

**The College of Idaho**

**INSTITUTIONAL REVIEW BOARD HANDBOOK**

<b>Table of Contents</b>	
<b>I. Institutional Commitment</b>	<b>3</b>
<b>II. Applicability: Activities Requiring Review</b>	<b>3</b>
<b>III. Committee Membership</b>	<b>5</b>
<b>IV. Records</b>	<b>5</b>
<b>V. IRB Procedures</b>	<b>7</b>
<b>A. Exempt Status</b>	<b>7</b>
<b>B. Expedited Review</b>	<b>9</b>
<b>C. Full Board Review</b>	<b>12</b>
<b>D. Informed Consent</b>	<b>14</b>
<b>E. Decision Levels and Resubmission Requirements</b>	<b>16</b>
<b>F. Protocols Requiring More Than Annual Review or Outside Verification</b>	<b>16</b>
<b>G. Modifications and Continuing Review</b>	<b>17</b>
<b>H. Proposed Schedule of IRB Deadlines and Meetings</b>	<b>20</b>
<b>VI. Complaints, Non-compliance, Suspension, Termination and Reporting</b>	<b>21</b>
<b>VII. Principle Investigators/Project Directors (PI/PDs)</b>	<b>24</b>
<b>VIII. IRB Office</b>	<b>26</b>
<b>IX. List of IRB Forms</b>	<b>26</b>

10/01/09

## **I. Institutional Commitment**

The College of Idaho is concerned with the protection of the rights and welfare of human participants in all research conducted by faculty, staff, and students and by outside entities using C of I faculty, staff, and students as part of their research. This concern, which is the primary purpose of the Institutional Review Board (IRB), includes the protection of rights to privacy, the need for informed consent, protection of confidentiality of data, protection against physical, psychological, social, or economic risks and an appropriate demonstration of benefit to risk ratio. The safeguarding and confidentiality of records and data collected on individuals and groups, the use of such data by the investigator conducting the original research or by other investigators, and the use of the data at a later time are all considered within the scope of this policy.

The purpose of the IRB is to ensure that all human research conducted by The College of Idaho faculty, staff and students will comply with the Federal Policy for the Protection of Human Subjects, [45 CFR 46 \(The Common Rule\)](#) and subparts B,C, & D.

The IRB will certify that all human research will follow the ethical principles described in the [Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research](#).

The IRB will ensure that engagement in non-exempt human research activities of each independent investigator who is not an employee or agent of The College of Idaho will be in accordance with a formal, written agreement of commitment to relevant human participant protection policies and IRB oversight. Such commitment agreements will be on file and available to OHRP upon request.

The purpose of the IRB does not include the critique of the research design of proposed projects beyond aspects that impact the rights and welfare of the human participants/subjects.

By meeting these requirements, the IRB will assist faculty and student researchers, staff, administrative personnel, and other involved college community members in avoiding errors or oversights that can result in justifiable complaints and actions, including lawsuits against the college and/or anyone acting in a college sanctioned capacity.

## **II. Applicability: Activities Requiring Review**

Based on U.S. Government regulations that govern this review process, called “The Common Rule” because the same set of regulations applies to 18 different federal agencies, “RESEARCH” is defined as: “[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.

According to “The Common Rule,” a “HUMAN SUBJECT” is defined as: “[A] living individual about whom an investigator (whether professional or student) conducting research obtains:

10/01/09

1. Data through intervention or interaction with the individual, or
2. Identifiable “private information.”

IRB approval must be obtained prior to any data collection for research involving human participants, if the research is sponsored by the College (this includes activities undertaken as part of the instructional process); is conducted by or under the direction of any faculty, staff, or student of the College in connection with institutional responsibilities or using any property or facility of the College; or involves the use of the College’s non-public information to identify or contact prospective students.

If the results of the work are meant to be published or disseminated to an unrestricted audience, or even if this is viewed as a possibility, then the work counts as research.

The following activities are NOT considered research:

Surveys and interviews for the purposes of:

1. Journalism (as protected by the freedom of the press and subject to journalistic ethics), such as polls done for the College newspaper.
2. Advocacy (as protected by freedom of speech), such as a campaign to get students to stop smoking.
3. Internal College use only, such as surveys of members of the College community where the results are made available to a limited audience within the College community; or evaluations of College faculty, programs, or services.
4. Class activities
  - A. Data collected from human participants (both in and outside the classroom) as part of the instructional process do not require IRB review as long as they meet the following requirements
    1. the information will not be presented or published beyond the classroom
    2. the data collection process will not constitute more than minimal risk (i.e. the likelihood of harm or discomfort are not greater than those experienced in everyday life)
  - B. However, participation in any teaching activity (whether it is to be published or not) that involves more than minimal risk to the student must be accompanied by the student’s voluntary informed consent and must be reviewed and approved by the IRB.
  - C. If the instructor/and or student wish to present or publish information beyond the classroom (e.g. in a departmental colloquium or a student research conference), the activity is considered research and must be reviewed by the IRB in advance of the research being conducted if it involves human participants. If the activity involves the entire class using similar protocols, then the faculty member may submit one proposal for the class. However, if each student’s project is fundamentally different, then separate protocols must be submitted.
5. Activities in which the primary purpose is of specific benefit or treatment to the individuals involved such as counseling, social work, physical or psychological therapy, or psychological testing. These activities are subject to the norms of confidentiality and standards of practice of the relevant professionals.

