INTRODUCTION
The Boise State University (Boise State) Human Research Protection Program Guide is a written
document detailing the policies, regulations, and procedures governing research involving
human subjects and the requirements for submitting research proposals for review by the
BOISE STATE Institutional Review Board (IRB) to ensure the protection of human subjects in
research. These 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 are continually evolving. Investigators
and research staff should become familiar with 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.

This guide presents the most current information for reference by investigators and their
staff. The field of human research protections is constantly evolving; this guide is subject to
change.

1. Institutional Authority under Which the IRB is Established
Boise State 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, Boise State 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.

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

1.2 VICE PRESIDENT FOR RESEARCH AND ECONOMIC DEVELOPMENT
The Institutional Official (IO) for the IRB is the Vice President for Research and Economic
Development (VPRED). The IO signs the Boise State Federalwide Assurance (FWA) with
the Office for Human Research Protections (OHRP), a subdivision of the Department of
Health and Human Services. The document provides written assurance that all research
conducted at Boise State which involves human subjects will be in compliance with the Code of Federal Regulations (CFR) Title 45, Part 46. The Boise State IRBs are registered with the Office of Human Research Protections.

2. IRB Purpose
The Boise State IRB is a committee established by the institution to protect the rights and welfare of human subjects recruited to participate in research activities. Federal, state and university regulations require all human subjects research conducted by Boise State University faculty, staff, and students to be approved by the IRB before the research can be conducted. The Office of Research Compliance provides administrative support to researchers.

2.1 Use of Federal Funds
Federal funds administered by a Federal department or agency may not be expended for research unless the requirements of the Common Rule have been satisfied (45 CFR 46.122).

2.2 Early Termination of Research Support
Research activities may be suspended or terminated by a Federal department or head if it is found that:
(a) an institution has materially failed to comply with the terms of the Common Rule; or
(b) the person who directs the research has failed to act responsibly for the protection of the rights and welfare of human subjects (45 CFR 46.123).

2.3 Conditions
Any supporting Federal department or agency may impose additional conditions prior to or at the time of approval when it has been determined necessary for the protection of human subjects.

3. Principles Which Assure the Rights and Welfare of Subjects are Protected
The Boise State IRB is governed by the ethical principles put forth in the Belmont Report and follows the DHHS Office for Human Research Protections (OHRP), Boise State regulations and guidance along with University policies.

Boise State University’s Federalwide 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, Boise State has agreed that it will apply these standards to all human subject research, regardless of funding. Therefore, all Boise State 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.
3.1 Statement of Ethical Principles

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.

a. 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.

b. 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.

c. 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.
4. Authority of the IRB

4.1 Scope of Authority
The Office of Research Compliance and IRB chair have the authority to determine research projects as exempt, including research activities for which limited IRB review is a condition of exemption. Investigators may not self-determine a project is exempt. The Boise State IRB has the authority to approve and review all non-exempt (expedited and full board) human subject research (prior to and after approval), require amendments or modifications in, or disapprove all research activities that fall within its jurisdiction as specified by both the federal regulations, state regulations, and university policy.

4.2 Authority to Disapprove, Modify, or Approve Studies Based upon Consideration of Human Subject Protection Aspects
Research that has been reviewed and approved by the Boise State IRB may be subject to further review and disapproval by officials of the Institution. However, those officials may not approve research if it has been disapproved by the Boise State IRB. The Boise State IRB functions independently of other committees and makes independent determinations to approve or disapprove the application based upon whether or not human subjects are adequately protected. The Boise State IRB has jurisdiction over all human subject research.

4.3 Authority to Require Progress Reports from the Investigators and Oversee the Conduct of the Study
Any approved non-exempt research is subject to continuing review and must be reviewed and approved no less than once per year (or more frequently, if specified by the IRB).

4.4 Authority to Suspend or Terminate Approval of a Study
The Boise State IRB has the authority to suspend or terminate approval of research not being conducted in accordance with the IRB’s requirements or that has been associated with unexpected serious harm to subjects. Any suspension or termination of approval shall include a statement of the reasons for the IRB’s action and shall be reported promptly to the Principal Investigator (PI). The suspension or termination of an application will also be reported to the IO and any federal funding agency as required by regulations.

4.5 Post Approval Review
The Boise State IRB has the authority to conduct post approval reviews on any applications for any reason. Review may consist of a review of documents and/or review of the activities to determine whether the research is being conducted in accordance with the IRB’s requirements (the approved application).
5. IRB Membership

5.1 Number of Members
Federal regulations (45 CFR 46.107) require the IRB to have no less than five voting members, including the Chairperson.

5.2 Qualification and Diversity of Members
The VP of Research and Economic Development 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.

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.

a. 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 Boise State 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.

b. 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 Boise State academic units as appropriate.

c. Community Members
Individuals serving in this capacity should represent the community who is not otherwise affiliated with Boise State and who is not part of the immediate family of a person who is affiliated with Boise State. 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.
6. Management of the IRB

6.1 IRB Members

a. Selection and Appointment
The Institutional Official (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 1st of the year appointed and end May 31st the following year. Appointments may begin at other times, but all appointments will end on May 31st 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.

b. 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. 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.

c. Removal
IRB Members may be removed or replaced by the IO at any time.

6.2 IRB Chair

a. 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.

b. 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 the ability to assign reviewers to the IRB Coordinator. The Chair also designates the IRB Coordinator to determine exemptions, 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. Ensuring proper conduct and review of all IRB protocols;
2. Conducting each of the monthly convened meetings;
3. Request special meetings when necessary;
4. Initial review of adverse events, unanticipated events, and assisting in investigating and resolving complaints;
5. With IO consultation, making decisions in emergency situations to protect subjects and remain in compliance with regulations;
6. Reviewing institutional policies, procedures and forms on an ongoing basis;
7. In consultation with IO, reviewing the make-up and performance of current committee members;
8. Relating concerns to administration regarding issues in human research review; and
9. Signing the IRB approval letters and other formal acknowledgment letters; and
10. Delegating responsibility to ORC staff as needed.

6.3 Education of IRB Members and IRB Chairperson
   a. Training and Continuing Education
      All IRB Members must complete the CITI training modules created specifically for IRB members.

      To ensure continuing education of the IRB members, educational information is continually distributed to members through newsletters and discussions at full board meetings. Webinars will also be offered to IRB members throughout the year. CITI training must be completed every three years.

   c. Reference Materials
      Each IRB member is given access to the Boise State Human Research Protection Program Guide. Members will be provided website resources for the regulations, the Belmont Report, and additional OHRP guidance and/or provided copies as necessary.

6.4 Consultants
The IRB is encouraged to use non-member consultants for advice and information in specialized areas as needed. These consultants may be Boise State faculty or staff, affiliates, or experts not affiliated with Boise State. The consultants may present their assessments in writing, by telephone or in person. These individuals may not vote with the IRB.
6.5 Liability Coverage for IRB Members
The University offers protection for university employees and authorized volunteers who are sued for duties and actions performed in the course of their employment and in good faith under the University’s liability and workers compensation insurance.

IRB members who are not employees of Boise State are considered authorized volunteers and are required to fill out an Authorized Volunteer Services Agreement Form. The signed forms will be kept on file within the Office of Research Compliance. In the event of a claim, the Office of Risk Management and Insurance will request the signed Authorized Volunteer Services Agreement Form from the Office of Research Compliance.

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

7. Conflict of Interest
Conflicts of interest in research arise when financial, professional, or other personal considerations compromise, or have the appearance of compromising an individual’s judgment in the review, design, conduct, or reporting of research. Human subjects research at Boise State is subject to the University-wide Conflict of Interest and Commitment Policy (Boise State Policy #1110).
7.1 Investigator Financial Conflict of Interest
If an investigator involved in research involving human subjects has disclosed a potential financial conflict of interest, the IRB Coordinator will refer the case to Boise State Conflicts of Interest Officer. The Conflict of Interest Officer will refer the case to the Boise State Conflict of Interest Committee as appropriate. The Conflict of Interest Committee will review the financial disclosure, and consider the potential conflict of interest. The IRB Coordinator will collect the information necessary to fully inform the IRB of any proposed management plans.

The IRB will carefully consider specific mechanisms to minimize the potential adverse consequences of the conflict in an effort to optimally protect the interests of the research subjects. In general, if there are any financial conflict of interest issues on the part of the researcher, he or she should not be directly engaged in aspects of the study that could be influenced inappropriately by that conflict. These could include: the design of the study, monitoring the study, obtaining the informed consent, adverse event reporting, or analyzing the data. The IRB will also consider if the source of funding and funding arrangements should be included in the consent form. In all cases good judgment, openness of process and reliance upon objective, third party oversight can effectively minimize the potential for harm to subjects and safeguard the integrity of the research.

7.2 No Selection of IRB Members by Investigators
Investigators are not able to select which IRB member will review their application. Additionally, any IRB member must recuse themselves from a review if they have any potential conflict.

7.2 IRB Member Conflict of Interest
Review of applications will be conducted with objectivity and in a manner to ensure the exercise of independent judgment of each member. Members may not participate in a vote by the IRB on actions concerning research in which they have an active role or conflict of interest (Boise State Policy #1110) related to any person or entity connected with the application. Failure to abide by these provisions may be cause for removal of a member from the IRB. IRB members must not vote on an application if they are investigators on the application or have any other conflict of interest with any person or entity connected to an application. The IRB member must make any conflict of interest known to the Chair and/or IRB staff. The member may provide information to the IRB if requested. The fact that an application is submitted by another investigator from an IRB member’s department or area does not, in and of itself, constitute a conflict of interest.

The member is not required to identify the exact nature of the conflict of interest. They may simply inform the Chair or IRB Coordinator that one exists. If the member has been assigned to review an expedited application they should inform their unavailability to review the protocol to the IRB Coordinator as soon as they can so that the application
can be reassigned to another reviewer. The member with conflict may participate in the
discussion or deliberation to answer committee’s questions regarding the application
under review to the same extent as any investigator when attending an IRB meeting. If
there are no questions for the conflicted member, or after the conflicted member has
answered any questions, he or she will be recused for committee’s deliberation and
vote.

