UNIVERSITY OF IDAHO

Office of Research Assurances

INSTITUTIONAL REVIEW BOARD

POLICIES AND PROCEDURES MANUAL

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10/14/2024

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1. Institutional Policy

The federal government requires the University of Idaho (UI) to designate an Institutional Review Board (IRB) to ensure that human subject research conducted under the auspices of the University meets federal requirements. The IRB committee fulfills administrative functions (prospectively reviewing and making decisions concerning all human subjects research conducted at U of I facilities and/or by its employees or agents or under its auspices regardless of location) and serves as an advisory body to the Vice President for Research and Economic Development for matters related to human subject research. Under the approved Federalwide assurance for the University, the IRB shall apply the regulations set forth by United States Department of Health and Human Services (HHS) at 45 CFR 46 to all federally funded human subject research and shall be guided by the ethical principles set forth in The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research of the National Commission for the Protection of Human Subjects. Equivalent protections are applied to all non-federally funded or unfunded human subject research and shall comply with these regulations unless otherwise specified by University policy. The IRB shall also apply the human subject research regulations established by the Food and Drug Administration for clinical investigations involving drugs, biologics, medical devices, and other test articles. (21 CFR 50; 56; 312, and 812). The IRB shall not approve FDA-regulated human subject research without prior approval for such research from the Office of Research and Economic Development. The IRB shall act in conformance with other federal laws and regulations germane to human subject research and with applicable state and local law. [See FSH 5200]

Human subject research that has been approved by the IRB may be subject to further review and approval by University officials, or other University Departments or Committees. However, a University official may not approve such research, or that portion of a research project that constitutes human subject research, if it has not been approved by the IRB.

2. Ethical Principles

The University of Idaho Institutional Review Board has adopted the Belmont Report as ethical guidance. The guiding principles are Beneficence, Autonomy, and Justice. This adoption will assist reviewers and investigators in ensuring that human subjects research is conducted ethically.

3. Regulatory Compliance

The University of Idaho Institutional Review Board is committed to assisting Investigators with complying with regulations and policies set forth by the DHHS, the FDA, State of Idaho laws, and University policies, among other laws, regulations, policies, and rules. This commitment will assist investigators in conducting ethical research and provide protection for human subjects' health, safety, welfare, and rights. The University of Idaho's Institutional Review Board is registered with the Office of Human Research Protections.

4. Structure, Membership and Appointments

A. Membership

The IRB is composed of at least five (5) members with varying backgrounds to promote a complete and adequate review of research activities commonly conducted at the University. The IRB is chaired by a faculty member.

The Director or Associate Vice President of Research Assurances serves as an ex officio non-voting member to assist in representing institutional commitments and regulations.

The IRB shall include at least one member whose primary concerns are in scientific areas and one member whose primary concerns are in nonscientific areas.

The IRB shall include one member who is not otherwise affiliated with the institution and who is not part of the immediate family of a person affiliated with the institution.

At its discretion, the IRB may invite individuals with competence in special areas to assist in the review of issues that require expertise beyond or in addition to that available on the IRB. These individuals may not vote with the IRB.

The Vice President for Research and Economic Development appoints all members of the IRB, including the alternates.

The Vice President for Research and Economic Development may remove and replace a committee member at any time the member is unwilling or unable to carry out committee functions.

The IRB Chair, or designee, may select an alternate member to substitute for, with vote, an absent voting member at a convened meeting. The alternate member shall have similar expertise as the absent voting member for whom they are serving as a replacement.

[FSH 1640.54]

B. Administrative Staff

The Institutional Official (IO) for the Institutional Review Board is the Director or Associate Vice President for the Office of Research Development.

The IRB Coordinator or other assigned staff are responsible for all aspects of processing applications for human subjects research, documenting the minutes of convened IRB meetings, providing administrative and clerical support, record retention, correspondence, and maintaining training records.

C. Other Related Units

Final approval of IRB protocols may require coordination with other units or committees, such as the Office of Technology Transfer, Institutional Biosafety Committee, Institutional Animal Care and Use Committee, Office of General Counsel, and other ORA or ORED units. Information relating to submitted applications may be shared with these units or committees as needed.

D. Term of Service

Board members are appointed to a term of three years. Board members may be requested to accept reappointment to the IRB for an additional term of three years at the discretion of the Chair. If a member declines full membership, they may be asked to become an alternate member. Reappointed members will be asked for an updated CV and updated ethics training.