6. Oral histories: Oral history interviewing activities are “not designed to contribute to generalizable knowledge and therefore do not involve research as defined by Department of Health and Human Services (HHS) regulations at 45 CFR 46.102(d) and do not need to be reviewed by an institutional review board (IRB) (Office for Human Research Protection, 2004) ”. For additional information, please see: <http://www.historians.org/Perspectives/Issues/2004/0403/0403new1.cfm>

### III. Committee Membership

1. Is comprised of at least five members with varying backgrounds and expertise to promote complete and adequate review of research activities commonly conducted by the Institution.
2. Is qualified through the experience and expertise of its members.
3. Is qualified through the diversity of its members including consideration of race, gender, and cultural backgrounds and sensitivity to such issues as community attitudes.
4. Is competent to review specific research activities and able to ascertain the acceptability of proposed research in terms of institutional commitments and regulations, applicable law, and standards of professional conduct and practice.
5. Includes at least one member whose primary concerns are in a scientific area, at least one member whose primary concerns are in a non-scientific area and at least one member who is not otherwise affiliated with the Institution and who is not part of the immediate family of a person who is affiliated with the Institution.
6. If the IRB is reviewing research involving a population vulnerable to coercion or undue influence, including but not limited to, prisoners, children, pregnant women, cognitively or decisionally-impaired, and economically or educationally disadvantaged,, the IRB will ensure that the protocol is reviewed by one or more individuals who are familiar with the population.
7. No member may participate in the review of any protocol in which he has a conflicting interest, except to provide information requested by the IRB. Members are expected to self-identify conflicting interests. A primary reviewer or expedited reviewer with a conflict of interest must notify the IRB staff who will re-assign the protocol.
8. All IRB members must meet the IRB education requirement by completing the Protecting Human Research Participants Modules provided by the NIH Office of Extramural Research (<http://phrp.nihtraining.com/users/login.php>).
9. Both the IRB chair and the Human Protections Administrator must also complete the Human Subjects Assurance Training provided by OHRP at <http://ohrp-ed.od.nih.gov/CBTs/Assurance/login.asp>.

### IV. Records

- A. The IRB will prepare and maintain adequate documentation of IRB activities, including the following:
  1. Protocol: All available and applicable documents related to submission of a research protocol including, but not limited to, the IRB application, protocol, grant, Investigator’s Brochure, consent form(s), progress reports submitted by the PI/PPD, recruitment and advertisement materials, study tools and instruments, reports of

unanticipated problems involving risks to participants or others, and reports of injuries to participants.

2. Minutes
  - a. Minutes of the committee meetings that document the:
    1. Attendance at meetings (including when an alternate member replaces a primary member)
    2. Actions taken by the Committee
    3. Vote on these actions (including the number of members voting to approve, disapprove, and abstaining). Votes will be recorded using the following format: Total = 5; Vote: For - 4, Opposed – 0, Abstain – 1, Recuse – 0, Not present for the vote – 0. The vote will reflect only those present. Any member who abstains, recuses him/herself, or is absent from the room (due to a conflict or unintentionally) will be noted by name in the voting record.
    4. Basis for requiring modifications or disapproving the research, and a summary of controverted issues and their resolution.
  - b. Minutes are distributed to the Chair of the meeting and to Committee members (via email). Approval of the minutes by the Committee members is indicated by their absence of response within five days of the IRB request for comments. Approval of the minutes by the Chair is documented by his/her signature on the minutes cover sheet.
  - c. Modifications of full board minutes that occur after committee approval will be communicated to members via email distribution of an addendum to the minutes. Approval of the addendum by the Committee members is indicated by their absence of response within five days of the IRB request for comments.
3. Continuing Review: Records of Continuing Review activities including, but not limited to, the IRB renewal form, the most current protocol, updated consent form(s), progress report (if funded by a granting agency and available), data monitoring reports (if applicable), study tools and instruments, recruitment and advertising materials, and an aggregate listing of reported unanticipated problems involving risks to participants or others.
4. Correspondence: Copies of all correspondence between the IRB and PI/PDs will be filed in the relevant protocol file.
5. Membership Lists
  - a. A list of Committee members including descriptive information
  - b. All changes in Committee membership will be reported to OHRP quarterly (as requested by OHRP).
6. Policies and Procedures: Written procedures which the IRB will follow for:
  - a. Conducting its initial and continuing review of research and for reporting its findings and actions to the investigator and the institution (See Section V of this Handbook);
  - b. Determining which protocols require review more often than annually and which protocols need verification from sources other than the investigators that no material changes have occurred since previous IRB review (See Sections V and VII of this Handbook);
  - c. Ensuring prompt reporting to the IRB of proposed changes in a research activity, and for ensuring that such changes in approved research, during the period for which IRB approval has already been given, may not be initiated without IRB review and approval except when necessary to eliminate apparent immediate hazards to the participant (See Section V(E) of this Handbook); and
  - d. Ensuring prompt reporting to the IRB, appropriate institutional officials, and the Department or Agency head of (i) any unanticipated problems involving risks to

participants or others or any serious or continuing noncompliance with this Policy or the requirements or determinations of the IRB; and (ii) any suspension or termination of IRB approval (see Section VI of this Handbook).

- B. The above administrative records and records relating to research will be retained by the IRB indefinitely.
- C. All records are accessible for inspection and copying by authorized representatives of HHS, FDA, representatives of federal funding agencies, Industry Sponsors, and C of I officials and internal auditors at reasonable times and in a reasonable manner.

## V. IRB Procedures

**New Proposals and Status Determination:** There is a three-level structure for the IRB review of **research** involving human participants.

- A. **Exempt:** At least one IRB committee member will verify that a proposal meets the necessary qualifications (see below) for exemption.
- B. **Expedited:** Research that presents no or minimal risk to participants is eligible for expedited review upon request.
- C. **Full:** Research which does not meet exempt or expedited status will be submitted to the chair for review by the IRB committee.

### A. **Exempt Status:**

The College of Idaho has determined that research (see Section II to determine whether an activity is considered “research”) meeting the following conditions is exempt from continuing IRB review:

#### **There are 6 categories of Exempt Research**

#### **To qualify for Category 1 (no age limitations on participants; no restrictions on research methods):**

Your research project must involve collecting data in an educational setting to study normal educational practices for the purpose of evaluating instructional strategies (e.g., research comparing those used in normal and special education), instructional techniques, curricula, or classroom management methods.

**This category does not apply to Food and Drug Administration (FDA) regulated research.**

#### **To qualify for Category 2 (participants must be adults – legal age of adulthood varies by location)**

Several types of research projects may fall under this category.

- a) Studies involving the collection of data using standardized educational tests (e.g., a subtest of an IQ or achievement test);
- b) Studies involving the observation of public behavior;
- c) Studies involving the administration of surveys or interviews as long as one of the following conditions is met:
  - 1) participation will be completely anonymous OR

10/01/09

- 2) participation is not anonymous, HOWEVER the information that will be gathered would not place participants at risk of criminal or civil liability or be damaging to the participants' financial standing, employability, or reputation;
- d) Studies involving focus groups as long as the data that is collected (or topics discussed) would be unlikely to place participants at risk (see (c) above).