8. Functions of the IRB and ORC
8.1 Initial Review
The IRB will review all non-exempt human subjects research. The ORC office staff is
responsible for the review and determination of exempt research. The IRB chair will
review any exempt application if the ORC staff has a conflict of interest or is unable to
review the application. Applications that are certified exempt from the federal
regulations (meeting one or more of the eight exemptions) do not require
continuing/annual renewals. However, changes to the research, subject population or
research personnel must be reviewed and approved prior to implementation.
Investigators must submit a Modification Form to the ORC for review and approval.
Changes in the research may change the type of review.

8.2 Reporting Findings and Actions to the Investigator
The IRB Coordinator will report all findings and actions of the IRB and ORC to the
principal and co-investigator(s) in a timely manner.

8.3 Continuing Review/Annual Renewals
The IRB will conduct a continuing review/annual renewal of all active full board protocol
applications no less than once per year. Expedited protocols will be asked to complete a
Status Update form annually. Exemptions do not require annual review. The IRB may
require a protocol to be reviewed more than once per year based on the nature and/or
risk of the research. In general, the annual renewals are conducted at the level of the
initial review, but the review level can be changed as necessary to conform to the risk
level, law and policy. In order to ensure continuing reviews are substantive and
meaningful, the reviewer(s) will receive an annual renewal form, consent form(s), as
well as the full application (background material containing previously approved
protocol and/or activities) and any additional information that is necessary.

Approved applications determined to present more than minimal risk category can be
reviewed annual under expedited review category 8 if:

- the research is permanently closed to the enrollment of new subjects;
- all subjects have completed all research-related interventions; and
- the research remains active only for long-term follow-up of subjects; or where
  no subjects have been enrolled and no additional risks have been identified; or
  where the remaining research activities are limited to data analysis.
At Boise State, each approved non-exempt protocol has a three-year life cycle and is allotted two annual renewals. If the study is not complete by the third year, the PI is required to submit a new IRB protocol application for review and approval instead of another annual renewal form. The ORC will send a reminder notice approximately 60 and 30 days prior to the protocol’s expiration date. The principal investigator has the primary responsibility to ensure a new protocol application is submitted in a timely manner. If a new protocol application is not submitted and approved before the expiration date, all research involving human subjects must stop until the new protocol is approved.

8.4 Changes in Approved Research
All changes (modifications) to currently approved research must be reviewed and approved prior to implementation. In general, amendments will be reviewed at the original application review level (exempt, expedited, full board, or limited IRB review). Minor changes that do not increase the risk to research subjects may be reviewed and approved at the expedited or administrative review levels. Minor administrative changes (adding personnel, updating phone numbers, minor editorial changes to consent documents, cover letters, etc.) may be reviewed and approved by the Chair and/or the IRB Coordinator.

Some modifications may change the type of review (exempt, expedited, full board, or limited IRB review) 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 with impaired decision-making ability or who could be susceptible to coercion or undue influence. 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.

Modifications to approved applications that may create more than minimal risk to subjects will be forwarded to the full IRB for review. Reviewers will receive the Modification Form and any modified items such as consent forms, applications, investigator brochures, study instruments, recruitment tools, etc. 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.

The IRB approval of a modification does not extend the approval period. For example, if the new or continuing review is approved on June 2, 2016 it will expire on June 1, 2017. If a modification is approved during this time, the expiration date of the protocol is still June 1, 2017.
a. Modifications in Approved Research Prior to IRB Review and Approval except Where Necessary to Eliminate Apparent Immediate Hazards to Subjects

There are situations where a serious unanticipated event or adverse event requires an immediate change to an application in order to relieve an apparent immediate hazard to research subjects. In these situations, the PI may implement a change necessary to protect the welfare of the research subjects. Investigators are encouraged to contact the IRB if this type of situation arises prior to implementation of the application change.

Investigators are required to notify the IRB in writing of the change, within one week, and include a written description of the change and events which necessitated immediate implementation.

8.5 Ensuring Prompt Reporting to the IRB of Adverse or Unanticipated Events

a. Reporting Internal Adverse Events by Investigators to the IRB

Upon becoming aware of an internal adverse event, the investigator should assess whether the adverse event represents an unanticipated problem (see the Guidance on Reporting Incidents to OHRP). If the investigator determines that the adverse event represents an unanticipated problem, the investigator must report the preliminary findings promptly to the IRB as soon as the PI is aware either verbally or in a written form. PIs may also call to consult with the IRB as to whether an event meets the definition of an adverse or unanticipated event. A follow up report with more information should be submitted on an Adverse Event Form. If the IRB receives a report of an adverse event, the IRB Coordinator or the ORC Director will report in writing as soon as possible (not more than one month) to the IRB Chair, and as necessary to Vice President for Research, other relevant Department or Agency Head (sponsor), any applicable regulatory body and OHRP, any report of adverse events as mandated in the Federal Regulations.

b. Reporting External Adverse Events by Investigators to the IRB

Investigators and IRBs may receive a large volume of reports of external adverse events experienced by subjects enrolled in multi center studies. These external adverse event reports frequently represent the majority of adverse event reports submitted by investigators to IRB. The investigator should review the external adverse event report and assess whether the event is unexpected, related or possibly related to participation in the research and serious or otherwise one that suggests that the research places or others at a greater risk of physical or psychological harm than was previously known or recognized. If the adverse event in the report meets all three criteria must be promptly reported to the IRB by investigator as unanticipated problem by the Adverse Event Form.
c. Reporting of Other Unanticipated Problems
Any other incident, experience, or outcome (not related to an adverse event) that may represent an unanticipated problem, should be assessed by the investigator to determine whether the incident, experience, or outcome represents an unanticipated problem (see the Guidance on Reporting Incidents to OHRP). If the investigator determines that the incident, experience, or outcome represents an unanticipated problem, the investigator must report it promptly to the IRB.

d. Timeframe for Reporting
Recommended by OHRP:

- Unanticipated problems that are serious adverse events should be reported to the IRB within 1 week of the investigator becoming aware of the event.
- Any other unanticipated problem should be reported to the IRB within 2 weeks of the investigator becoming aware of the problem.
- All unanticipated problems should be reported to IRB, supporting agency and OHRP within one month of the IRB receipt of the report of the problem from the investigator.

9. Operations of the IRB

9.1 IRB Meeting Schedule
The full IRB committee shall meet once every month unless there is no business to be conducted. Additional full board meetings or subcommittee meetings may be called by the Chair. Monthly meetings will be arranged by the IRB Coordinator. All full board protocols are due 15 calendar days prior to the scheduled meeting. IRB meeting dates and protocol submission deadlines are located on the IRB website.

9.2 Meeting Preparation
Approximately 14 calendar days prior to the IRB meeting, the IRB Coordinator will send to each committee member the following items (as applicable):

- Meeting agenda
- Minutes from the previous meeting
- A list of expedited applications (new, modifications, annual renewals) approved since the last full board IRB meeting and for the fiscal year
- All full board protocol applications (new, modifications, and annual renewals) for review by the full board
- Adverse event reports
- Continuing education materials

Committee members are asked to send the IRB Coordinator any initial items that need clarification by the PI after 7 calendar days.
Approximately 7 calendar days prior to the monthly meeting, the IRB coordinator will contact each researcher submitting an application and inform them of the procedures of review if they are invited to attend the meeting. The IRB coordinator will also send the PI a list of initial questions or concerns sent by the committee members so they can prepare a response at the full board meeting.

9.3 Review Types

a. Pre-Review
The ORC is the administrative office responsible for oversight of the human subjects review process. Within one to two days of submission, the Office of Research Compliance will provide an initial administrative review for completeness. This is completed by the IRB Coordinator and not part of the regulatory review process. Upon receipt of an application, the IRB Coordinator will review the application for signatures, CITI training verification and completion (the application is typed, no sections are missing and all applicable documents, such as consent forms, are attached). If the application is complete, it will be assigned for review. Incomplete or handwritten protocols will be returned to the investigator for resubmission. The IRB Coordinator will also verify the type of review. The IRB Coordinator will contact the Principal and Co-Investigator(s) via phone or email if any additional materials are required.

b. Exempt Review
Research involving minor children may be exempt only as it applies to categories 1, 4, 5, 6, 7 and 8. 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. 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. Research involving prisoners may not be exempted.

1. Research conducted in established or commonly accepted educational settings that specifically involves normal educational practices and does not impact students’ opportunity to learn the required educational content, or impact the assessment of educators providing the instruction, 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 on adults involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior (including visual or auditory recording) uninfluenced by the investigator if:
a. information obtained is recorded in such a manner that human subjects cannot be identified, directly or through identifiers linked to the subjects; OR
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, educational advancement or reputation; OR
c. a Limited IRB Review is done for data that can be linked with identifiers.

Research can be conducted with minors, only if it is limited to educational tests (cognitive, diagnostic, aptitude, achievement) or observation of public behavior where the researcher does NOT participate in the activity observed.

3. Research involving the use of benign behavioral (non-medical) interventions in conjunction with the collection of information from an adult subject. Information obtained must be collected in such a way that:
   a. the identity of the human subjects cannot readily be ascertained directly or through identifiers; or
   b. any public disclosure of the responses would not reasonably place the subject at risk of criminal or civil liability, be damaging to the subjects’ financial standing, educational advancement, or reputation; OR
   c. a Limited IRB Review is conducted for data that can be linked with identifiers.

4. Secondary research for which consent is not required. This can include identifiable private information or identifiable bio-specimens, if at least one of the following conditions are met:
   a. the identifiable private information or identifiable bio-specimens are publically available;
   b. information (including about bio-specimens) is recorded in such a way that the identity of the subjects cannot be readily ascertained directly or through identifiers, and the investigator will not contact subjects or attempt to re-identify subjects;
   c. the research involves only information collection and analysis involving the investigator’s use of identifiable health information for the purpose of “health care operations”; or
   d. research is conducted by, or on behalf of, a Federal department or agency using government-generated or government-collected information obtained for non-research purposes if maintained per compliance with section 2(b) of the E-Government Act of 2002.