5. Conflict of Interest

No regular or alternate IRB member with a financial or non-financial conflict of interest should participate in the review of an application, although they may participate in discussion or provide information if requested by the committee. It is the responsibility of the regular or alternate members to disclose any conflict of interest and recuse themselves from deliberations and voting. If the member has been assigned a review and has a conflict of interest, it is their responsibility to notify the IRB Coordinator so that the application can be reassigned to another reviewer. Investigators are not able to select which IRB member will review their application. The University of Idaho IRB will follow the Faculty Staff Handbook Section 6240 – Conflicts of Interest or Commitment policy.

6. Training and Agreements

Regular and Alternate Board Members, and designated staff will be responsible for completing the following:

A. Training

Appropriate training including reading the Belmont Report, familiarization with 45 CFR 46, the Faculty Staff Handbook Chapter Five: 5200 Human Participant Research, and IRB policies. Additional required training may include modules from The Collaborative Institutional Training Initiative (CITI Program) - https://about.citiprogram.org/, or information from OHRP. Further training can include relevant conferences, webinars, seminars, or other information sources.

B. Signing of Documents

Signing the IRB Member Acceptance of Responsibilities, providing a copy of their resume/curriculum vitae, and signing a Non-Disclosure Agreement and returning these to the IRB Coordinator.

7. Duties

A. Chair and/or Vice-Chair

The Chair carries responsibilities and an obligation to:

1. Conducts IRB meetings in accordance with federal regulations
2. Ensure proper conduct and review of all IRB applications
3. Participate in pre-IRB planning meetings with the ORA to ensure optimal review procedures, assignment of duties, and preparation of convened meeting agendas

4. Assist in investigating and resolving complaints, unanticipated events, and adverse events
5. Works to ensure the rights and welfare of research participants are protected
6. Assist in communications with federal agencies
7. Assist in communicating with faculty and administration regarding IRB resources and functionality
8. Designates the reviewers for expedited and full-board protocols or may delegate this task to the IRB Coordinator or other members of the Office of Research Assurances.

B. IRB Regular and Alternate Members

Regular and Alternate Members have the responsibilities and an obligation to:

1. Attend and participate in Board Meetings
2. Protect the rights and welfare of human research participants
3. Review, approve, and monitor protocols
4. Assist in ensuring that human subjects research is consistent with federal regulations, state and local laws, and the University's guidelines and policies.
5. Review assigned IRB applications for Full Board and Expedited research.
6. Review assigned IRB applications for Exempt or Limited IRB review.

C. ORA Staff

The IRB Coordinator or other assigned staff are responsible for:

1. All aspects of processing applications for human subjects' research
2. Documenting the minutes of convened IRB meetings
3. Providing administrative and clerical support, record retention, correspondence, and maintaining training records.
4. The IRB Coordinator or other assigned ORA staff may also be assigned by the Chair to certify the exemption from the federal regulations for IRB applications.

D. Consultants

The IRB may use non-member consultants for advice and information as needed. These consultants may, or may not, be affiliated with the University of Idaho. The consultants may present their assessments in writing or in person.

8. Functions and Operations

A. Functions

1. The IRB is responsible for reviewing all research involving human subjects conducted under the auspices of the University of Idaho. This includes initial applications, status checks, continuing reviews, amendments, personnel changes, unanticipated problems or adverse events, post-approval monitoring, and other situations as warranted.

2. Investigators are responsible for submitting initial applications, status checks, continuing reviews, amendments, personnel changes, unanticipated problem or adverse event reports, and post-approval monitoring form promptly and with sufficient time for the IRB to conduct a thorough review.

