving prisoners. These requirements are found in Subpart C of the DHHS regulations (45 CFR Part 46).

A prisoner includes any person who is sentenced to a penal institution under a criminal or civil statute as well as individuals detained in other facilities by virtue of statutes or commitment procedures which provide alternatives to criminal prosecution or incarceration in a penal institution 45 CFR 46.303(c). Subpart C contains many specific requirements for research involving prisoners and should

be reviewed by the researcher. In order to review research involving prisoners the IRB is required to have a prisoner or prisoner representative with appropriate background and expertise to serve in that capacity on the committee. The OHRP has specific guidance for involving prisoners in research <http://www.hhs.gov/ohrp/>.

Research involving prisoners does not qualify for an exemption.

### 7.2.3 Children

The federal regulations have specific requirements for research involving children. Children are defined as "persons who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted" 45 CFR 46.402(a). Therefore, "children" include any persons under the age of 18 (unless the child has been emancipated by court order, marriage, or is on active military duty).

45 CFR 46, Subpart D, classifies research involving children into one of four categories depending upon the risks and benefits of the proposed research, which can be approved as follows:

1. **Research involving no greater than minimal risk.** Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examination or tests. This research is approvable in accordance with the general IRB review criteria provided that adequate provisions are made for soliciting the assent of the child and parental permission. [Requires one parent/guardian permission and child assent.]
2. **Research involving greater than minimal risk, but presenting the prospect of direct benefit to individual subjects.** This research is approvable in accordance with the general IRB review criteria if a) the risk is justified by the anticipated benefit to the subjects; b) the relationship of risk to benefit is at least as favorable as any alternative approach; and c) adequate provisions are made for soliciting the assent of the children and permission of their parents or guardians. [Requires one parent/guardian permission and child assent.]
3. **Research involving greater than minimal risk and no prospect of direct benefit to individual subjects but likely to yield important generalizable knowledge about the subject's disorder or condition.** This research is approvable in accordance with the general IRB criteria if: a) the risks represent a minor increase over minimal risk; b) the intervention or procedure presents experiences to subjects that are reasonably commensurate with those inherent in their actual or expected medical,

dental, psychological, social, or educational situations; c) the intervention or procedure is likely to yield generalizable knowledge about the subjects' disorder or condition which is of vital importance for the understanding or amelioration of the subjects' disorder or condition; and d) adequate provisions are made for soliciting assent of the children and permission of their parents or guardians. [Requires both parents' permission, unless one is not reasonably available, deceased, unknown, legally incompetent, or does not have legal responsibility for care of the child; and child assent.]

4. **Research not otherwise approvable which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children.** This research is generally not approvable by an IRB without the appointment of and review by a separate panel of experts.
5. **Assent and Permission Required.** The federal regulations require both assent of a child and permission by a parent or legal guardian for research.

#### **Wards of State**

Where children are wards of the state or another agency or institution, additional restrictions apply, and they may only be included in research that is related to their status as wards, or which is conducted in schools or other institutions in which a majority of children are not wards. If the IRB approves research under this provision (45 CFR 46.409), it must appoint an advocate for each child that is a ward.

**No Exemption for Research Involving Surveys or Interviews.** Unlike research involving adults, the exemption at 45 CFR 46.101(b)(2) for research involving survey procedures, interviews, educational tests, or public observations (except where the investigator does not participate in the activities being observed) does not apply to research involving children 45 CFR 46.401(b).

## **8. INFORMED CONSENT REQUIREMENTS**

Every researcher (faculty, staff, or student) at Boise State University must obtain the informed consent of any human subject before involving that person in the research project. Obtaining the informed consent of subjects is a matter of professional research ethics in every discipline at the University. Samples of consent forms are available [online](#). It is strongly suggested that researchers use the sample informed consent documents as a model.

The investigator must ensure that the circumstances under which consent is sought will provide the subjects (or their representative) with sufficient opportunity to consider whether or not to participate. The circumstances must also minimize the possibility of coercion or undue influence, which might be experienced by the subjects. Many times, the situation of obtaining consent of the subjects may be inherently coercive, i.e., their freedom of choice may be restricted by the nature of their employment, their age, associations with certain groups, or their mental or physical capacities. Restriction of freedom of choice may also occur due to confinement in a mental hospital or in a jail, penitentiary, or correctional institution. Subjects in any of these categories are not excluded from research; rather, the investigator must make special efforts to ensure that potential subjects are given every opportunity to exercise free choices in consenting to participate in a research project.