**To qualify for Category 3:**

Your research project must meet certain exceptions with respect to the possibility of risk in items c) and d) of the previous category. These exceptions involve participants running for public office and other special groups.

**This category does not apply to Food and Drug Administration (FDA) regulated research.**

**To qualify for Category 4:**

Your research project must use existing data or records that are either available to the public (e.g., court records) or data that have been stripped of any direct identifiers (e.g., names, addresses, telephone numbers, social security numbers) and any indirect identifiers (e.g., codes that can be used to link data to participants). Note: According to the Office for Human Research Protections (“OHRP”), “... to qualify for this exemption, the data, documents, records, or specimens must be in existence BEFORE the project begins. The principle behind this requirement is that the rights of individuals should be respected; subjects should provide permission for their individually identifiable information to be used for research purposes.

**This category does not apply to Food and Drug Administration (FDA) regulated research.**

**To qualify for Category 5:**

This category is limited to very specific types of research or demonstration projects that are conducted by or subject to the approval of federal Department or Agency heads. The following criteria must be satisfied to invoke the exemption under this category:

- the program under study must deliver a public benefit (e.g., financial or medical benefits as provided under the Social Security Act) or service (e.g., social, supportive, or nutrition services as provided under the Older Americans Act);
- the research or demonstration project must be conducted pursuant to specific federal statutory authority;
- there must be no statutory requirement that the project be reviewed by an Institutional Review Board (IRB); and
- the project must not involve significant physical invasions or intrusions upon the privacy of participants.

This exemption is for projects conducted by or subject to approval of federal agencies, and is most appropriately invoked with authorization or concurrence by the funding agency.

**This category does not apply to Food and Drug Administration (FDA) regulated research.**

**To qualify for Category 6:**



10/01/09

This category covers taste and food quality evaluations and consumer acceptance studies:

- if wholesome foods without additives are consumed; or
- 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 FDA or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

Research falling into the above categories must complete the Exempt status form and submit it to the chair of the IRB or a designee prior to the beginning of research. All other research must be reviewed either as an expedited or full committee review.

**The following can NOT be Exempt**

- research involving prisoners;
- surveys or interviews of children;
- observation of children when the investigator will interact with them;
- data obtained from adults through administration of educational tests, survey procedures, interview procedures, or by observation of public behavior IF the information is recorded in such a way that the identity of individuals can be identified either directly or through identifiers linked to the individuals AND disclosure of participants' responses could reasonably place them at risk of criminal or civil liability or be damaging to an individual's financial standing, employability, or reputation;
- observation of behavior that takes place in settings in which participants have a reasonable expectation of privacy;
- research techniques which expose participants to discomfort or harassment beyond levels encountered in daily life (i.e., greater than minimal risk);
- deception of research participants; and
- research that involves a test article regulated by the FDA unless the research meets the criteria for exemption described in 45 CFR 46.101(b)(6).

**B. Expedited Status:**

An expedited review is conducted by the IRB chair or a designee. Only research that meets the specific criteria outlined in "Research Activities Which May Be Reviewed Through Expedited Review Procedures" ([63 FR 60353-60356](#) and [63 FR 60364-60367](#)) AND involves no greater than minimal risk will be reviewed by an expedited review process.

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 examinations or tests.

Categories of research eligible for expedited review

According to 63 FR 60364-60367, November 9, 1998 and 63 FR 60353-60356, November 9, 1998 [www.hhs.gov/ohrp/humansubjects/guidance](http://www.hhs.gov/ohrp/humansubjects/guidance) the following 9

categories of research are permitted to receive expedited review. Most behavioral research falls under Category 7.

Category 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 [www.hhs.gov/ohrp/humansubjects/guidance](http://www.hhs.gov/ohrp/humansubjects/guidance) 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.)

(b) Research on medical devices for which (i) an investigational device exemption application [21 CFR Part 812 [www.hhs.gov/ohrp/humansubjects/guidance](http://www.hhs.gov/ohrp/humansubjects/guidance)] is not required; or (ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.

Category 2: Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:

(a) from healthy, nonpregnant adults who weigh at least 110 pounds. For these subjects, 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 subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, 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.

Category 3: Prospective collection of biological specimens for research purposes by noninvasive means.

Examples: (a) Hair and nail clippings in a nondisfiguring manner; (b) deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction; (c) permanent teeth if routine patient care indicates a need for extraction; (d) excreta and external secretions (including sweat); (e) uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gumbase or wax or by applying a dilute citric solution to the tongue; (f) placenta removed at delivery; (g) amniotic fluid obtained at the time of rupture of the membrane prior to or during labor; (h) supra- and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques; (i) mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings; (j) sputum collected after saline mist nebulization.

Category 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, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.

Category 5: Research involving materials (data, documents, records, or specimens) that have been collected or will be collected solely for nonresearch purposes, such as medical treatment or diagnosis. (NOTE: Some research in this category may be exempt from the DHHS regulations for the protection of human subjects--see Exempt Research and 45 CFR 46 101(b)(4)-- [www.hhs.gov/ohrp/humansubjects/guidance](http://www.hhs.gov/ohrp/humansubjects/guidance) this listing refers only to research that is not exempt).

Category 6: Collection of data from voice, video, digital, or image recordings made for research purposes.

Category 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 subjects--see Exempt Research and 45 CFR 46.101(b)(2) and (b)(3) [www.hhs.gov/ohrp/humansubjects/guidance](http://www.hhs.gov/ohrp/humansubjects/guidance) -this listing refers only to research that is not exempt).

Category 8: Continuing review of research that is greater than minimal risk and has been initially reviewed and approved by the convened full-board IRB as follows: (a) where (i) the research is permanently closed to the enrollment of new subjects; (ii) all subjects have completed all research-related interventions; and (iii) the research remains active only for long-term follow-up of subjects; or (b) where no subjects have been enrolled and no additional risks have been identified; or (c) where the remaining research activities are limited to data analysis.