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 at least one of the following:
   a. public benefit or service programs;
   b. procedures for obtaining benefits or services under those programs;
c. possible changes in or alternatives to those programs or procedures;
d. possible changes in methods or levels of payment for benefits or services under those programs.

In order fall under category 5, the project must be published on a publically accessible Federal website prior to commencing the research and conducted pursuant to a specific federal department or agency.

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.

7. Storage or maintenance of identifiable private information or identifiable bio-specimens for use in secondary research when broad consent has been obtained, appropriately documented, or waived in accordance with the regulations regarding informed consent. If a change is made for research purposes in the way the identifiable private information or identifiable bio-specimens are stored or maintained, adequate provision must be made to protect the privacy of subjects and maintain the confidentiality of the data.

A Limited IRB Review of research conducted under this category is required.

8. Research involving the use of identifiable private information or identifiable bio-specimens for secondary research use can be conducted if broad consent for storage, maintenance, and secondary research use was obtained in accordance with the regulations regarding informed consent, documentation of informed consent is in place, or a waiver of documentation of informed consent was obtained. The investigator cannot include returning individual research results to subjects as part of the study plan, except in cases required by law.

A Limited IRB Review of research conducted under this category is required.
c. Expedited
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:
   a) 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); or
   b) 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:
   a) from healthy, non-pregnant 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
   b) 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 non-disfiguring 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) uncanannulated 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 non-research 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:
   a) 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
   b) where no participants have been enrolled and no additional risks have been identified; or
   c) 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.

d. Full Board
   Any research project involving the use of human participants which does not fall into an exempt or expedited review category must be submitted for full board 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 qualify for full board review.

e. Annual Renewals
   The IRB is required to continue to review full board approved research at intervals appropriate to the degree of risk, but not less than within 12 months from the review date. Expedited protocols have a three-year life cycle and can be renewed within those three years. If the research is not complete by the third year a new protocol application must be submitted.

   Exempt protocols do not require annual renewal; however they expire after 3 years.

Expires
   All protocols have a 3 year expiration period. Full Board approved protocols require annual renewal during this 3 year period, Expedited protocols will need to have a Status Update form completed.

f. Modifications
   Any modifications to an approved protocol (exempt and non-exempt) must be brought forward to the Office of Research Compliance and the IRB. The IRB Coordinator will review any changes to an exempt protocol, as changes that increase the risk may require the protocol to undergo an expedited or full board review. The IRB will review any changes to non-exempt research after its approval. Again, the review level may vary from the original review depending on the risk level. The approval of the amendment will not extend the continuing approval date, unless the research was originally exempt and is now determined
to be non-exempt.

9.4 The Review Process

a. Exempt

Investigators must submit a completed exempt protocol application and all relevant materials to HumanSubjects@boisestate.edu. An email sent from the Principal Investigators Boise State email account will suffice for documenting the signature.

Complete applications will be reviewed by the IRB Coordinator, IRB Chair, or trained ORC staff to determine if the research falls under the criteria for exemption under 45 CFR 46.104. The Office of Research Compliance will notify the PI if additional information or clarification about the research project is needed. The exempt reviewer also has the authority to request that an application submitted as exempt undergo expedited or full board review as appropriate.

Once the application has been determined to qualify for an exemption, the Office of Research Compliance will send a Notification of Exemption letter via e-mail to the PI. Exempt review and final determination 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 PI or the Boise State University IRB, within the three year approval period. 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), when the review category changes as described above, or 3 years after original approval date.

Limited IRB Review may apply under certain Exempt Categories. The IRB may require additional information in order to make a determination of the research.

Exempt submissions that fall into Exempt Category 7 and/or 8 will be reviewed by the IRB Chair and/or one IRB member.

b. Expedited

Investigators must submit a completed expedited protocol application and all relevant materials to 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 member or members for review. Expedited protocols are reviewed electronically by the Chair or a designated IRB member. The IRB reviewer(s) is responsible for
reviewing the protocol application and determining the research involves minimal risk and falls under one of the expedited research categories under 45 CFR 46.110. The IRB Coordinator will act as a liaison between the reviewer and the IRB and will notify the PI if additional information or clarification about the research project is needed. The IRB reviewer(s) also has the authority to request that an application submitted as expedited undergo full board review. The IRB reviewer(s) does not have the authority to disapprove an expedited protocol. If the expedited reviewer(s) cannot come to a determination for approval, the application must be brought before the full board at a convened meeting.

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 and co-investigator(s). Expedited review and approval may take up to four weeks.

The approval is effective for 12 months unless terminated in writing by the PI or the Boise State University IRB. The IRB may also require continuing review at intervals appropriate to the degree of risk, but at minimum a Status Update will be required annually. The Office of Research Compliance will send a reminder notice approximately 60 and 30 days prior to the expiration date. The PI has the primary responsibility to ensure a renewal form or status update is submitted in a timely manner. If the protocol is not reviewed and approved for renewal before the expiration date, all research activity involving human subjects must cease and 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.

The PI must submit a Final Report Form when the human subjects research is completed.

c. Full Board

Investigators must submit a completed full board protocol application and all relevant materials to 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 and application submission deadlines is on the ORC website.
PIs are often invited and strongly encouraged to attend the full board meeting. Student researchers must attend with their faculty advisor or a faculty member representative.

The committee is given at eight to ten business days to review the application for initial comments and questions. The IRB Coordinator will email the PI and Co-PI(s) initial comments and questions from the committee. The PI can either respond to the questions via email or bring responses to the full board committee meeting. Additional questions may arise during the meeting.

After the meeting, the IRB Coordinator will notify the PI if additional information or written 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 PI and Co-PIs. Full board review and approval may take 6 to 8 weeks.

The approval is effective for 12 months unless terminated in writing by the PI 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 PI 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. The review level may vary from the original review depending on the risk level; however, this may not change the overall review category of the protocol.
When the research is completed, the PI must submit a Final Report Form.

(i) Voting Requirements
A quorum of more than half of the voting membership is required to conduct business. At least one member whose primary concerns are in non-scientific areas must be present. Each member has one vote. No proxy votes are allowed. Members may attend the IRB meeting by video conference or by telephone. It is the responsibility of the member to contact the IRB Coordinator to ensure the necessary equipment will be available. IRB members who are an investigator on or have any other potential conflict of interest with any person or entity connected to an application must be recused from the vote and will not be counted as part of the voting quorum. See section 7, Conflicts of Interest.

d. Annual Renewals
Investigators must submit a completed Annual Renewal Form or Status Update Form and all relevant materials to HumanSubjects@boisestate.edu. The signature page (if applicable) can be faxed, mailed, or brought to the IRB Coordinator in person.

Complete forms and materials will be forwarded for review. Exemptions do not require annual review. Expedited renewals will be forwarded to the designated IRB member or members for review. Expedited protocols are reviewed electronically by the Chair or one IRB member. If there are no changes to a protocol submitted for an annual renewal, the IRB Coordinator may conduct an administrative review for approval. The expedited renewal review and approval may take up to two weeks.

Full board renewals must 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. The PI must be aware of the protocol’s expiration date and the scheduled IRB meeting. The protocol may expire before the IRB is scheduled to meet. It is the PI’s responsibility to submit the renewal in a timely manner so that the review and approval can occur before the protocol expires.

Approved applications determined to present more than minimal risk category can be reviewed annual under expedited review category 8 if:
• the research is permanently closed to the enrollment of new subjects;
• all subjects have completed all research-related interventions; and
• the research remains active only for long-term follow-up of subjects; or where no subjects have been enrolled and no additional risks have been identified; or where the remaining research activities are limited to data analysis.
e. Modifications

Investigators must submit a completed Modification Form and all relevant materials to HumanSubjects@boisestate.edu. The signature page (if applicable) can be faxed, mailed, or brought to the IRB Coordinator in person. Complete forms and materials will be forwarded for review. The review level may vary from the original review depending on the risk level; however this will not change the overall review category of the protocol. The approval of the amendment will not extend the continuing approval date.

Modifications to exempt protocols will be reviewed by the IRB Coordinator, IRB Chair, or trained ORC staff to determine if the research still falls under the criteria for exemption. The Office of Research Compliance will notify the PI if additional information or clarification about the research project is needed. The exempt reviewer also has the authority to request that an application submitted as exempt undergo expedited or full board review if the modification increases the risk to the project to minimal or more than minimal. Review of modifications to exempt protocols may take up to one week.

Modifications to expedited protocols will be forwarded to the designated IRB member or members for review. Expedited protocols are reviewed electronically by the Chair and/or one IRB member. If the change is minor, the IRB Coordinator may conduct an administrative review for approval. The expedited review and approval may take up to two weeks.

Modifications to full board protocols that involve more than minimal risk must be reviewed by the full committee at their monthly convened meetings.

9.5 Criteria for Approval (Expedited and Full Board)

Federal regulations dictate the criteria the IRB must follow to approve a protocol at 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 be particularly cognizant of populations with impaired decision-making or those susceptible to coercion or undue influence, such as children, prisoners, 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 susceptible to coercion or undue influence, such as children, prisoners, or economically or educationally disadvantaged persons, additional safeguards have been included in the study to protect the rights and welfare of these subjects.