### **8.1 The Informed Consent Document**

The consent document is not meant to be merely a legal record of the consent process, nor is it meant to be the only communication between researcher and prospective subject. On the contrary, the document should be one part of the total consent process. 45 CFR 46.116 (a)(1-8) defines eight required elements of consent. Broadly, the informed consent document communicates to the prospective research subject the purpose, procedures, risks and benefits of the study, the subject's rights in participating in research, and the freedom to decline to participate without any jeopardy. If applicable, the alternative treatments available will be explained. The individual will also be given the opportunity to obtain further information and answers to questions related to the study. The consent form should serve as a written summary of the exact information that was presented to the prospective subjects before their agreement to participate in the study. As such, it will provide a useful reference for both the research subject and the investigator.

The subject must also be given a clear and free choice to accept the invitation to participate or to refuse without prejudice or penalty. If subjects are students, patients or employees of an institution in which research is being conducted, they must be informed that nonparticipation or withdrawal from the study at any time will not affect their grade, treatment, care, employment status or benefits to which the subject is otherwise entitled.

If the research involves the deception of participants (withholding particular information about the research project from participants until completion of their participation when prior knowledge would adversely affect the integrity of the data gathered), the investigator will plan a debriefing session after completion of the subject's participation in order to provide the subject with the missing information, and give the subject the option of including his/her data in the study or having it destroyed. In no case should an investigator seek to withhold information about the research or the subject's role in it solely to reduce the chances of refusal to participate by potential subjects

### **8.2 Assent**

If the subject is a minor (under the age of 18), an assent form must be signed by those subjects capable of reading and understanding a simplified version of the consent form signed by the parent or guardian. The assent applies to subjects between the ages of 11 and 17. For those subjects younger than 11, Boise State's IRB has determined that verbal assent may be obtained. A copy of this assent form must accompany the parental consent form. The age, maturity, and psychological state of the subjects must be taken into account by the principal investigator when creating an assent form.

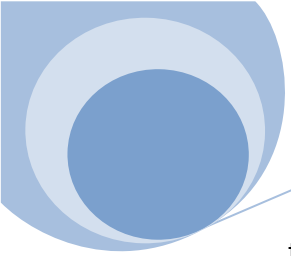
### **8.3 Waiving or Altering Informed Consent**

Under certain circumstances, the IRB has the authority grant a waiver of informed consent, an alteration of the consent elements or procedures, or the requirement to have subjects sign a consent document. All requests to waive consent must be fully justified and the IRB must assess the risk or harms inherent in the informed consent process or documentation of informed consent. Include a "Request to Alter or Waive Consent" form with the IRB application submission.

Waiver of written consent procedures does not imply waiver of the researcher's responsibility to obtain consent from the subject. In all cases, the researcher must provide the subject with a statement of the research that includes all relevant elements of informed consent. It is the recommendation of the BSU IRB that, wherever practicable, when an Informed Consent Form is waived, a cover letter may be submitted to the subjects which outlines the purpose and procedures of the project.

### **8.4 Retaining and Storing Signed Informed Consent Documents**

Signed informed consent forms are legal documents, and the researcher has legal responsibilities to handle them confidentiality. They should be stored in a secure location, accessible to the University in the event that an inquiry should require an examination of them. Access to these documents should be limited to those persons who have a need to know their contents, ordinarily the investigator (and co-investigators), a representative of the IRB (usually the chair), the IRB Coordinator on behalf of the University, and authorized federal officials. In compliance with federal regulations, consent documents must be retained for a period of three years following



the completion of the research.

Consent documents become part of the IRB file of a project and, as such, are subject to Federal audit. Therefore, the IRB will review carefully both the content of and the storage provisions for all consent forms.

An investigator who leaves the University prior to the end of the three-year retention period for consent forms should notify the IRB and specifying the new location of the consent documents. If consent documents are maintained by a graduate student or research assistant, they must be turned over to the responsible faculty member after data collection is completed. A change of location within the University that results in a new storage place for consent forms should also be reported to the IRB.