B. Operations

1. In the event a change is needed to eliminate an immediate hazard to human subjects' an investigator may implement a change to protect the welfare of the research subject. Investigators are required to notify the IRB in writing of this change within five business days via an Amendment to the protocol. The investigator may also need to submit an adverse event or unanticipated problem report within five business days. Such reports will be brought to the attention of the Chair and will are addressed at convened IRB meetings.
2. The IRB will report the results of the review in writing to the Investigators as promptly as possible.
3. The full IRB is scheduled to convene monthly. Additional full board or subcommittee meetings may be called by the Chair. The IRB Coordinator is responsible to arrange the meetings, distribute materials to members, provide a list of exempt and expedited applications approved in the prior month, provide a status report on any actions from the prior meeting, provide continuing education, and complete the meeting minutes. These materials will be distributed electronically. Meetings may be held in person, or via teleconference on video or via phone. Emergency Meetings may be called as necessary. Meetings may be held via email voting for single issues if a quorum cannot be convened.
4. For IRB meetings, a quorum of more than half of the voting membership is required. At least one non-scientific member must also be present. Each member has one vote. Proxy votes are not allowed. As designated by the Chair, alternate members may vote in place of a regular member who is not present. If quorum is lost, no additional Board business may be voted upon although the meeting may continue for other purposes.
5. Materials provided to the Board prior to the meeting include an agenda, the prior meeting's minutes, the status of Full Board protocols reviewed at the last meeting, a report on Expedited and Exempt protocols reviewed since the last meeting, and other materials as appropriate.
6. All IRB decisions will be conveyed to the investigator in writing. If an investigator would like to request the IRB reconsider a decision, they may respond in writing and request an opportunity to appear before the IRB with a re-submitted application.

9. Record Requirements

A. IRB Membership Roster

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

B. Retention of Records

All applications reviewed, consent documents, and related materials will be kept on file at the Office of Research Assurances for a minimum of five years after the completion of the expiration of the application.

C. Location

Meeting agendas, minutes, and IRB rosters will remain on file at the Office of Research Assurances as a record of the committee's activities in accordance with University guidance on record retention or as long as they are useful to the Office of Research Assurances.

10. Protocol Review Process

All requests to utilize human subjects in research must be submitted by the Principal Investigator to the IRB via a protocol form available in the VERAS electronic system and approved by the IRB prior to recruiting, consenting, or performing human subjects' research. The IRB may approve new, renewing, or modified/amended protocols through Full Board Review, Expedited Review, or Exempt Review processes. The IRB will review submitted materials for regulatory compliance, compliance with University policies and procedures, and ethical principles under The Belmont Report, along with other standards that may apply (such as local standards, investigator training and qualifications, adequacy of the research site, etc.).

For all protocols, in addition to the application form, the following materials may be necessary to complete the review process. The IRB Office will review application packets to ensure completion prior to member review:

- Application form
- Recruitment materials
- Consent or assent forms
- Survey or interview questions
- Protocol materials
- Other relevant materials
- Training records

Research involving vulnerable populations, medical procedures, tribal relations, or other novel research, may require additional review by experts with experience with the population or procedure being performed. Any member can call for additional, expert reviewers. The IRB standard is that all prisoner protocols require review by a non-conflicted prisoner IRB representative, protocols involving Native American Tribal entities are reviewed by the UI Tribal Relations Office, and protocols with complex or novel medical procedures are reviewed by a nonconflicted medical IRB representative. Other expert opinions may be solicited based upon need.

All IRB members receive training on the Designated Member Review policy and procedure during new member orientation. Additionally, all members are required to sign the "Member Acceptance of Responsibilities" stating they agree with the process described above and understand that Designated Member Review may be assigned by the Chair or the Chair's designee, usually the IRB office.

A. Full Board Review

Full Board review of a protocol by the convened IRB at an IRB meeting is conducted for research that does not meet Exempt or Expedited criteria.

The purpose is to allow all IRB members to be involved in protocol review and decision-making through interactive discussion. Absent members may provide review comments prior to a convened meeting, however these may not be counted toward a vote or considered as part of the quorum. Additional expert opinions may be solicited as needed.

The committee may vote to approve, require modifications or clarification, disapprove a protocol, or approve within a limited time frame. When the committee votes to require modifications to a Full Board protocol, the members present at a convened meeting must decide whether to finalize the review by Expedited review or Table for review at the next convened meeting. If the quorum of members is in agreement for Expedited review, the chair appoints one or more designated member reviewers to conduct the re-review, although usually this is the primary reviewer by default. This is documented in the meeting minutes. If more than one designated member reviewer is used, they must be unanimous in the decision to approve. The reviewers may require additional modifications to secure approval. If the designated member reviewers cannot come to a unanimous decision to approve the protocol, the Chair may make the final decision or return the protocol back to the Full Board for a decision. Experts may also be consulted as deemed necessary. If the Board approves a protocol with a limited time frame, a Continuing Review or report may be requested more frequently than annually.