The IRB will also consider the following issues when reviewing human subjects research:

a. Study Design

Federal regulations, the Nuremburg Code, and the Declaration of Helsinki require that the IRB consider the scientific design of a study to determine that the risks to subjects are minimized by using procedures which are consistent with sound research design and the benefits of the research justify the potential risks. The IRB must assess whether the study design will produce reliable and valid information of sufficient value and importance to justify the risks. The scientific quality will be have more potential weight in the risk/benefit evaluation in studies posing more than minimal risk to participants. In university settings, many social science student studies may have less than optimal design, but involve little or no risk to participants. In the absence of significant risk, the benefits of the study to participants, society, and the student’s education may be weighed more heavily.

b. Risks and Benefits

The IRB will assess whether the risks to subjects are reasonable in relation to the anticipated benefits, if any, to the subjects and to society as well as the
importance of the knowledge reasonably expected to result from the research. The IRB will consider only those risks and benefits that may result from the research. The federal regulations do not allow the IRB to evaluate the possible long range effect of applying the knowledge gained through the research. [45 CFR 46.111] The IRB is required to review any possible benefits a subject may derive from participation in research, and/or the benefits of new knowledge that may justify asking a person to undertake the risks of the study. Payment for participation in research is not considered a benefit.

c. Equitable Selection of Subjects
The selection of subjects should be equitable and free of coercion or undue influence. The IRB will consider the purpose of the research and the setting of the research. The IRB will closely examine research which is conducted on Native American tribal lands or which targets subject populations, such as children, prisoners, subjects with impaired decision-making abilities, or economically or educationally disadvantaged subjects.

d. Identification of Subjects
The IRB is required to review the method for prospective identification of subjects (subject recruitment). 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.

e. 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 in the protocol application.
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 National Institutes of Health (NIH). Certificates protect against compulsory legal demands, such as court orders and subpoenas, for identifying information or identifying characteristics of a research participant. Federal funding is not a prerequisite for Certificate.

f. Informed Consent
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.

g. 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.

h. 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 these categories of subjects, the IRB ascertains
the use of these specified populations are 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:

(i) 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).

(ii) Prisoners
The federal regulations have specific requirements for research involving prisoners. Research involving prisoners does not qualify for an exemption. 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.

(iii) 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.

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.
Unlike research involving adults, the exemption at 45 CFR 46.104(2)(i) for research involving survey procedures interviews, or collection of identifiable information does not apply to research involving children.

9.6 Requirements for All Protocol Submissions

a. CITI Training
The IRB requires that all PI and Co-PIs listed on IRB protocol applications must successfully complete the Collaborative Institutional Training Initiative (CITI) online training program before final IRB approval can be attained. The CITI program is widely accepted as an industry standard among university IRBs and by the federal government. Key personnel involved in any interaction or intervention with a research participant, including obtaining consent, or access to private identifiable information are also required to take this training. Investigators and key personnel will need to create a password and login and affiliate with Boise State University in order to access the tutorial. FAQs regarding CITI training can be found on the [Boise State website](#).

A refresher course will be required every three years. The IRB requires the completion of the Social & Behavioral Researchers or Biomedical Researchers course identified with Boise State. The IRB Coordinator will verify the CITI training has been successfully completed on all IRB protocol application submissions. The PI on the IRB application is responsible to ensure that all other research personnel are properly trained through CITI and have the experience necessary to perform the research.

b. Principal Investigator Eligibility
Conducting research with humans is a privilege and carries with it ethical and legal responsibilities. The Principal Investigator (PI) is the individual responsible for writing an accurate protocol to utilize human subjects, and for designing practices and implementing the approved use(s) of those subjects. Ultimately, the PI assumes the responsibility for the ethical conduct of the project and for the welfare of the human subjects. This responsibility includes the intellectual conduct of the project, fiscal accountability, administrative aspects, and the project’s adherence to relevant policies and regulations. For that reason, PIs must have a reasonable prospect of long-term employment at Boise State University. Certain other titles are allowed to serve as PIs within the exceptions described below.

Eligible PIs include faculty with the following titles:

- Professor
- Associate Professor
- Assistant Professor
(i) Exceptions

If you are not eligible to be a PI and you are not a student researcher, you may still be listed as the PI if an eligible PI is listed as your Co-PI. If you are not able to do this, you may request a PI Exception to be the sole PI on an IRB protocol application. This exception must be approved by the Vice President of Research and Economic Development as well as your College Dean and your Department Chair. Contact the IRB Coordinator for additional information on how to obtain approval for an exception to the PI eligibility requirements.

(ii.) Student Investigators

If you are a graduate student submitting an IRB for Social Behavioral research related to your thesis or dissertation, or a Doctorate of Nursing Practice student, you may also be listed as the PI if someone who is eligible to be a PI is listed as your Co-PI. If you are a graduate student and submitting an IRB for BioMedical research, you will need someone who is eligible to be the PI and you may be the Co-Investigator.

If you are an undergraduate student you are not permitted to serve as the PI. You must be listed as the Co with an eligible faculty member listed as the PI.

(iii.) Funded Projects

If the research is funded, OSP PI Eligibility Policy #5020 will apply for PI eligibility.

(iv.) Non-Affiliated Investigators

If an investigator is not affiliated with Boise State, the IRB may review the protocol application for a fee.

c. Signatures

The protocol application must be signed by the PI before the study will be approved. If the PI is a graduate student or someone who is not eligible to serve as a sole PI, the eligible faculty member listed as the Co-PI must also sign the application. Student investigators must obtain faculty signature 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 or not eligible to serve as the sole-PI.
The signature page can be faxed, mailed, emailed as a scanned PDF, or brought to the IRB Coordinator in person.

**d. Complete Protocol**

Researchers applying for review must submit a completed application according to the review category. In order for the application to be processed, it must be typed and include all supplemental materials. Supplemental materials include but are not limited to:

- Grant Proposal
- Recruitment Materials (flyers, scripts, emails, letters, etc.)
- Consent Documents (informed consent form, assent form, parent informed consent form, cover letter, verbal informed consent script, debriefing statement, etc.)
- Research Tools (questionnaires, surveys, interview questions and scripts, focus group questions and scripts, acknowledgement letters, etc.)
- Site Acknowledgement Letters

Incomplete or poorly prepared applications may be returned to the investigator before they are reviewed.

**9.7 Appeal of IRB Decisions**

If an IRB application reviewed during full board review is disapproved, the reasons for disapproval will be conveyed to the investigator in writing. The investigator may request the IRB to reconsider by responding in writing, and may request an opportunity to appear before the IRB. The application may be resubmitted.

**9.8 Allegations of non-compliance**

The IRB will investigate any allegations of non-compliance (based upon the federal regulations). Any allegation will be discussed with the PI of the IRB application in question. Any investigation of alleged noncompliance will require close cooperation and coordination with the PI of the research.

If there appears to be credible evidence of non-compliance the situation will be presented to the IO. Any non-compliance (based upon the federal regulations) will be reported to federal agencies and funding agencies as required by the federal regulations.

**9.9 Complaints**

The IRB Coordinator will communicate any research participants’ complaints or concerns that may arise to the IRB Chair and ORA Director. In general the IRB can respond to complaints or concerns regarding the participant’s rights as a volunteer in
the research. The IRB Coordinator will assist the participant to get answers to any other complaints or concerns from the PI.

9.10 Post approval review and monitoring
The IRB may initiate reviews of approved IRB applications at any time. Post approval reviews may be initiated for cause (request of the PI, allegation of non-compliance, questions from research participants, post-approval monitoring, etc.) or for no cause (random sampling of approved applications, etc.). The findings of post approval review will be discussed with the PI to verify and/or correct. Any post approval review findings that indicate variances from approved applications, adverse events, or unanticipated events will be reported to the IO and federal agencies as required by the federal regulations.

9.11 Unanticipated Events and Adverse Events Reporting
Any unanticipated or adverse events encountered that pose actual or potential risks to subjects must be reported to the IRB immediately but not later than seven days following the event. Such events should be reported in writing to the IRB. The IRB Coordinator or the ORC Director will collect all relevant information and work with the Chair and other University administrators as necessary. The IRB will report to the Chair, IO, relevant Department or Agency Head (sponsor), any applicable regulatory body and OHRP, any report of adverse events as mandated in the Federal Regulations.

i. Unanticipated events are generally situations where events which were not articulated in the IRB application or consent form occur in the course of the approved research. Unanticipated events may fall into two categories:
   1. Not-serious: those unanticipated events that do not increase the risk to the human participant.
   2. Serious: those unanticipated events that increased the risks to the human participants.

ii. Adverse events are generally considered events that, even if considered in the application review, still increased the risks to the human participants.

Serious unanticipated events and adverse events will generally be reported to OHRP (based upon the federal regulations, and discussions with the Chair and Institutional Official). Non-serious adverse events may be reported to OHRP as a courtesy (based upon the discussions with the Chair and IO) as OHRP has generally communicated expectations to IRBs to receive such information.

10. Informed Consent Requirements
Obtaining the informed consent of subjects is a matter of professional research ethics in every discipline at the University. Every researcher must obtain the informed consent of any human subject before involving that person in the research project. Informed consent is a process, not
just a form. The amount of information and the manner of presentation is generally related to
the complexity and risk involved in the research study.

The principal investigator is responsible for ensuring that the circumstances under which
consent is sought will provide the subjects (or their legal representative) with sufficient
opportunity to consider whether or not to participate. The circumstances must also minimize
the possibility of coercion or undue influence experienced by the subjects.

10.1 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. Rather, the consent document is one part of the total consent process. 45 CFR
46.116 (a)(1-9) defines nine 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 must be explained. The individual must 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
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.

Generally, 6th-8th grade reading level is appropriate for average adults. When
recruitment for research is anticipated for a particular non-English speaking population,
a translation of the written informed consent document should be provided to the
prospective participant or their legally authorized representative in a language they
understand. The IRB must approve the translated consent form before use. The written
presentation of information is used to document the basis for consent and for the
subjects' future reference. Therefore, when a written form is used the subject should
receive a copy for their records.