## 9. PRINCIPAL INVESTIGATOR RESPONSIBILITIES

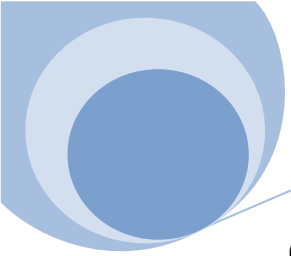
The Principal Investigator (PI) is the individual with the primary responsibility for the design and conduct of a research project. The IRB requires principal investigators to be a Boise State University full, assistant, or associate professor, or director. Visiting faculty, adjuncts, instructors, and staff may be listed as a principal investigator as long as a BSU full, assistant, or associate professor or director is listed as the co-principal investigator (co-PI).

1. All PIs (and co-PIs) listed on IRB protocol applications must successfully complete the Collaborative Institutional Training Initiative (CITI) online training program (<https://www.citiprogram.org>) prior to submitting a protocol for consideration.
2. The PI is responsible for ensuring all key personnel involved in the project (including student research assistants) are properly trained. The IRB may require key personnel complete the CITI training in some cases, but the ultimate responsibility of training these individuals is that of the PI.
3. The PI shall complete and sign the “Exempt Protocol Application” or the “Expedited or Full Board Protocol Application” submitted for IRB review.
4. The IRB does not permit students to serve as PIs on protocol applications except in the cases of thesis and dissertation research activities. Graduate students working on their thesis or dissertation may be designated as the PI as long as their advisor is identified as the Co-PI. In all other circumstances, a faculty member must be designated as the PI and the student as the Co-PI.

The faculty advisor serving as the PI on student research projects will meet with the student investigator on a regular basis to monitor the progress of the study. The faculty advisor will be available to personally supervise the student investigator in solving problems as they arise. An alternate faculty advisor will be arranged to assume responsibility if the initial faculty advisor becomes unavailable, as when on sabbatical leave or vacation, and will notify the IRB of this change.

The application must be signed by the principal investigator before the protocol will be approved. If the principal investigator is a graduate student, the faculty advisor must also sign the application. **The faculty advisor’s signature must be received before the protocol application will move forward to the IRB for review.**

5. The principal investigator shall submit one electronic copy of the protocol application and all relevant appendices to [HumanSubjects@boisestate.edu](mailto:HumanSubjects@boisestate.edu). The signed application shall be sent to the Office of Research Compliance, Mail Stop 1138, Simplot Micron Building, Room 216 or faxed to 208.426.2055. The ORC will also accept a scanned version of the signature page.



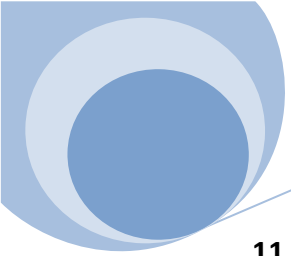
6. The informed consent process must be understood by all subjects involved. If the informed consent document needs to be translated for someone that does not speak or read English, the PI is responsible for translating the consent document into the appropriate language for that subject. The PI must certify the translation of the document is accurate. If a translator needs to be hired, the cost of translation is also the PIs responsibility.
7. Any emergence of problems or development of hazardous conditions for the subjects must be reported immediately to the IRB by the PI on the "Incident Report Form."
8. Any modifications or amendments to a current approved protocol must be reviewed and approved by the IRB before the requested changes are implemented. PIs shall complete a "Modification/Amendment Form" and submit to the ORC for IRB review.
9. The PI has the primary responsibility to ensure the "Annual Renewal Form" is submitted in a timely manner. If a request for renewal has not been received by the annual expiration date, the protocol will be closed. To continue the research after it has closed, a new protocol application must be submitted for IRB review and approval.
10. The principal investigator, upon completion of the project, shall provide the IRB with a final report. This report should include total number of subjects, summary of the research, adverse events, and location of project files.

## **10. ADVERTISING FOR PARTICIPANTS**

Solicitation of subjects by use of advertisements, signs, or pamphlets soliciting volunteers for research is part of the recruitment process. Under existing policies and in compliance with federal regulations, all advertisements for research subjects must be approved by the IRB. This includes those participating in research through the use of university student subject pools within the various disciplines.