Category 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.

**The following can NOT be reviewed through the Expedited process.**

10/01/09

1. Research where identification of the subjects and/or their responses would reasonably place them at risk of criminal or civil liability or be damaging to the subjects financial standing, employability, insurability, reputation, or be stigmatizing, unless reasonable and appropriate protections will be implemented so that risks related to invasion of privacy and breach of confidentiality are no greater than minimal.
2. Classified research involving human subjects.
3. Research that involves more than minimal risk to human subjects (i.e. the probability and magnitude of harm or discomfort anticipated in the research are greater than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests).
4. Research with prisoners is not eligible for expedited review.

Expedited review is conducted by IRB members with appropriate qualifications (i.e., background and training) who review for consistency with ethical principles, and compliance with federal regulations and C of I policies and procedures.

Designated reviewers may exercise all of the authorities of the IRB except that the reviewers may not disapprove the research. The research may only be disapproved after review in accordance with the non-expedited review procedure set forth in 45 [CFR 46.108\(b\)](#) and [21 CFR 56.108\(c\)](#). When applicable, contingencies will be communicated to the PI/PD in writing. If a PI/PD does not agree to make the reviewer's requested revisions, the PI/PD's justification will be reviewed by the IRB Chair. The IRB Chair will accept the PI/PD's justification, resolve the issue with the PI/PD, or refer the submission to a full board.

The IRB will employ the use of the expedited review mechanism only for minor modifications to ongoing research involving prisoners. Such expedited review will be conducted by the prisoner representative who will follow the procedures described below for confirming that the request meets the criteria for expedited review. Initial and continuing reviews of protocols involving prisoners will be conducted by the full board.

Requests for expedited review that, upon review, are determined not to meet the criteria for expedited review will be referred to a full board review.

### **C. Full Board Review**

1. All protocols that are not determined to qualify as Expedited or Exempt will be reviewed by the full board. New submissions and "Greater than Minimal" risk protocol renewals will be individually presented, discussed, and voted on at a convened meeting.

2. Full Board review of protocols will take place only when a majority (one more than 50% of the full committee) of the Committee members are present, including at least one member whose primary concerns are in nonscientific areas. No official actions will be taken at a meeting where a majority of the members, including a non-scientist, are not present.
3. IRB meetings will take place with all participating members physically present unless circumstances warrant conducting an IRB meeting via telephone conference call or using speakerphone.
  - a. Telephone conference call: Official actions may be taken at a meeting in which members participate via telephone when each participating IRB member (i) has received all pertinent material prior to the meeting, and (ii) can actively and equally participate in the discussion of all protocols (e.g. each member can hear and be heard by all other participating members). Satisfaction of these two conditions in addition to the standard regulatory requirements will be documented in the meeting minutes.
  - a. Speakerphone: If a member is not able to be physically present during a convened meeting but is available by telephone, the meeting can be convened using speakerphone. The member who is not physically present will be connected to the rest of the members via speakerphone so that all members will be able to discuss the protocol. Members participating by speakerphone may vote provided they have had an opportunity to review all of the materials the other members have reviewed.
- D. All Committee members' votes will be deemed equal and no proxy votes (written or by telephone) will be considered.
- E. The IRB will review all new and continuing protocols to determine the appropriateness of the research in the local research context. Review and approval will be based on detailed applicable information provided in the IRB submission forms (e.g. participant population, participant selection, benefits to participants, mechanisms for protecting privacy, method for minimizing the possibility of coercion, etc.).
- F. Approval of a protocol at Full Board requires the approval of a majority of those members who are present at the meeting.
- G. The Committee's decision regarding approvability of new research and continuation of ongoing research is based on satisfaction of the regulatory criteria outlined by HHS in [45 CFR 46.111\(a\)\(1-7\)](#).

#### **D. Informed Consent**

Informed consent means the knowing consent of an individual (or his/her legally authorized representative such as parent, guardian etc.) to participate in research. (see Federal Guidelines in the IRB Guidebook [http://www.hhs.gov/ohrp/irb/irb\\_chapter3.htm](http://www.hhs.gov/ohrp/irb/irb_chapter3.htm)).

An investigator shall provide the prospective participant or the representative sufficient opportunity to consider whether or not to participate, and minimize the possibility of coercion or undue influence. The information that is given to the participant or the representative shall be in language understandable to the participant or the representative. No informed consent, whether oral or written, may include any exculpatory language through which the participant or the legal representative of the participant releases or appears to release the investigator, the sponsor, the institution, or its agents from liability for negligence.

The basic elements of informed consent are:

1. A statement that the study involves research, an explanation of the purposes of the research, the expected duration of the participant'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 factors that may be expected to influence a participant's willingness to participate such as potential risks, discomfort, or adverse effects.
3. A description of any benefits to the participant or to others, which may reasonably be expected from the research.
4. A statement describing the extent, if any, to which confidentiality of records identifying the participant will be maintained, and any limitations to confidentiality.
5. For research involving more than minimal risk, an explanation as to whether any compensation or medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained. This should include information such as an explanation of whom to contact for answers to pertinent questions about the research and research participants' rights, and whom to contact in the event of a research-related injury to the participant and the name and telephone number of the investigator.
6. A statement that participation is voluntary. Refusal to participate will involve no penalty or loss of benefits to which the participant is otherwise entitled. The participant may discontinue participation at any time without penalty or loss of benefits to which the participant is otherwise entitled.

When appropriate, the following information shall also be provided to each participant:

- a. A disclosure of appropriate alternative procedures or courses of treatment, if any, which might be advantageous to the participant.
- b. Anticipated circumstances under which the participant's participation may

- be terminated by the investigator without regard to the participant's consent.
- c. Any additional costs to the participant that may result from participation in the research.
- d. The consequences of a participant's decision to withdraw from the research and procedures for orderly termination of participation by the participant.
- e. Details regarding authorization for access to the participant's personal records (school, college, hospital, employment, or others).
- f. Details regarding any recording of their voices or images for data collection unless the research consists solely of naturalistic observations in public places, and it is not anticipated that the recording will be used in a manner that could cause personal identification or harm.