Consent documents are more understandable if they are written just as the investigator
would give an oral explanation to the subject; that is, the subject is addressed as "you"
and the investigator as "I/we." This second person writing style also helps to
communicate that there is a choice to be made by the prospective subject. Use of the
first person may be interpreted as presumption of subject consent, i.e., the subject has
no choice. Also, the tone of the first person "I understand" style seems to misplace
emphasis on legal statements rather than on explanatory wording enhancing the
subject's comprehension. In this manual, the word “subject” is used to refer to the
people who will take part in the study. Depending on the nature of the research, the
word “participant” may be more applicable. Generally, one term or the other is used
consistently throughout the consent according to the investigator’s preference and the research purposes.

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 participation, 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 subjects (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.

10.2 Assent and Parental Consent (see 45 CFR 46 Subpart D)

Under 45 CFR 46 Subpart D, assent is defined as a child’s affirmative agreement to participate in research. A child is defined as a person who has not attained the legal age for consent to procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted. In Idaho, the legal age of consent is 18.

The IRB shall determine that adequate provisions have been made for soliciting the assent of children. The IRB will take into consideration the ages, maturity and psychological state of the children involved. As a general rule, children under the age of 11 should be assented verbally and the researcher must provide a verbal assent script along with their IRB application for review. Children ages 11 to 17 should, in most cases be assented with a written assent form. The researcher must provide a copy of the written assent form along with their IRB application for review. When a researcher provides assent documentation to the IRB for review, they must also provide a copy of the parental permission form that will be used. Assent form and parental permission form templates are available on the IRB website.

Parental and assent forms may be separate or combined; however, whether the forms are combined or separate both the parental permission and the child assent should include information indicating that the child may refuse to assent to participate in the research even if the parent/guardian has provided permission. In this way the child is treated as an autonomous agent.

**Additional elements for the child assent as needed**

1. Explanation that parent(s) know(s) the child is being asked to take part;
2. Purpose, procedure, risks, benefits, and data confidentiality explained in developmentally-appropriate lay language;
3. Description of what, if any, information the be shared with shared with their
parent(s), if applicable;
4. Statement about audio or video taping if required for participation; check
box or signature to opt out of taping, if not required; and
5. When relevant, statement of mandatory reporting requirements included.

Additional elements for the parent permission as needed
1. Statement that the researcher is asking for parent permission:
   a. for their child to take part in research, and
   b. to ask the child if they are willing to take part in the study (assent);
2. Description of procedures explained in terms of what the child will be asked
to do;
3. Statement that child may choose not to take part even if parent gives
permission;
4. Description of what, if any, study data about their child will be shared with
the parent, if applicable;
5. Purpose, risks, risk minimization, benefits, procedures, and confidentiality
   protections described in relation to the child as participant; and
6. When relevant, statement of mandatory reporting requirements included.

10.3 Required Elements
Per 45 CFR 46.116(a)(i)(ii), informed consent must begin with a concise
presentation in sufficient detail of the key information that is most likely to assist
a prospective subject or legally authorized representative in understanding the
reasons why one might or might not want to participate in the research and must
be done in a way that facilitates comprehension.
Informed consent disclosures must include all of the following 8 elements, when
applicable, as required by 45 CFR 46.116(b):
1. A statement that the study involves research, an explanation of the purposes
   of the research and the expected duration of the subject's participation, a
description of the procedures to be followed, and identification of any
   procedures which are experimental;
2. A description of any reasonably foreseeable risks or discomforts to the
   subject;
3. A description of any benefits to the subject or to others which may
   reasonably be expected from the research;
4. A disclosure of appropriate alternative procedures or courses of treatment, if
   any, that might be advantageous to the subject;
5. A statement describing the extent, if any, to which confidentiality of records
   identifying the subject will be maintained;
6. For research involving more than minimal risk, an explanation as to whether
   any compensation and an explanation as to whether any medical treatments
   are available if injury occurs and, if so, what they consist of, or where further
   information may be obtained;
7. An explanation of whom to contact for answers to pertinent questions about
   the research and research subjects' rights, and whom to contact in the event
   of a research-related injury to the subject; and
8. A statement that participation is voluntary, refusal to participate will involve
no penalty or loss of benefits to which the subject is otherwise entitled and
the subject may discontinue participation at any time without penalty or loss
of benefits to which the subject is otherwise entitled.

9. One of the following statements about any research that involves the
collection of identifiable private information or identifiable biospecimens:
   (i) A statement that identifiers might be removed from the identifiable
   private information or identifiable biospecimens and that, after
   such removal, the information or biospecimens could be used for
   future research studies or distributed to another investigator for
   future research studies without additional informed consent by the
   subject or legally authorized representative or;
   (ii) A statement that the subject’s information or biospecimens
   collected as part of the research, even if identifiers are removed,
   will not be used or distributed for future research studies.

10.4 Additional Elements
When applicable, one or more of the following elements of information shall also be
provided to each subject per 45 CFR 46.116(c):
   1. A statement that the particular treatment or procedure may involve risks to
   the subject (or to the embryo or fetus, if the subject is or may become
   pregnant) which are currently unforeseeable;
   2. Anticipated circumstances under which the subject's participation may be
   terminated by the investigator without regard to the subject's consent;
   3. Any additional costs to the subject that may result from participation in the
   research;
   4. The consequences of a subject's decision to withdraw from the research and
   procedures for orderly termination of participation by the subject;
   5. A statement that significant new findings developed during the course of the
   research which may relate to the subject’s willingness to continue
   participation will be provided to the subject;
   6. The approximate number of subjects involved in the study;
   7. A statement that the subject’s biospecimens (even if de-identified) may be
   used for commercial profit and whether the subject will or will not share in
   this commercial profit;
   8. A statement regarding whether clinically relevant research results, including
   individual results, will be disclosed to subjects, and if so, under what
   conditions; and
   9. For research involving biospecimens, whether the research will (if known) or
   might include whole genome sequencing.

10.6 Boise State Required Elements
The Boise State IRB requires the following (when applicable) on the consent form:
   1. Study title and name(s) of principal and co-principal investigator(s) at the
      beginning of the consent form;
   2. Name of the co-principal investigator must be included on the consent form
      if the principal investigator is a student researcher;
   3. Contact information for the IRB Office (Office of Research Compliance);
   4. Consent document written at a reading and comprehension level appropriate
for the age and/or background of the participant (6th-8th grade for most);

5. The language and its documentation (especially explanation of purpose, duration, experimental procedures, alternatives, risks, and benefits) written in "lay language," (i.e. understandable to the people being asked to participate);

6. Signature block include participant, researcher(s), witness if appropriate, and date of signature;

10.5 Elements of Broad Consent

If the subject or legally authorized representative is asked to provide broad consent, the following shall be provided, per 45 CFR 46.116(d):

1. All of the following:
   - A description of any reasonably foreseeable risks to discomforts to the subject;
   - Any benefits to the subject or others that may reasonably be expected;
   - A statement describing (if any) to which confidentiality of records identifying the subject will be maintained; and
   - A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

And when appropriate:

   - A statement that the subject’s biospecimens (even if identifiers are removed) may be used for commercial profit and whether the subject will or will not share in this commercial profit;
   - For research involving biospecimens, whether the research will (if known) or might include whole genome sequencing.

2. A general description of the types of research that may be conducted with the identifiable private information or identifiable biospecimens, with sufficient information such that a reasonable person would expect that the broad consent would permit the types of research conducted;

3. A description of the identifiable private information or identifiable biospecimens that might be used in research, whether sharing of identifiable private information or identifiable biospecimens might occur, and the types of institutions or researchers that might conduct research with the identifiable private information or identifiable biospecimens;

4. A description of the period of time that the identifiable private information or identifiable biospecimens may be stored and maintained (even if indefinite), and a description of the period of time that the identifiable private information or identifiable biospecimens may be used for research purposes (even if indefinite);

5. Unless subject or legally authorized representative will be given details about specific research studies, a statement that they will not be informed of the details of any specific research studies that might be conducted using the subject’s identifiable private information or identifiable biospecimens, including the purpose(s) of the research, and that they might have chosen not
to consent to some of those specific research studies;
6. Unless it is known that clinically relevant research results, including individual results, will be disclosed to the subject in all circumstances, a statement that such results may not be disclosed to the subject; and
7. An explanation of whom to contact for answers to questions about the subject’s rights and about storage and use of the subject’s identifiable private information or identifiable biospecimens, and whom to contact in the event of a research-related harm.

10.6 Documentation of Informed Consent (45 CFR 46.117)
Unless the IRB has granted a specific waiver of documentation of consent, informed consent shall be documented by the use of a written informed consent form approved by the IRB and signed by the subject, or subject’s legally authorized representative. A copy of the consent form shall be given to the person signing the form. The informed consent form may be either of the following:
1. A written informed consent form that meets all of the specified federal and institutional requirements. The subject, or subject’s legally authorized representative, must be given adequate opportunity to read the form before it is signed. Or alternatively, the form may be read to them.
2. A short written form stating that all of the elements of informed consent have been presented orally to the subject, or the subject’s legally authorized representative, and that the key information required was presented first to the subject, before other information, if any, was provided. The IRB shall approve a written summary of what is to be said to the subject or the legally authorized representative. When this method is used, there shall be a witness to the oral presentation. Only the short form itself is to be signed by the subject, or legally authorized representative. However, the witness shall sign both the short form and a copy of the summary, and the person obtaining consent shall sign a copy of the summary. A copy of the summary shall be given to the subject or subject’s legally authorized representative, in addition to a copy of the short form.

10.7 Waiving or Altering Informed Consent (.116(f))
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.

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 Boise State 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.

A. Waiver or Alteration of Consent in Research Involving Public Benefit and Service Programs conducted by or subject to the approval of state or local officials (.116(e))
An IRB may waive the basic elements of informed consent and/or the additional elements of informed consent requirements OR approve a consent procedure that alters or omits some or all, of the consent elements (basic and additional), provided the IRB satisfies the following requirements:

(i) The research or demonstration project is to be conducted by or subject to the approval of state or local government officials and is designed to study, evaluate, or otherwise examine:
   1. Public benefit or service programs;
   2. Procedures for obtaining benefits or services under those programs;
   3. Possible changes in or alternatives to those programs or procedures; or
   4. Possible changes in methods or levels of payment for benefits or services under those programs.