B. Amendments of Full Board Protocols Under Expedited Review

Amendments of Full Board protocols that are allowable by Expedited Review

Minor changes in ongoing research projects originally reviewed by Full Board Review may be reviewed and approved by the IRB via Expedited review prior to their implementation. Minor changes should not increase the risk of the study participant. Some examples of minor changes include: Amendments that would fall within Expedited Categories 1-7, minor changes to other study documents (surveys, recruitment materials, interview questions, etc.), additional study documents that are similar to those previously approved, changes in payment schedule to subjects that are insubstantial enough as to not cause undue influence, decrease in number or volume of sampling or procedures as long as it does not increase the risk to the participant, changes for clarification in any of the study documents, additional translated versions of previously approved study documents. Examples of major changes that could require Full Board review include: Changes that increase the risk to the participant, addition of new subject populations, changes to exclusion or inclusion criteria that could adversely impact the risk/benefit ratio, new or significant changes in study documents or procedures, especially those that increase or include new risks, complex changes to a protocol design, and changes to the informed consent documents that adversely affect the rights and welfare of study participants.

(45 CFR 46 & 21 CFR 56)

Decisions of whether an Amendment should be reviewed as Expedited or Full Board will be determined by whether the Amendment is below minimal risk. These initial decisions are left up to the IRB Coordinator under direction and guidance from the Chair. However, if a reviewer determines that the Amendment should be reviewed at a Full Board Meeting, the reviewer will

notify the IRB Coordinator, and the Amendment will be placed on the agenda for the next scheduled IRB meeting (provided there is adequate time to notify members).

C. Expedited Review

Expedited review may be used to perform protocol reviews outside of a convened meeting, if the protocol submitted falls within one of the nine categories allowable by federal law at 45 CFR 46. The Chair may designate the IRB Coordinator or other Office of Research Assurances staff to assign reviewers.

Expedited reviewers may require modifications to secure approval, approve the protocol, or refer the protocol to the full IRB to be reviewed at the next convened meeting. After the expedited reviewer has approved the submission, the Chair reviews the final version of the protocol before IRB approval is granted. The convened IRB is appraised of the approval at the next monthly meeting.

D. Other Considerations for Full Board and Expedited Reviews

In addition to the statutory, legal, and ethical principles, researchers should take into account the following when conducting a review:

1. Risk to participants meets the definition of “minimal risk” or less in 45 CFR 46.102(i) for Expedited research
2. Participant risks are minimized when appropriate, or reasonable in relation to anticipated benefits
3. Safety monitoring criteria is in place
4. Adequate provisions for privacy are in place
5. Adequate provisions for confidentiality are in place
6. Additional safeguards are in place for vulnerable populations
7. Consent is properly obtained or a waiver from the IRB is received
8. Equitable selection criteria are used

E. Exempt Review & Certification

The IRB Coordinator and members of the Office of Research Assurances may perform exempt protocol review and certification. In the event there is a question over whether the research qualifies as exempt, the Chair or other IRB members may be consulted. If a Limited IRB Review is conducted, a member of the Board will complete the limited portion of the review.

F. Modifications, Re-Reviews, or other Reports

Depending upon the level of initial review and the risk to human subjects, reviews of modifications, re-reviews, or other reports will be assigned to either the Full Board, a designated member reviewer, or the IRB staff.

G. Administrative Updates

The IRB Coordinator or members of the Office of Research Assurances may administratively process minor changes to an approved protocol. These requests must be made by in writing by the PI but need not be approved by the IRB. They can include changes in personnel other than the Primary Investigator or closing a protocol.

H. Notification of Review Determinations

Notifications are sent through the VERAS system to the Primary Investigator and designated Study Contacts. A copy of the notification is also sent to irb@uidaho.edu.

11. Investigator Responsibilities

Investigators who intend to conduct human subject research under the auspices of The University of Idaho are responsible for ensuring that their human subject research activities are reviewed and approved (or certified as exempt) by the IRB prior to engaging in such research. The IRB (or designated staff of the Office of Research Assurances), not the investigator, shall make the determination as to whether a particular research activity involving human participants is exempt under federal human subject regulations and University policy.