7. The amounts and terms of any proposed payments or other form of remuneration to participants.

8. When experimental treatments are used, clarify to participants at the outset of the research

- a. the experimental nature of the treatment;
- b. the services that will or will not be available to the control group(s) if appropriate;
- c. the means by which assignment to treatment and control groups will be made;
- d. available treatment alternatives if an individual does not wish to participate in the research or wishes to withdraw once a study has begun; and
- e. compensation for, or monetary costs of, participating, including whether reimbursement from the participant or a third-party payer will be sought if appropriate.

### **Waiver of Information Consent**

A waiver of the requirements for informed consent is granted only where research would not reasonably be assumed to create distress or harm and involves:

- 1. the study of normal educational practices, curricula, or classroom management methods conducted in educational settings
- 2. anonymous questionnaires, naturalistic observations, or archival research for which disclosure of responses would not place participants at risk for criminal or civil liability or damage their financial standing, employability, or reputation, and confidentiality is protected
- 3. the study of factors related to job or organization effectiveness conducted in organizational settings for which there is no risk to participants' employability, and confidentiality is protected
- 4. the study of situations in which the usual procedure for obtaining written informed consent would surely invalidate objectives of considerable, immediate importance. In this case, verbal instructions should assure the fully informed and voluntary consent of each participant to participate in the research.

The IRB typically honors requests for waiver of written informed consent when

- 1. the participants of the investigation are illiterate;

2. the risks, usually psychological risks, inherent in asking participants for their signatures outweigh the risks of not obtaining the signatures; or
3. requests for signatures demonstrably violate or distort the participants' perceptions of the nature and purpose of the investigation.

#### **E. Decision Levels and Resubmission Requirements**

Decisions are made on one of three levels: Approved, Conditional Approval and Denied.

Approved: The reader or committee has determined from the information provided that the proposed study has met all ethical guidelines. The researcher may proceed with data collection. The chair of the IRB will notify the researcher via email, and an official letter will follow, containing the IRB research number.

Conditional Approval: The reader or committee has determined from the information provided that the proposed study has not met all the ethical guidelines but the adjustments are minor. The researcher will be notified via email of the changes that must be made, or of the information that was lacking. The researcher will work directly with her or his reader or, in the case of full-review, will be assigned a board member to whom the researcher must report. The researcher will be given one month to make the corrections and complete this process. However, research may not begin until approval has been granted. If this is not done or if the committee does not receive a request for an extension, the case will be closed and the researcher will be required to resubmit her or his full proposal. When the additional tasks have been completed, the reader will sign the proposal as approved. The researcher will be notified and the chair will send the official letter.

Denied: The reader or committee has determined from the information provided that the proposal is sufficiently lacking in its completeness or does not meet ethical standards. The researcher will be sent an email from the reader or the chair of the IRB listing the reasons for the denial. A follow-up letter will be sent. The researcher must resubmit her or his proposal in its entirety, along with a letter of explanation addressing the deficiencies of the proposal. A new IRB number will be assigned.

#### **F. Protocols Requiring More Than Annual Review or Outside Verification**

At the time of initial review and at continuing review, the Committee will make a determination regarding the frequency of review of the research protocols. All protocols will be reviewed by the IRB at intervals appropriate to the degree of risk but no less than once per year for the duration of the research (including when study activity is limited to long-term follow-up and data analysis that involves collection or analysis of identifiable data). In some circumstances, a shorter review interval (e.g. biannually, quarterly, or after accrual of a specific number of participants) may be required. The determination regarding the appropriate review intervals will be made based on considerations of the potential or actual risks of the research, the degree of novelty of the research intervention, the number of participants to be enrolled, any specific vulnerability associated with the



research population, and/or the magnitude or frequency of risk to participants. The meeting minutes will reflect the Committee's determination regarding review frequency. When the Committee assigns a review frequency less than one year, the review period will begin the date the protocol is released for participant accrual.

Protocols in which there is the possibility of a financial conflict of interest and more than minimal risks may require verification from sources other than the investigator(s) that no material changes have occurred since previous IRB reviews.

## **G. Modifications & Continuing Review**

### A. Review of modifications in previously-approved research

1. Minor modifications are defined as those that do not considerably affect an assessment of the risks and benefits of the study and do not substantially change the specific aims/design of the study. Examples of minor modifications include but are not limited to:
  - a. The addition of research activities that would be considered exempt or expedited if considered independent from the main research protocol;
  - b. A minor increase or decrease in the number of participants;
  - c. Changes to the dosage form (e.g. tablet to capsule or oral liquid) of an administered drug;
  - d. Adding or revising a study instrument or task condition;
  - e. Small changes in remuneration;
  - f. Changes to improve the clarity of statements or to correct typographical errors;
  - g. The addition or deletion of qualified collaborators, including study team members and faculty sponsors;
  - h. Change in funding source; and
  - i. Adding or deleting research performance (study) sites.
2. Review of proposed modifications that are not minor will be sent to a full board for review if the modified study does not qualify for an expedited category (see Section V(C) of this Handbook).
3. The PI/PD will submit a summary of the proposed revision(s), an explanation or reason for the proposed modification, and the revised documents (protocol, consent document, recruitment materials, questionnaires, etc.) for IRB review (see IRB website for applicable form). The reviewer will conduct an in-depth review of this information.
3. The reviewer's decision regarding approvability of modifications to previously approved research is based on continued satisfaction of all the conditions outlined in [45 CFR 46.111\(a\)\(1-7\)](#) and [21 CFR 56.111\(a\)\(1-7\)](#).

4. When reviewing modifications to the consent document, the reviewers will take into consideration both prospective research participants and research participants already enrolled in the study. New findings developed during the course of the research which may affect a participant's willingness to continue participation must be provided to the participant in a letter of notification, an addendum to the initial consent document, or by re-consenting the participant using the modified consent document. All such revised documents must be approved by the IRB.
5. The IRB will promptly notify the PI/PD in writing of its decision regarding the proposed modification.