(ii) And the research could not practicably be carried out with the waiver or alteration.

*NOTE: If an individual was asked to provide Broad Consent for the storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens, under those consent elements (.116(d)) and refused to consent, an IRB cannot waive consent for the storage, maintenance, or secondary use of the identifiable private information or identifiable biospecimens.

B. General Waiver or Alteration of Consent (.116(f))
An IRB may waive or alter some elements of informed consent, under specific conditions. An IRB may not omit or alter any of the elements required for Broad Consent.

The IRB may consider waiving or altering some or all of the requirements for informed consent (45 CFR 46.116(f)) when the research meets all of the following conditions (the researcher needs to explain for each condition how it applies to his/her research):a. The research involves no more than minimal risk to the subject;
   b. The research could not practicably be carried out without the requested waiver or alteration;
   c. If the research involves using identifiable private information or identifiable biospecimens, the research could not practicably be carried out without using such information or biospecimens in an identifiable format;
   d. The rights and welfare of subjects will not be adversely affected; and
   e. Whenever appropriate, the subjects or legally authorized representatives will be provided with additional pertinent information after participation.

Note: The investigator needs to describe which elements of consent will be altered, and /or omitted, and justify the alteration. IRB does not approve alteration of the consent process for research that is subject to FDA regulations, except for planned emergency/acute care research as provided under FDA regulations.
Note: The IRB does not approve waiver of the consent process for research that is subject to FDA regulations, except for planned emergency/acute care research as provided under FDA regulations.

C. Screening, Recruiting, or Determining Eligibility (.116(g))
An IRB may approve a research proposal in which an investigator will obtain information or biospecimens for the purpose of screening, recruiting, or determining eligibility of prospective subjects without the informed consent of the prospective subject or the subject’s legally authorized representative, if either of the following conditions are met:
1. The investigator will obtain information through oral or written communication with the prospective subject, or legally authorized representative; OR
2. The investigator will obtain identifiable private information or identifiable biospecimens by accessing records or stored identifiable biospecimens.

D. Posting of Clinical Trial Consent Form (.116(h))
For each clinical trial conducted or supported by a Federal department or agency, one IRB-approved informed consent form used to enroll subjects must be posted by the awardee or the Federal department or agency conducting the trial on a publicly available Federal Website that will be established as a repository for such forms.

If the Federal department or agency supporting or conducting the clinical trial determines that certain information should not be made available to the public on a Federal Website (i.e. confidential information), such Federal department may require redactions to the information posted.

The informed consent form must be posted on the Federal Website after the clinical trial is closed to recruitment, and no later than 60 days after the last study visit by any subject, as required by the protocol.

E. Preemption (.116(i))
The informed consent requirements are not intended to preempt any applicable Federal, state, or local laws (including tribal laws passed by the official governing body of an American Indian or Alaska Native tribe) that require additional information to be disclosed in order for informed consent to be legally effective.

F. Emergency Medical Care (.116(j))
These regulations and policies are not intended to limit the authority of a physician to provide emergency medical care, to the extent the physician is permitted to do so under application Federal, state, or local law (including triable law passed by the official governing body of an American Indian or Alaska Native tribe).
10.8 Retaining and Storing Signed Informed Consent Documents
Signed informed consent forms are legal documents, and the researcher has legal responsibilities to handle them confidentially. 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.

10.9 Consent Process for Exemptions
Even if a study is considered to fall under an exemption from IRB review, investigators are ethically bound to follow the principles listed in the Belmont Report, particularly the first principle, respect for persons, which emphasizes the importance of ensuring that subjects are fully informed about the nature of a research project in order to make an informed decision to participate. The use of a signed consent document, for example in cases of anonymous data collection, would not be required, but those participants must still be informed about the purpose of the study. An investigator will provide a participant an IRB approved information sheet or use an oral consent script explaining the purpose of the study, how the data will be used, how the data will be kept anonymous, etc. Contact the ORC for further assistance.

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

11.1 PI Eligibility
Conducting research with humans is a privilege and carries with it ethical and legal responsibilities. The Principal Investigator (PI) is the individual responsible for writing an accurate protocol to utilize human subjects, and for designing practices and implementing the approved use(s) of those subjects. Ultimately, the PI assumes the
responsibility for the ethical conduct of the project and for the welfare of the human subjects. This responsibility includes the intellectual conduct of the project, fiscal accountability, administrative aspects, and the project’s adherence to relevant policies and regulations. For that reason, PIs must have a reasonable prospect of long-term employment at Boise State University. Certain other titles are allowed to serve as PIs within the exceptions described below.

Eligible PIs include faculty with the following titles:

- Professor
- Associate Professor
- Assistant Professor

Exceptions:
If you are not eligible to be a PI, you can still be listed as the PI if an eligible PI is listed as your Co-PI. If you are not able to do this, you may request a PI Exception to be the sole PI on an IRB protocol application. This exception must be approved by the Vice President of Research and Economic Development as well as your College Dean and your Department Chair. Contact the IRB Coordinator for additional information on how to obtain approval for an exception to the PI eligibility requirements.

If you are a graduate student submitting an IRB for Social Behavioral research related to your thesis or dissertation or a Doctorate of Nursing Practice (DNP) student, you may also be listed as the PI if someone who is eligible to be a PI is listed as your Co-PI. If you are a graduate student submitting an IRB for BioMedical research related to your thesis or dissertation you may be the Co-PI with an approved faculty as PI.

If you are an undergraduate student you are not permitted to serve as the PI. You must be listed as the Co-PI with an eligible faculty member listed as the PI.

If the research is funded, OSP PI Eligibility Policy #5020 will apply for PI eligibility.

11.2 Training/Education Requirements
All PIs are required to successfully complete and maintain human subjects research training certification through the Collaborative Institutional Training Initiative (CITI) online training program. The PI is responsible to ensure that all other research personnel are properly trained through CITI and have the experience necessary to perform the research.

11.3 Responsibilities/Acknowledgements
The PI is responsible for certifying that the information provided in the protocol application is complete and accurate. The PI has the ultimate responsibility for the conduct of the study, the ethical performance of all procedures, the protection of the rights and welfare of human participants, and strict adherence to any stipulations designated by the IRB. The PI will accept and will conform to all federal, state, and institutional provisions concerning the protection of human participants in research.
The PI is responsible for submitting any proposed changes/modifications for review and approval before they are implemented. The PI must the IRB and Office of Research Compliance of any adverse events that may occur during the study.

Any emergence of problems or development of hazardous conditions for the subjects must also be reported immediately to the IRB by the PI on the Incident Report Form.

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.

The PI has the primary responsibility to ensure the Annual Renewal Form is submitted in a timely manner.

The PI, upon completion of the study, 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.

11.4 Consent Responsibilities
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.

11.5 Co-PI Faculty Advisor Responsibilities
The faculty advisor serving as the PI or Co-PI on student research projects or research conducted by someone who is not eligible to serve as a sole PI has as much responsibilities as a PI. Faculty advisors should 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 PI before the protocol will be approved. If the PI 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. The Faculty Advisor should carefully read over the application and supplemental materials before signing.

11.6 Retention of Records
The PI is responsible for following through with the storage and destruction of data as outlined and approved in the protocol application. Data will be stored for no less than three years after the completion of a project. Please note that other departmental and funding agencies may require that data be stored for longer than three years. Boise State owns the research data. If the PI chooses to transfer to another institution, they
will need to obtain departmental approval to take the data with them. 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. IRB Record Requirements

All applications (new, continuing reviews, amendments, adverse event report forms) consent documents and all related supplemental materials will remain on file in the ORC for a minimum of three years after the completion of the expiration of the application. Meeting agenda, minutes, and IRB rosters will remain on file in the ORC as a permanent record of the committee’s activities. A curriculum vitae or resume of active members of the IRB will be maintained in the ORC and will be updated in content as necessary. Policy guidance and forms will be disseminated from and stored in the ORC until replaced by new and/or revised documents.

12.1 IRB Membership Roster
The IRB Coordinator will submit to OHRP a copy of the membership roster along with the registration renewals or updates as necessary.

12.2 Written Procedures and Guidelines
Written procedures and guidelines are contained in the Boise State University Human Research Protection Program Guide.

12.3 Minutes of Meetings
Minutes will be taken at each meeting by the IRB Coordinator or an individual designated by the ORC. The minutes of regular meetings must contain:
   a. Names and roles of each person present (members, staff, guests, PIs, etc.)
   b. Each application reviewed (continuing review/amendments, continuing reviews, amendments and initial)
   c. A summary of discussion on debated issues
   d. Required changes and recommendations
   e. Record of all motions and voting
   f. Report of any adverse event(s)
   g. List of expedited applications reviewed:
      • New, amendment and continuing review) approved since the last meeting and also for the fiscal year.

12.4 Retention of Records
The ORC will retain records as required by law and per this Human Research Protection Program Guide. The IRB Coordinator is responsible for the ongoing process of identifying the records, which have met the required retention period, and overseeing their destruction. Destruction of records will be accomplished by cross shredding or similar methods approved by the ORC and/or the University. The IRB Coordinator will track the location of protocol applications (stored in the ORC, University Archives, or destroyed). This will be updated as necessary to maintain an accurate accounting of records destroyed.
All applications reviewed (new, continuing reviews, amendments), adverse event report forms, consent documents and all related materials and appendices will remain on file at the ORC for a minimum of three years after the completion of the project or the expiration of the application. Funded projects will be stored in University Archive three years after the end of the project.

Meeting agenda, minutes, and IRB rosters will remain on file at the ORC as a permanent record of the committee’s activities. Policy guidance and forms will be disseminated from and stored at the ORC until replaced by new and/or revised documents.

12.5 Communication To and From the IRB
Applications for human subject research are available from the IRB or are located at the IRB website. Any questions regarding IRB review or the content of the manual should be directed to the IRB Coordinator. The IRB Coordinator communicates with researchers regarding IRB decisions and requests for additional information.