Investigators who receive permission from the IRB to conduct human subjects research are responsible for ensuring that:

1. That persons assigned certain roles in the research meet the qualifications outlined in the University of Idaho's Administrative Procedures Manual 45.22.
2. The IRB approved (or certified as exempt) protocol is followed.
3. Ensuring Adverse Event or Unanticipated Problem Reports are submitted in a timely manner (generally within five business days).
4. Items are submitted in a timeframe that gives the IRB adequate time for review.
5. Responses to IRB phone calls or emails are completed in a timely manner (generally within five business days).
6. Federal regulations, local laws, ethical guidelines, and IRB policies are followed.
7. Sponsor requirements are met.
8. All material information is disclosed to the IRB.
9. Obtaining and documenting informed consent, assent, and permission.
10. Submission of Close Out report at the end of the study or when there is no longer identifiable data or biospecimens being used for research.
11. Submission of Amendments prior to making modifications in the research protocol, except those necessary to eliminate apparent immediate hazards to subjects.
12. Ensuring that progress reports, requests for continuing review, status checks, or safety reports are submitted to the IRB in a timely manner.
13. Providing to the IRB prompt reports of serious or continuing noncompliance with the regulations or the requirements or determinations of the IRB (generally within five business days).
14. Keeping records as required by regulation or policy for at least five years after the completion of the study.
15. Securing research data appropriately.
16. Providing and documenting informed consent on an ongoing basis to human subjects.
17. Appropriate reports or data is supplied to federal agencies or the IRB upon request

18. Data repositories and other websites (e.g., ClinicalTrials.gov) are updated as per the agreed upon sponsor schedule.
19. Complying with the University of Idaho and Idaho State Board of Education policies and procedures, regulations and guidelines, the terms of its Federal Wide Assurance, and all applicable federal, state, and local laws regarding the protection of human participants in research.
20. Ensuring that research does not take place until the IRB has approved the initial protocol, continuing review, or modifications.
21. Bear ultimate responsibility for the protection of the rights and welfare of human participants and the ethical performance of the research.
22. Assume responsibility for the custody of records and data in accordance with the University's policy on retention of data, and to provide the University free access to such records and data.
23. Provide truthful and accurate information to the IRB.
24. Acting in accordance with local customs and the International Compilation of Human Research Standards along with any necessary foreign entities for research conducted outside of the United States.
25. All researchers on the protocol who are intervening or interacting with human subjects, providing consent, or working with identifiable data or biospecimens have the appropriate and current IRB required training, as well as supplemental training and experience if needed.
26. Providing verification upon request from third parties, sponsors, or others.

Human Subject Research education is provided by CITI (Collaborative Institutional Training Initiative in an online format. All personnel on a protocol must have the required training in place prior to IRB approval of a protocol. In addition, refresher education will be required every three years. The IRB requires the completion of the CITI Social/Behavioral or Biomedical modules identified. The researchers may submit a certificate indicating completion of human subject education from the CITI program along with their application. The researcher is responsible to maintain records of their human subject education and provide copies with their application submissions.

If additional training is required by study sponsors, the PI is responsible for ensuring that all personnel on the protocol complete the additional training requirements. The University of Idaho also has training on Responsible Conduct of Research, Clinical Trials, and Good Clinical Practice, among other training courses, through CITI.

For non-University of Idaho researchers who are external personnel on a protocol, they may provide their institution's equivalent training. If external personnel on a protocol are not affiliated with an institution, the PI should contact the IRB Coordinator for information on how to access CITI for non-UI personnel who do not have a Vandal Number.

12. University Quality Improvement and Quality Assurance Activities

Research involving human subjects, as defined by federal regulations and in the Faculty Staff Handbook, Section 5200 B, that is to be conducted under the auspices of the University of Idaho must be reviewed and approved by the University of Idaho Institutional Review Board (IRB) before it is performed. In most cases, however, University "quality improvement" or "quality assurance" activities (whether at university-wide, college, or departmental levels) that

are intended solely to improve or assure the quality of programs or services provided at the University or to support the development of new programs and services at the University do not qualify as human subject research activities that require IRB review and approval under federal regulations. University quality improvement and quality assurance activities may include not only endeavors involving University faculty, staff, and students and designed for the immediate benefit of the University, but also those activities engaging or required by third parties, when they are intended to inform the University's provision of programs and services or ensure that programs and services meet established standards. The purpose of this guidance is to clarify the criteria that must be met in order for institutional activities to fall within the category of "university quality improvement/quality assurance activities" and not be, therefore, subject to oversight by the IRB.