#### B. Continuing Review

1. In order for the IRB to determine whether the proposed research continues to meet the requirements outlined in [45 CFR 46.111](#) and [21 CFR 56.111](#), the PI/PD must submit sufficiently detailed updated materials regarding the research. Materials are distributed to IRB members sufficiently in advance of the meeting (seven days) in order to allow adequate time for review.
2. Primary Reviewers: The IRB will assign two primary reviewers to each "Greater than Minimal" risk protocol renewal. Primary reviewers will be assigned protocols based on related expertise. When making reviewer assignments, IRB staff will take into consideration the vulnerable populations involved in the research and assign the protocol to at least one individual who has experience with this population. The primary reviewers are responsible for conducting an in-depth review of all pertinent documentation (see below) and presenting the research to the committee. Materials provided to the primary reviewer:
  - a. Complete IRB renewal form which includes :
    1. Protocol summary;
    2. Status report on the progress of the research;
    3. Number of participants accrued and their racial and ethnic background (if applicable);
    4. Summary of any adverse events or unanticipated problems involving risks to participants or others, withdrawal of participants from the research, and complaints about the research since the last IRB review;
    5. Most recent data monitoring report (when applicable);
    6. Summary of any relevant recent literature, findings obtained thus far, amendments or modifications to the research since the last IRB review, any relevant multi-center trial reports
    7. Any other relevant information (especially information about risks associated with the research)
    8. The original signature of the PI/PD documenting his/her agreement to adhere to the policies of the C of I IRB.
  - b. Complete protocol including any modifications previously approved by the IRB;
  - c. Granting agency progress report, if applicable and available

- d. A copy of the current consent document(s) and any newly proposed consent document (If the protocol is closed to accrual but participants continue to receive treatment, the IRB will review the most current approved consent form with the renewal.) If there are proposed changes to the consent form, such changes will be highlighted in the revised version of the consent form.
  - e. Data and safety monitoring progress reports (if applicable).
  - f. Recruitment materials and advertisements intended to be seen or heard by potential participants that are being revised or added at the time of IRB review.
  - g. If new amendments are submitted at the time of continuing review, an explanation of the amendment and any supporting documents (i.e. revised protocol) will be reviewed by the continuing review committee. Amendments may not be implemented by the PI/PD prior to review and approval by the continuing review committee.
  - h. A copy of the expedited reviewers comments (when applicable).
  - i. Study tools and instruments (when applicable).
3. All other Committee members receive the IRB application form (the specifics of which are outlined above), a copy of the current consent document(s), and any newly proposed consent document with any changes highlighted. Complete documentation and relevant IRB minutes are available to all members for review upon request.
  4. All “Greater than Minimal risk” protocol renewals and renewals of protocols involving active treatment with an investigational drug or device will be individually presented, discussed, and voted on.
  5. All “Minimal Risk” protocol renewals that meet the criteria required in Categories 8 or 9 of the list of research activities which may be reviewed through expedited review procedures ([63 FR 60364-60367](#)), will be reviewed by qualified members who have been designated by the IRB Chair to conduct expedited review. All expedited reviews of minimal risk protocols will be reported to the Full Board (see Section V (B) of this Handbook).
  6. The IRB may reclassify the risk level based on information provided in the renewal submission or the status of the protocol (e.g. follow-up only, data analysis, etc.). When reclassification results in a “Greater than Minimal” risk classification, the IRB will vote on that protocol individually.
  7. Expiration of IRB Approval: There is no grace period extending the conduct of research beyond the expiration date of IRB approval. Extensions beyond the expiration date will not be granted.

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- a. Enrollment of new participants may not occur after the expiration of IRB approval.
- b. Research interventions or interactions involving already enrolled participants should only continue with written documentation that the IRB finds that it is in the best interest of the individual participants to do so and when the IRB has confirmed that the PI/PD is actively pursuing protocol renewal.

When continuing review of a research protocol does not occur prior to the end of the approval period specified by the IRB, IRB approval expires automatically. Such expiration of IRB approval will not be reported to OHRP as a suspension of IRB approval under HHS regulations.

## **H. Proposed Schedule of IRB Deadlines and Meetings**

At the beginning of fall and spring semesters the IRB chair will publish, for the benefit of the C of I community, meeting dates for that semester.

All protocols submitted for Full Review are due to the chair of the IRB by the first of the month in which the researcher wishes the protocol to be reviewed. For example, for a protocol to be reviewed in the November meeting, the completed protocol must be received by the chair by November 1. If the first day of the month falls on a weekend or a school holiday, the following Monday or the first official work day after the holiday will be the due date. Any protocol received following the first day of the month will normally be held for review the following month.

Exempt and expedited proposals are accepted on a rotating basis. A decision will be rendered within 2 weeks. However, if a proposal is referred to a full board either because 1) the proposal does not meet the criteria for exempt or expedited or 2) the Chair or designee does not approve the proposal, the proposal will be referred to the next scheduled full board meeting.

The IRB Committee will meet the third week of each month starting in September and through May to review protocols received the first of that month. For the month of January, protocols are due by January 3<sup>rd</sup> for review during the third week of January. There will be a special meeting in May for all summer protocols. All summer protocols must be submitted by May 1<sup>st</sup>. The specific day during the third week will be determined by the chair of the IRB by the end of the first full week of the month. This will be announced to the IRB members and all researchers who submitted protocols. If no protocols are received by the first, there will be no meeting of the IRB for that month unless other business is pending.

**The researcher is responsible for providing the number of copies required by the level of review required (see below). The IRB will issue to the principal investigator a signed cover sheet and/or letter of status within one week of the review meeting.**

**Level of Review/Number of Copies**

<b>Level</b>	<b>Original/Signed</b>	<b>Electronic File</b>
<b>Exempt</b>	1	1
<b>Expedited</b>	1	1
<b>Full</b>	1	1

## **VI. Complaints, Non-compliance, Suspension, Termination, and Reporting**

### **A. Complaints and Concerns to IRB,**

1. A designated member of the IRB will promptly handle and, if necessary, investigate all complaints and concerns received including those from PI/PDs and research participants.

### **B. Allegations and reports of Non-Compliance**

All members of the C OF I community involved in human research are expected to comply with the highest standards of ethical and professional conduct in accordance with federal and state regulations and institutional and IRB policies governing the conduct of research involving human participants. The IRB Chair (or designee) will respond to allegations brought to IRB's attention regarding violations of regulations and policies related to human research from both inside and outside C OF I according to the procedures described below.