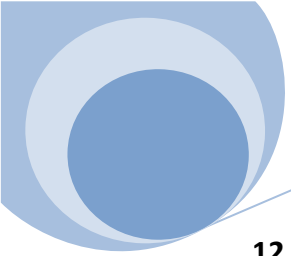
When advertising for subjects, investigators must follow these guidelines:

1. Information shall not be misleading or coercive to subjects, especially when a study will involve vulnerable populations.
2. Information shall include the name and contact information of the investigator, the purpose of the research and eligibility criteria for participation as subjects, a clear description of any benefits and/or risks of participating, remuneration for participation (if applicable), the affiliation of the researcher, and the location of the research.
3. If a drug or device is to be used in the research, no claim should be made as to its superiority, safety or effectiveness.
4. A copy of all forms of advertisement must be submitted with the protocol application.



## **11. STUDENT RESEARCH AND CLASS PROJECTS**

The IRB does not review classroom projects/activities. Classroom projects/activities are generally considered to be conducted for educational purposes and turned in to the faculty/instructor. In certain situations where a class project will be used as part of larger research, IRB review and approval may be required. Contact the IRB Coordinator for help and assistance in determining the need for and completing the appropriate application.



## **12. RECORD KEEPING**

### **12.1 Investigator Records**

Research records (e.g., consent forms, study-related correspondence, etc.) must be kept for at least three years. Records must be kept in a secured place with limited access for the research team, to maintain confidentiality that has been promised to the subjects as well as to the sponsors. Before transferring custody of the records or destroying the study records, contact the sponsor of the study, if applicable.

### **12.2 IRB Records**

All applications (new, continuing reviews, amendments, adverse event report forms) reviewed, consent documents and related materials will remain on file at the ORC for a minimum of three years after the completion of the expiration of the application.

Meeting agendas and minutes will remain on file at the ORC as a permanent record of the committee's activities for three years.

Curriculum vitae of active members of the IRB will be maintained in the ORC and will be updated in content as necessary. Each member's membership term status will be monitored and updated as necessary.

## DEFINITIONS

### **ASSENT**

Affirmative agreement by an individual not competent to give legally valid informed consent (e.g., a child or person who is cognitively impaired) to participate in research.

### **BELMONT REPORT**

A statement of basic ethical principles governing research involving human subjects issued by the National Commission for the Protection of Human Subjects in 1979.

### **CHILD/MINOR**

A person who has not attained the legal age for consent to treatments or procedures involved in the research.

### **COERCION**

Use of a credible threat of harm or force to control another. Pertaining to unacceptable subject recruitment methods which involve undue influence or indirect pressure for participation from a subject. (For example, an employee may feel pressure from their supervisor if told to participate in a research project or a subject may feel coerced to participate if the payment were unusually large.)

### **COMMON RULE**

The central federal policy adopted "in common" by 16 federal departments and agencies (and concurred, with some modifications, by the FDA) that support and/or conduct research involving human subjects. The adoption of the federal policy in 1991 implements a recommendation of the President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research that all federal departments and agencies "adopt as a common core the regulations governing research with human subjects issued by the Department of Health and Human Services (codified at 45 CFR 46, Subpart A), as periodically amended or revised, while permitting additions by any department or agency that are not inconsistent with these core provisions" (OPRR Guidebook, Chapter 2).

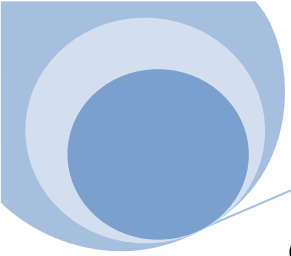
### **CONFIDENTIALITY**

Confidentiality refers to data. It is the treatment of information already revealed and states that there is an expectation that it will not be divulged to others in ways that are inconsistent with the understanding of the original disclosure without authorization.

### **CONSENT**

See Informed Consent

### **CO-PI**



**Co-Principal Investigator.** Any individual who collaborates with the principal investigator in the design and/or conduct of a research project, including those with access to data.

### **DATA**

Refers to information that is collected for analysis or used to reason or make a decision.

### **DECEPTION**

Withholding particular information about the research project from participants until completion of their participation when prior knowledge would adversely affect the integrity of the data gathered.

### **EXEMPT**

Exempt does not mean review is not required. Some research may be eligible for an exemption from IRB review (expedited or full board review) according to the Common Rule codified in [45 CFR 46.101\(b\)](#). Only minimal risk research qualifies for exemption and shall only be determined by the IRB, not the investigator.