A. Criteria for "University Quality Improvement and Assurance (Non-Research)" Determination

Quality improvement/quality assurance activities do not require IRB review if all of the following criteria are met:

1. The activities are designed to:
    a. contribute to the immediate or continuing improvement of University programs or services, or
    b. ensure that University programs or services are meeting regulations or standards established by outside entities and applicable to postsecondary or professional education institutions; and
2. the activities are managerial/administrative in nature and are not considered part of the scholarly responsibilities of faculty members or an element of the educational requirements for students
3. the data *will not* be used by either University investigators or third parties for "research" (as defined by federal human subject research regulations) in addition to the intended quality improvement/quality assurance purposes, i.e.:
    - the quality improvement/assurance activity, involving human subjects, is not undertaken to test a new, modified, or previously untested intervention, service, or program to determine whether it is effective and can be used elsewhere, or
    - the quality improvement activity does not entail the systematic comparison of standard or non-standard interventions, or
    - the quality improvement activity does not involve the prospective collection of data for contribution to a data repository and later use for research purposes; and
4. the activities involve *no more than minimal risk* to the participants, and *Minimal risk* means that the probability and magnitude of harm or discomfort anticipated in the activities 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.

Should faculty, students, or staff wish to use the results of or data collected for research, in addition to the intended administrative purposes of the quality improvement and quality assurance activity, prior review and approval by the IRB will most likely be required.

Common examples of university quality improvement and assurance activities are:

- course evaluations (e.g., anonymous student evaluations of [for-credit] courses or extension classes)
- customer service or academic program evaluation surveys (e.g., dining services satisfaction surveys or departmental surveys of student interest in proposed courses)
- institutional research and assessment and strategic planning initiatives (e.g., institutional collection and assessment of data on student retention and focus groups on mandatory on-campus housing for first-year students)
- reports to and evaluations by accrediting bodies (e.g., the Northwest Commission on Colleges and Universities or the American Bar Association)
- reports to federal or state agencies for quality measurement or public health monitoring that are required by law
- initiatives in which the University, or unit of the University, collects and submits identifiable data to an outside entity that will aggregate the data with information from other institutions and report benchmarking standards to the participating institutions, unless the outside entity will also be using or sharing the data for research purposes
- initiatives in which the University, or unit of the University, permits the collection and submission of data by an outside entity that will aggregate the data with information from other institutions and report benchmarking standards to the participating institutions, when the University, or its unit, is not engaged in research

Common examples of quality improvement activities that also constitute human subject research are:

- projects in which University faculty, students, or staff propose to: collect and/or study identifiable data from a quality improvement initiative, analyze the data for general trends, and either publish a paper on his or her findings in a scientific or other professional journal or give a presentation at a scholarly conference.
- an initiative in which University units, employees, or staff submit identifiable (including coded) data to a database maintained by an outside entity that will use and/or share the data for research purposes, in addition to providing any benchmarking analyses to participating institutions.
- an initiative that is required by law, but in which the University, the relevant state or federal agency/government body, and/or a third party will be using or sharing the data for research purposes, in addition to quality measurement purposes.

Please note that other laws and regulations, such as FERPA or HIPAA, may apply to quality improvement and quality assurance activities, irrespective of the applicability of human subject research regulations.

B. Criteria for Research Practica Determination

Research involving human subjects, as defined by federal regulations (See "Human Participant Research Activities," FSH 5200), that is to be conducted by undergraduate and graduate students must be reviewed and approved by the University of Idaho Institutional Review Board (IRB) before it is performed. However, certain course-related activities involving human subjects (or data linked to living individuals) are educational in nature and are not intended to develop or contribute to generalizable knowledge. These activities, or "course-related research practica," are designed to offer students opportunities to learn various research methodologies through practice. Because such activities, do not meet the definition of "research" that falls within the responsibilities of the IRB, the IRB does not need to be contacted for a determination of "not research" nor does a protocol need to be submitted for review and approval provided the activities fall within the guidance provided below. Any questions should be directed to the Office of Research Assurances for assistance and clarification.