#### 1. Definitions

- a. Non-compliance: Any violation of any regulation that governs human research or the IRB Policies and Procedures. Non-compliance may be minor or sporadic or it may be serious or continuing.
- b. Minor and sporadic non-compliance: Non-compliance that is neither serious nor continuing non-compliance.
- c. Serious non-compliance: Violations that increase risks to participants, decrease potential benefits, compromise the integrity of the human research protection program, or violate the rights or welfare of participants.
- d. Continuing non-compliance: A pattern of repeated or continuing non-compliance, within reasonably close temporal proximity, that suggests that instances of non-compliance will continue unless addressed by an appropriate intervention. This definition includes failure to respond to a request to resolve an episode of non-compliance.
- e. Report of non-compliance: An instance of non-compliance that does not require further information to confirm.
- f. Allegation of non-compliance: An assertion made by a second party that must be proven or supported with evidence to either confirm or deny.

2. Reports of non-compliance or suspected non-compliance: Reports/allegations of non-compliance or suspected non-compliance may be submitted by a PI, research staff, IRB staff, Committee members, or a research participant. Such reports/allegations may be made to the IRB office, to the Human Protections Administrator or through other institutional offices. When human research-related reports/allegations are received by other offices, the IRB Chair shall be notified promptly. Reports/allegations should include as much information as possible regarding the event(s) or action(s). The identity of the informer will be kept confidential unless he/she provides permission for the IRB to disclose identifying information.
3. Handling allegations of non-compliance:
  - a. The individual staff member who first learns of the event or action will gather all relevant information and then refer the situation to the IRB Chair (or designee) for further investigation.
  - b. If the IRB Chair (or designee) determines that the allegation has no basis in fact, no further action will be taken under this Policy. If the IRB Chair (or designee) determines that the allegation involves noncompliance in fact, the remainder of this procedure for report of non-compliance is followed. If, in the course of handling the allegation of noncompliance, the IRB Chair (or designee) is unable to resolve whether the allegation has a basis in fact, the matter will be referred to the Human Protections Administrator for further investigation.
  - c. If the Human Protections Administrator determines that the allegation has no basis in fact, no further action will be taken under this Policy. If the Human Protections Administrator determines that the allegation involves non-compliance in fact, the remainder of this procedure for a report of noncompliance is followed.
4. Handling reports of non-compliance:
  - a. The individual staff member who first learns of the event or action will gather all relevant information and then refer the situation to the IRB Chair (or designee) for further investigation.
  - b. Further investigation of the noncompliance will include contact with the PI/PD and, when appropriate, consultation with the Human Protections Administrator or another institutional office, as appropriate.
  - c. PIs/PDs may voluntarily initiate suspension or termination of their research until the allegation or report of noncompliance has been investigated and resolved.
  - d. Once the investigation has been completed, the IRB Chair (or designee) will make an initial determination regarding whether the non-compliance constitutes serious or continuing noncompliance.
    - i. If, after investigation, the IRB Chair (or designee) determines that the noncompliance is clearly minor and sporadic and the proposed corrective action plan is appropriate, the event and corrective action plan will be documented in the file. No further action is required.

- ii. If the IRB Chair (or designee) determines that the noncompliance is clearly minor and sporadic, but the proposed action plan does not seem appropriate, the IRB Chair (or designee) may work with the PI/PD on a proposed corrective action plan. Once the plan is appropriate, the event and corrective action plan will be documented in the file. No further action is required.
- iii. If the IRB Chair (or designee) determines that the noncompliance is minor and sporadic but is unable to determine an appropriate proposed corrective action plan, the report is referred and reviewed by the Human Protections Administrator for determination of an appropriate corrective action plan.
- iv. A report of all minor and sporadic non-compliance will be presented to the IRB Committee at the next regularly scheduled meeting.
- v. If the IRB Chair (or designee) determines that the report of noncompliance represents serious or continuing noncompliance, the report is referred and reviewed by the Human Protections Administrator who will make a recommendation to the committee.

**C. Suspension and Termination**

1. The IRB has the authority to suspend or terminate approval of research that is not being conducted in accordance with IRB policies or that has been associated with unexpected serious harm to participants.
2. Suspensions or terminations by the committee may result from recommendations made by the IRB, the IRB Chair, the Chair of the PI/PD or investigator's school or the Human Protections Administrator.
3. Effect of suspension or termination on participants:
  - a. When research is suspended or terminated, the IRB will require that current participants be notified of the suspension, as IRB determines is appropriate, and termination.
  - b. If termination of the research is likely to adversely affect the rights or welfare of current participants, the IRB will require procedures for withdrawal that protect current participants.
  - c. If follow-up of participants for safety reasons is permitted or required by the IRB, the participants will be informed and any events that may represent unanticipated problems involving risks to participants or others must be reported to the IRB.
4. Investigators may voluntarily initiate suspension or termination until the allegation or report of noncompliance has been investigated and resolved.
8. The IRB Chair may suspend or terminate research in situations where there is immediate risk of serious harm to participants. Such suspensions or terminations will be reviewed by the IRB Committee at the next convened meeting.

**D. Reporting**

1. Reports of problems determined to represent unanticipated problems involving risks to participants or others, noncompliance determined to represent serious or continuing noncompliance, and suspensions and terminations of IRB approval will be reported to OHRP within 30 days of IRB notification. Reports will include:
  - a. The nature of the event (Unanticipated problem involving risks to participants or others, serious or continuing non-compliance, suspension or termination of approval of research).
  - b. Name of the institution conducting the research.
  - c. Title of the research project and/or grant proposal in which the problem occurred.
  - d. Name of the principal investigator on the protocol.
  - e. Number of the research project assigned by the IRB and the number of any applicable federal award(s) (grant, contract, or cooperative agreement).
  - f. A detailed description of the problem including the findings of and the reasons for the IRB's decision.
  - g. Actions the institution is taking or plans to take to address the problem (e.g., revise the protocol, suspend subject enrollment, terminate the research, revise the informed consent document, inform enrolled subjects, increase monitoring of subjects, etc.)
  - h. Plans, if any, to send a follow-up or final report by a specific date.