### **EXPEDITED**

A level of review by the committee. The Common Rule codified in [45 CFR 46.110](#) specifies that research activities may be eligible for expedited review if the protocol involves only minimal risk or a previously reviewed protocol is receiving modifications that are only minor. Expedited review is carried out by the IRB Chair or by one or more experienced reviewers designated by the chair. Such expedited reviews have the force of full reviews, except that if the protocol is found not acceptable, then it must receive review by the full committee; the chair or designee alone cannot reject a protocol.

### **FULL BOARD**

A level of review by the committee. This category of review applies to all research that does not fall under exempt or expedited review categories. In general, full board review will be required for all projects involving: a) more than minimal risk to participants, b) the deception of subjects, c) sensitive behavioral research (such as research relating to illegal or sexual activity), and d) at-risk populations (e.g., pregnant women, human fetuses, neonates, prisoners, children, individuals with cognitive impairments).

### **FWA**

Federal Wide Assurance. A written documentation of an institution's commitment to comply with the federal regulations that establishes standards for human subjects research. The FWA is submitted to and approved by the Office for Human Research Protection (OHRP). Boise State University has received an FWA.

### **GUARDIAN**

An individual who is authorized under applicable state or local law to consent on behalf of another person (e.g., children).

## **HUMAN SUBJECT**

A living individual about whom an investigator (whether professional or student) conducting research obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information. 45 CFR 46.102(f)

## **INFORMED CONSENT**

An individual's voluntary agreement, based upon adequate knowledge and understanding of relevant information, to participate in research. In giving informed consent, subjects may not waive or appear to waive any of their legal rights, or release or appear to release the investigator, the sponsor, the institution or agents thereof from liability for negligence.

## **IRB**

Institutional Review Board. A committee formed to ensure the protection of human subjects in research.

## **IRB APPROVAL**

The determination of the IRB that the research has been reviewed and may be conducted at an institution within the constraints set forth by the IRB and by other institutional and federal requirements. 45 CFR 46.102(h)

## **MINIMAL RISK**

The probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests. 45 CFR 46.102(i)

## **OHRP**

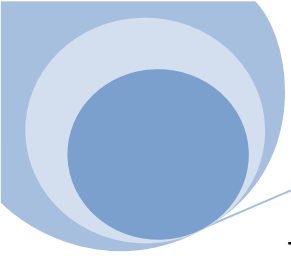
Office of Human Research Protections. The office under the Department of Health and Human Services (DHHS) responsible for monitoring and promoting compliance with regulations (45 CFR 46) governing the ethical standards of biomedical and behavioral/social science research involving human subjects.

## **ORC**

Office of Research Compliance. The administrative office responsible for oversight of the human subjects review process.

## **PI**

Principal Investigator. The individual with the primary responsibility for the design and conduct of a research project.



The IRB requires principal investigators to be a Boise State University full, assistant, or associate professor, or director. Visiting faculty, adjuncts, instructors, and staff may be listed as a principal investigator **as long as a BSU full, assistant, or associate professor or director is listed as the co-principal investigator.**

If you are not affiliated with BSU, the IRB will review your research for approval, but you may be charged. Please contact the Office of Research Compliance for additional information.

If this protocol application is part of a grant requesting federal money, the PI must fall under the BSU PI eligibility policy #5020.

### **PRIVACY**

Privacy refers to persons. It is the control over the extent, timing, and circumstances of sharing oneself (physically, behaviorally, or intellectually) with others.

### **PROTOCOL APPLICATION**

The formal design or plan of an experiment or research activity to be reviewed by the IRB committee for approval. Often referred to as just “protocol.”

### **REMUNERATION**

Payment for participation in research.

### **RESEARCH**

A systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities which meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program which is considered research for other purposes. For example, some demonstration and service programs may include research activities. 45 CFR 46.102(d)

### **SPECIAL POPULATIONS**

The Office for Human Research Protections (OHRP) has identified populations in need of special protections in research, including fetuses, pregnant women, children and minors, and prisoners. IRBs must apply additional regulations and criteria and give special consideration to recruitment, subject selection, informed consent, privacy, and confidentiality issues before approving research involving these populations.