13. Special Topics
a. Advertising for Participants
Solicitation of subjects by use of advertisements, signs, or pamphlets soliciting volunteers for research is part of the recruitment process and must be approved by the IRB.

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 populations with impaired decision-making abilities.
   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 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.

b. Case Studies
The Boise State IRB does not require review and approval for single case studies. A single case does not meet the federal definition of research if:
   1. generalizable knowledge would not be gained from this anecdotal sharing of one or a few cases;
   2. it is a scholarly teaching activity that is part of the operations of an academic department;
   3. does not fall under the FDA definition of research.
However, if you are planning to present or publish more than a few case studies, please contact the IRB Coordinator to discuss whether or not this would meet the federal definition of research.

c. Certificate of Confidentiality
A Certificate of Confidentiality helps researchers protect the privacy of human research participants enrolled in biomedical, behavioral 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.

Please notify the ORC if you plan to submit for a Certificate of Confidentiality. The IRB approval must be in place before you can submit for a Certificate of Confidentiality, and this process may be a lengthy process, so plan accordingly.

d. Clinical Trials/FDA
Boise State University’s Federalwide Assurance issued and approved by the Office of Human Research Protection (OHRP) obligates the University to comply with federal human subject research regulations and requirements. According to this assurance, all research involving human subjects is subject to DHHS regulation under 45 CFR 46. If, however, the human subjects research is considered a clinical investigation regulated by the FDA under sections 505(i) (21 U.S.C. 355(i)) or 520(g) (21 U.S.C. 360j(g)), or if the research involves a clinical investigation intended to support applications for research or marketing permits for FDA-regulated products, the research is also subject to FDA regulation. Boise State’s IRB is not registered with the FDA and therefore will not review clinical trials or clinical investigations involving human subjects that are subject to FDA regulations.

If an investigator does need FDA regulated human subject review, use commercial IRB (WIRB, etc.) is advised. The use of a commercial or other IRB will also require an Institutional Authorization Agreement between Boise State and that external entity. Therefore, investigators must inform the ORC if you plan on using a commercial or external IRB for the review of a clinical trial.

There may be some projects that are identified as “clinical trials” or “clinical investigations” that are not subject to FDA regulations.

If you are not sure if your study will be subject to FDA regulations, contact the IRB Coordinator.
e. Computer/Internet-Based Research
Use of the internet and other computer based research methods are evolving rapidly and offering many new methods for researchers to contact research participants and collect data for research (including opportunities for large numbers of participants, ease of data collection, possibilities for anonymity, etc.). All of the same IRB considerations and federal regulations apply; however, use of the internet also creates challenges for the IRB.

1. Recruitment
There are many methods of recruitment. Indirect recruitment would include using flyers and announcements which direct individuals to websites to participate in the research. Direct recruitment may include sending e-mails or letters directly to individuals whom the researcher would like to recruit. Researchers should ask themselves the following questions: For direct recruitment, would the participants reasonably expect the research to contact them regarding the research topic? Authentication can be a major challenge for internet based research. How does the researcher know who they are actually communicating with/recruiting?

2. Informed consent: Minimal risk research may qualify for a waiver of consent or a waiver of documentation of consent. The IRB would generally require the information normally contained in the consent be provided to participants so participants may make an informed decision as to whether to participate. Greater than minimal risk research may require more traditional methods, such as mailing an informed consent document and receiving the participant’s signed copy, although, researchers may present suggestions to the IRB. Again, authentication may be a challenge for internet based consent.

3. Anonymity/confidentiality: The internet and computer based research can offer a “false sense” of anonymity/confidentiality. The researcher will be required to explain to the IRB how anonymity/confidentiality will be maintained. This will often rely heavily on server administration/security. The use of encryption should be considered and may be encouraged or required by the IRB. Whenever possible, identifiable data should be de-identified. Any code linking data to identities should not be stored on the same server as the data.

f. EXTERNAL RESEARCHERS
   (i) Collaborating with Boise State Researchers
(ii) Boise State as a Site for External Researchers
If you are an outside researcher (meaning you are not affiliated with Boise State), and you would like to conduct your research at Boise State or with Boise State students or employees, you will need to complete the following:

- IRB approval from your institution. (Note: If you do not have an IRB at your institution that can review and approve your research, see Seeking and IRB Review and Approval for a fee below. You will be charged a fee unless you are collaborating with a Boise State researcher.)
- Submit to the Boise State IRB Office, the full packet of materials submitted to your IRB including:
  - Letter of IRB approval for the project;
  - The IRB protocol application;
  - Consent form or information sheet;
  - Recruitment flyer or ad;
  - Instruments or measures to be used; and
  - any additional supporting documentation.

The ORC staff and IRB Chair will review the request and issue indicating the compliance and IRB concerns have been met. The IRB reserves the right to have requests for permission to recruit on campus go to the full board for review and approval, should the Chair decide that the nature of the study requires the independent scrutiny of the IRB to protect its students and employees.

If the research involves recruiting a very specific set of students (i.e. Psychology, College of Engineering), then you must also contact that department, college, or Vice President for Student Affairs for permission to recruit their students. You will need to let them know you have already contact the ORC and have met all compliance concerns.

(iii) Using Boise State’s IRB for a Fee
The IRB at Boise State will conduct an IRB review of research for investigators that are not affiliated with Boise State for a fee. Contact the ORC for additional information.

g. FERPA
The Family Educational Rights and Privacy Act (FERPA) is a federal law that protects the privacy of personally identifiable information contained within a student’s education record. Researchers are required to apply FERPA regulations and human subjects protections when accessing education records.

In accordance with FERPA, an educational institution has the authority to determine what information may be accessed from an education record. If an institution denies an
investigator access to information in an education record, the IRB cannot overrule the decision.

Directory Information
The following are considered directory information and may be released without consent:
- Email address
- Date of birth
- Dates of attendance
- Full-time/Part-time status (based on 12 credit hours)
- Mailing address and telephone number
- Class standing (freshman, sophomore, etc.)
- Major and minor plans
- Degree(s) earned and date degree was earned

Note: If a student has requested privacy over their education records, no information, including directory information, may be released without the student’s specific written consent. You should work with the Registrar’s Office to determine if students have requested their information as private.

If researchers will obtain data from education records beyond directory information for the purpose of research, they are generally limited to two options:

Researchers may contact and obtain written consent from each student to participate in the study and authorize the release of his/her education records for research purposes. School officials other than the researcher (such as Institutional Assessment) with legitimate access to the data or information may strip the records of any identifying information and provide the data to the researcher. Under 34 CFR 99.31, education records may be released without consent if all personally identifiable information has been removed. Officials must work with the Registrar’s Office to determine if students have requested their information as private.

Data Warehouse
If you are collecting data from the Data Warehouse, you must have Registrar approval as well as IRB approval to access this information for your research. If you already have access to the Data Warehouse for non-research purposes, you still must obtain registrar approval and IRB approval to access the Data Warehouse for research purposes.

For more information on Boise State’s policies regarding FERPA, visit the Boise State Registrar’s Office.
h. HIPAA
The Privacy Rule regulates the way covered entities under the Rule, handle individually identifiable health information known as Protected Health Information (PHI). Researchers should be aware of the Privacy Rule because it establishes the conditions under which covered entities can use or disclose PHI for many purposes, including for research. Although not all researchers will have to comply with the Privacy Rule, the manner in which the Rule protects PHI could affect certain aspects of research.

Applications must include Addendum 7 when the study will be accessing PHI. In order to render PHI anonymous, all 18 identifiers must be removed. Visit the IRB website for more information or contact the IRB Coordinator.

If you are a Boise State researcher and you are collaborating with an investigator from another institution (or vice versa), you may or may not need to obtain IRB approval from both institutions.

OHRP supports the idea of IRBs from collaborating institutions also collaborating – in essence, permitting one institution’s IRB to defer review of a human subjects research application to another IRB. This collaboration eliminates redundancies in the review of a study, and may provide a more efficient process. In order for the IRB to consider such an arrangement, both IRBs must have a Federal-Wide Assurance from the OHRP. If the outside IRB does not include the data collection methods to be used with Boise State subjects, the IRB will require the Boise State researcher to submit a separate application to Boise State’s IRB.

The Boise State IRB enters into written Institutional Authorization Agreements (IAAs) with other IRBs (e.g. at another University of Hospital) when such agreements facilitate and streamline the IRB process while ensuring that the rights and welfare of human participants are fully protected. In general, the institution with the primary employment or the lead PI on a funded project will be the IRB of record. Each IRB may decide on the appropriateness of ceding or accepting responsibility for the IRB review.

If the collaborating institution has a FWA and their IRB is registered with OHRP, Boise State will agree to sign an IAA with the collaborating institution. The IAA documents that Boise State’s IRB will rely on another IRB as the IRB of record. The IAA can also document that the collaborating IRB will rely on Boise State’s IRB to be the IRB of record.

After the IRB of record has reviewed and approved the protocol application, a copy of the approval letter must be sent to the institution relying on the IRB of record for the review. The IAA must be signed by the Institutional Official (or representatives) at both institutions.
j. International Research
Research conducted by Boise State investigators in foreign countries remains under Boise State purview and guidelines. While adjustments may be made to some requirements to respect cultural differences, our standards for ethical conduct are not relaxed.

The IRB may require that research projects be approved by the local equivalent of an IRB before the IRB will grant final approval. Where there is no equivalent board or group, investigators must rely on local experts or community leaders to provide approval. The PI must provide the IRB with documentation of this “local approval” and documentation of the authority and expertise of the individual or group who granted approval. There must also be detailed plans in place for local monitoring of studies that pose more than minimal risk to participants. Researchers must describe what, if any, knowledge or experience they possess regarding the language and culture of the country in question. If the IRB is not satisfied with the review of local experts and/or the plans for continued monitoring there is the possibility that the study will not be approved.