## **VII. C OF I Principal Investigators/Project Directors (PI/PDs)**

### **A. Qualifications**

1. All personnel performing any procedures associated with a research protocol must have appropriate training and expertise, in addition to proper licensure and/or credentials to do so (if applicable). Exceptions must be approved in writing by the Department Chair or designee and provided to IRB for approval.
2. The PI/PD's qualification to conduct research is documented by virtue of his/her faculty, staff, or student status.
3. The PI/PD must have adequate resources including funding, facilities, staff, and equipment to conduct proposed research.
4. If research is conducted by an undergraduate or graduate student or by a non-College of Idaho investigator, the IRB requires that the research be sponsored by a member of the C of I full-time faculty.

### **B. Education Requirements**

1. The IRB requires that PI/PDs and research personnel comply with the C OF I policy regarding education related to the protection of the rights and welfare of research participants prior to conducting research. Completion of the



required NIH modules (<http://phrp.nihtraining.com/users/login.php>) constitutes adequate training.

2. It is the responsibility of the PI/PD to ensure that research personnel are qualified and adequately trained in the protection of the rights and welfare of human participants.
3. C OF I faculty who serve as research sponsors or advisors are expected to understand the regulatory and ethical considerations for research with human participants, and as such, must comply with these educational requirements whether or not they are engaged in the research.

### **C. Financial Conflicts of Interest**

1. The IRB requires all individuals (which includes respective spouse and dependent children) engaged in the research disclose any financial interests that the individual, or the individual's spouse or dependent children, have with the sponsor of the study, the supporting organization, or company that owns or licenses the technology being studied.
2. When a financial interest is indicated on the IRB forms, the financial interest will need to be reviewed, approved, and, if necessary, managed by the Human Protections Administrator. A summary of the findings and recommended management strategy will be provided to IRB members for review and discussion at a full board meeting or will be reviewed as part of the expedited review process. Documentation of the IRB's review of the financial conflict of interest is required in order for the IRB to approve the research.
3. The IRB will require disclosure of the financial interest to participants in the consent form if a financial conflict of interest is identified.

### **D. Appeal Process**

1. Full Board Reviews: The PI/PD has the right to contact the IRB, the IRB Chair or staff to request re-review of his/her protocol, reconsideration of stated contingencies, or reevaluation of points relevant to the regulatory criteria for approval. In these instances, subsequent reviews would be conducted by the original reviewing committee. Accordingly, protocols are not disapproved by the full board without giving the PI/PD the opportunity to present to the committee.
2. Expedited Reviews: If a PI/PD does not agree to contingencies recommended by the expedited reviewer, the PI/PD's justification will be reviewed by the IRB Chair. The IRB Chair will accept the PI/PD's justification, resolve the issue with the PI/PD, or refer the submission to a full board.

### **G. Record Retention**

1. All signed consent forms must be kept in their original form at least three years beyond completion of the study.

Note: Additional retention may be required under State and Federal laws, some discipline specific organizations may have different requirements for the retention of both consent forms and study data (e.g. the APA requires a study's data be retained at least 5 years after publication) or at the request of the study sponsor.

#### **H. Final Report**

1. The PI/PD is required to submit a final report when closing a protocol. The information provided in the report allows for final review to ensure that the rights and welfare of the research participant are protected.
2. If a final report is not submitted within the designated time, prior to expiration of the IRB approval, then the IRB will not accept any new projects from the PI/PD or from anyone working under the sponsorship of the PI/PD until the appropriate documentation is submitted to permit closure of the study.
3. Protocols may be closed and a Final Report submitted when either of the following conditions apply:
  - a. the data have been stripped of all identifiers (including codes) with which individual identities of participants could be ascertained; or
  - b. the data remain identifiable but will no longer be used for the current research protocol.
  - c. After a protocol has been closed, a Revision/Amendment (Modification) to re-open the current protocol, or new study application, must be submitted and approved by IRB before any identifiable or coded data may be used, even by the same investigator/study team.

### **VIII. IRB Office**

- A. The IRB physical office space includes adequate resources (meeting area, filing space, equipment, and computers) to support the IRB mission.
- B. The IRB office is located in Suite 200 Covell Hall, (208) 459-5600.

### **IX. List of IRB Forms**

- A. New Proposals
  - a. New Proposal Cover Sheet
  - b. Exempt New Proposal Form
  - c. Student Project Exempt New Proposal Form
  - d. Expedited New Proposal Form
  - e. Student Project Expedited New Proposal Form

- f. Expedited (Minors) New Proposal Form
- g. Full Review New Proposal Form
- B. Consent & Information Forms
  - a. Basic Consent Form
  - b. Basic Consent Form (Spanish translation)
  - c. Minimal Risk Request for Waiver/Alteration of Consent
  - d. Exempt Information Sheet for Participants
  - e. Debriefing Form (required for Psychology Participant Pool use)
  - f. Full Review Request for Waiver of Informed Consent
  - g. Full Review Request for Alteration of Informed Consent
  - h. Full Review Request for Waiver of Written Consent
  - i. Waiver of Third Party Consent
  - j. Request for Short Form Written Consent
- C. Modification, Continuation & Unanticipated Problems & Final Report Forms
  - a. Expedited Continuation Form
  - b. Full Review Continuation Form
  - c. Modification Form
  - d. Unanticipated Problems Report Form
  - e. Final Report Form
- D. Additional Forms
  - a. Studies Involving Minors Form
  - b. Pregnant Participants Form
  - c. Research with Prisoners Form
  - d. Audio-visual Record Form
  - e. Sponsored Research Form
  - f. Research with the Cognitively Impaired Form
  - g. Research Outside the US Form
  - h. Research with Stored Data for Future Research
  - i. Financial Disclosure Form
- E. Assurances & Guidelines
  - a. Individual Investigator Agreement Form
  - b. Faculty Sponsor Assurance
  - c. Behavioral Consent Guidelines
  - d. Behavioral Local Research Context Guidelines
  - e. Confidentiality Guidelines
- F. Example Protocol Templates
  - a. Quantitative Behavioral Protocol template
  - b. Qualitative Behavioral Protocol template
  - c. Exempt Behavioral Protocol template