The IRB may seek guidance first from OHRP’s International Compilation of Human Subject Research Protections or it may contact OHRP to determine whether procedures described by a foreign institution afford protections that are at least equivalent to U.S. regulations 45 CFR 46.101(h) and may be substituted for the U.S. regulations. Under this provision, OHRP investigates the foreign country’s guidelines for human participants’ research, and if the foreign guidelines are found to be equivalent to U.S. regulations, the investigator is permitted to substitute those foreign procedures.

Informed Consent
The informed consent process, as well as the document, must be in the participants’ native language or they must be fluent enough in English to fully understand the information and ask appropriate questions.

k. Native American Participants
In more than minimal risk studies, they IRB may call on a Native American or an experienced Native American advocate as a consultant for the review of the study. In order to respect the sovereign governments, research to be conducted on Native American tribal lands will require a letter from the Tribal Council (or equivalent authorized signatory) to the IRB acknowledging the research activity and their willingness to allow the proposed activity.

l. Non-English Speaking Participants
The involvement of non-English speaking individuals in research studies raise concerns with issues of informed consent as well as their inclusion and exclusion in research.
While these studies may qualify for exempt or expedited review, the Chair or authorized designee reserves the right to require full board review.

Investigators must be aware that individual participants, and sometimes significant portions of the potential participant population, may not speak English. Investigators must plan for populations that are likely to be recruited into the research and incorporate translations into the study design to allow for appropriate recruitment and enrollment. When applicable, the PI must outline in the protocol application procedures to recruit non-English speaking participants as well as procedures to translate study material and consent documents. The protocol must also describe procedures for ensuring that informed consent is presented to participants in a language understandable to them.

Non-English speaking participants, who meet enrollment criteria, may not be excluded because they cannot understand or read English. Non-English speaking participants may not be excluded from research that may have direct potential benefits. If non-English speaking participants will be specifically excluded from research, the PI must provide an ethical and scientific explanation for doing so.

m. Oral Histories
In general, OHRP recognizes that oral historians have specific concerns and need to conduct research. However, the OHRP has not indicated that oral histories do not require IRB review. The Oral History Association has information available to members to help determine whether oral history research and activities require IRB review.

n. Pilot Projects
Pilot projects which are used to develop or test measures are not considered human subjects research as long as you have no desire to publish or share this information. If it is possible that the data collected in your pilot study will be used solely or in combination with other data for publication purposes, IRB review and approval is required before data collection begins.

o. Prisoners
The federal regulations have specific requirements for research involving prisoners. These requirements are found in Subpart C of the DHHS regulations. A “prisoner” is any individual involuntarily confined or detained in a penal institution. The term is intended to encompass individuals sentenced to such an institution under a criminal or civil statute, individuals detained in other facilities by virtue of statutes or commitment procedures which provide alternatives to criminal prosecution or incarceration in a penal institution, and individuals detained pending arraignment, trial, or sentencing.

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.

**p. Recording Participants (Audio, Video, Photographs)**
The federal regulations (45 CFR Part 46) require that whenever voice, video, digital, or image recordings are made the application must be reviewed at the expedited review level (provided that the other requirements for expedited review are met) or full board review.

The type of recording must be disclosed in the informed consent document. When the recording is deemed necessary to the research the informed consent must clearly indicate such. When recording is not absolutely necessary to the researcher a separate signature line for the recording acceptance should be included on the consent form so that a participant could choose to participate in the study but decline the recording of their participation.

The IRB considers recording for purposes of transcription only not to be part of the research that would automatically require expedited review.

**q. Refugees**
Investigators must be aware of the cultural differences when using this population. Subjects may not speak English, and their language may not be in written form. These and other cultural differences will need to be taken into consideration for your data collection methods, recruitment, and consent processes. In general, we recommend you follow the guidelines for non-English speaking individuals above, as many refugees have English as a second language.

**s. Student Research**

**(i.) Undergraduate Research**
Undergraduate students may be involved with classroom activities or other research involving human subjects (i.e. surveys, observing behavior, etc.). In general, classroom activities that are not intended for generalizable knowledge are not considered research and therefore, do not require review. The IRB Coordinator is available to help make this determination.

Undergraduate students who are initiating research are permitted to do so, but must have a faculty advisor listed at the PI on their IRB application. The advisor is ultimately responsible for the conduct of the research project all other responsibilities as the PI.
(ii.) Graduate Research
IRB policy requires the PI on an IRB application be a BSU faculty or staff member. Student-initiated research involving human subjects, whether dissertation, thesis, or other research, should include the student as a Co-PI or “other study personnel” when submitted to the IRB for review. Regardless of who fills out the form (e.g. PI, student, research assistant, etc.) the PI is responsible for the content.

IRB review and final approval should take place during the proposal stage of a dissertation or thesis and IRB approval and determination will not be granted retrospectively. Prior to graduation, the Graduate School will require a copy of the graduate student’s IRB approval letter if they have not already received it. The ORC will copy the Graduate College on all notification of approval letters for graduate student research. If it comes to the attention of the IRB that IRB approval has not been obtained for a thesis or dissertation prior to initiation of research involving human subjects, the IRB will refer the student researcher’s advisor(s) and the Graduate School.

(iii.) Class Projects/Assignments
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 project, 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. The IRB Coordinator is also available to present full or abbreviated human subject education to undergraduate and graduate classes.
14. Definitions

**ADVERSE EVENT**
An event that occurs during the course of the research that either causes physical or psychological harm or increases the risk of such harm or results in a loss of privacy or confidentiality to a research participant or to others. The IRB must determine with the help of the PI if such events are anticipated or unanticipated, and also if they are serious and related to the research.

**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.

**ATTRITION**
A reduction or decrease in numbers. Subject attrition is the withdrawal of a research subject from a study.

**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.

**BROAD CONSENT**
Written consent, granted at a prior time for use of an individual’s identifiable private information and/or biospecimen(s) allowing future research to take place with that information and/or biospecimen(s).

**CLINICAL TRIAL**
A research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of the interventions on biomedical or behavioral health-related outcomes.

**CHILD/MINOR**
A person who has not attained the legal age for consent to treatments or procedures involved in 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 PI 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 46.104. 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
Federalwide 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, (2) identifiable private information, or (3) identifiable biospecimen. 45 CFR 46.102(e)(1)

IDENTIFIABLE BIOSPECIMEN
A biospecimen for which the identity of the subject is or may readily be ascertained by the investigator or associated with the biospecimen. 45CFR46.102(e)(6)

IDENTIFIABLE PRIVATE INFORMATION
Private information for which the identity of the subject is or may readily be ascertained by the investigator or associated with the information. 45CFR46.102(e)(5)

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.

INSTITUTION
Any public or private entity, or department or agency (including federal, state, and other agencies), or IRB for the purpose of enacting an Institutional Authorization Agreement. 45CFR46.102(f)

INSTITUTIONAL AUTHORIZATION AGREEMENT (IAA)
A signed Agreement between two Institutional Review Boards designating the primary and secondary responsibilities of IRB review and oversight as outlined by OHRP Template.
INTERACTION
Communication or interpersonal contact between investigator (or designee) and subject. 45CFR46.102(e)(3)

INTERVENTION
Both physical procedures by which information or biospecimens are gathered (e.g. venipuncture) and manipulations of the subject or the subject’s environment that are performed for research purposes. 45CFR46.102(e)(2)

IRB
Institutional Review Board. An institutional committee formed to ensure the protection of human subjects in research per federal mandates. 45CFR46.102(g)

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)

LEGALLY AUTHORIZED REPRESENTATIVE
An individual or judicial or other body authorized under applicable law to consent on behalf of a prospective subject to the subject’s participation in the procedure(s) involved in the research, including parent or guardian (as designated by law) and recognized by institutional policy as acceptable for providing consent on behalf of the subject. 45CFR46.102(i)

LIMITED IRB REVIEW
A type of review that uses identifiable private information and/or identifiable biospecimens for research, gaining access to that data through consent granted previously with Broad Consent.

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(j)

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, whether funded or not funded.

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

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

If you are not affiliated with Boise State, 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 Boise State PI eligibility policy #5020.

PRIVATE INFORMATION
Information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information that has been provided for specific purposes by an individual and that the individual can reasonably expect will not be made public (e.g., a medical record). 45CFR46.102(e)(4)

PROTOCOL APPLICATION
The form used to summarize 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.” Available on the ORC IRB Forms webpage.

PUBLIC HEALTH AUTHORITY
An agency or authority of the United States, a state, a territory, a political subdivision of a state or territory, an Indian tribe, or a foreign government, or a person or entity acting under a grant of authority from a contract with such public agency, including the employees or agents of such public agency or its contractors or persons or entities to whom it has granted authority, that is responsible for public health matters as part of its official mandate. 45 CFR 46.102(k)

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(l)
SECONDARY RESEARCH
Research using data gathered initially for non-research purposes.

SPECIAL POPULATIONS
The Office for Human Research Protections (OHRP) has identified populations in need of special protections in research, including fetuses, children and minors, those with impaired decision-making abilities or susceptible to coercion or undue influence, 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.

UNANTICIPATED PROBLEMS
OHRP guidance, unanticipated problems or events include any incident, experience, or outcome that meets all of the following criteria:

- **unexpected** (in terms of nature, severity, or frequency) given (a) the research procedures that are described in the protocol-related documents, such as the IRB-approved research protocol and informed consent document; and (b) the characteristics of the subject population being studied;

- **related or possibly related** to participation in the research (in this guidance document, possibly related means there is a reasonable possibility that the incident, experience, or outcome may have been caused by the procedures involved in the research); and

- **suggests** that the research places subjects or others at a greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized.

WRITTEN, or IN WRITING
Refers to writing on a tangible medium (e.g. paper) or in an electronic format.

15. Acknowledgements
Boise State University would like to acknowledge and thank Washington State University for the use of language and guidance borrowed from their IRB Manual for the Protection of Human Research Subjects.