The purpose of this guidance is to clarify the criteria that must be met in order for student course activities to fall within the category of "course-related research practica" and not be, therefore, subject to oversight by the IRB. Should students or faculty wish to use the results or data collected for a research practicum for research purposes, in addition to the intended educational purpose of the practicum, prior review and approval by the IRB will be required. *Some student activities that involve human subjects (or data linked to living individuals) — including independent undergraduate research projects and honors theses, masters' theses, and dissertations — are presumed to be research (to contribute to generalizable knowledge) and must follow formal IRB review and approval procedures*.

Ethical Obligations of Course Instructors and Students
Even when course activities meet the criteria for course-related research practica, and are not within the jurisdiction of the IRB, course instructors and students remain responsible for ensuring that the ethical principles established by the Belmont Report are followed (See FSH 5200, A-3.). Instructors should provide guidance to students concerning how to collect information from human participants in a manner that minimizes harm (including unintentional harm), especially if students will interact with or collect private information about vulnerable individuals.

Instructors are responsible for providing training in the ethical standards set forth in the Belmont Report; professional ethical standards appropriate to the information collection methodology employed (e.g. Ethical Principles of Psychologists and Code of Conduct, Society of Professional Journalists Code of Ethics, etc.); techniques for preserving the anonymity and privacy of practicum participants as well as the confidentiality of data. Course instructors should provide, or guide their students in providing, participants with a description of the project and an explanation of the manner in which the information collected will be used. Participants should also be provided with contact information for the course instructor.

Students are responsible for following the training and guidance provided by their instructors when performing research practica and for supplying information regarding the project and instructor contacting information to participants.

Student course-related activities do not require IRB review when all four of the following criteria are met:

1. the activities are designed to *foster the learning of research techniques and methodologies through practice*; [EDUCATIONAL PURPOSE] and
2. the results of the activities, including any data gathered, will not be used or disseminated beyond the classroom environment; [NOT GENERALIZABLE] and
3. the participant activities involved:
    a. present *no more than minimal risk to the participants*, and *Minimal risk* means that the probability and magnitude of harm or discomfort anticipated in the activities 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.
    b. would not, in the event of disclosure of participant identities or responses, reasonably place the participants at risk of criminal or civil liability or be damaging to the participants ' financial standing, employability, or reputation; and [RISKS: NOT MORE THAN MINIMAL]
4. data collected and/or analyzed are:
    a. publicly available *or*
    b. anonymous *or*
    c. maintained in a confidential manner, when participant identities are known to those engaged in the research practicum in question, so that participant identities and responses cannot be readily identified by individuals who are not members of the class [SECURITY/PRIVACY]

13. Agreements

The IRB may enter into agreements with other IRBs when such agreements facilitate IRB processes while ensuring that human research subjects are protected. In general, these agreements (known as “reliance agreements” or “Inter-institutional agency agreements” or “IRB Authorization Agreements”) allow investigators to complete one IRB application and receive review from one IRB, thus facilitating the IRB process. The Principal Investigator will work with the IRB staff to provide appropriate information for the drafting of such an agreement. Such agreements are signed by the Institutional Official or Associate Vice-President or Director of the Office of Research Assurances.

The IRB may enter into agreements with individual non-affiliated researchers via an Independent Investigator Agreement. These agreements are put into place when a Primary Investigator affiliated with the University of Idaho adds individuals who are not affiliated with an institution and are working with human subjects or their identifiable data in a protocol. In such cases, the independent investigator will be asked to sign an agreement stating that he or she is familiar with certain human subjects’ research principles and will employ them during the time

he or she is working with human subjects in research under the auspices of the University of Idaho.

The University of Idaho recognizes tribal sovereignty and requires that applications targeting tribal populations or being conducted on tribal lands be reviewed by the tribal IRB or equivalent and that the University of Idaho Office of Tribal Relations be notified of the research as well.

The IRB staff will work with the Office of Technology Transfer to ensure that Data Transfer and Use Agreements and Material Transfer Agreements that relate to IRB approved protocols match the approved usage, receipt, and/or transfer of data or materials.

14. Post-Approval Review

The IRB may conduct a post-approval review for cause or without cause. Such reviews may stem from allegations of non-compliance, failure to respond to IRB communications, complaints, or regularly scheduled without cause reviews.

The purpose of the Post-Approval Monitoring Program is to ensure that approved or certified research protocols are ethically protecting human research participants, compliant with policy, procedures, and regulations, and as a means of providing education to researchers.

The Post Approval Monitoring (PAM) program will provide additional oversight, quality assurance, and education during human subjects' research projects. Designated ORA staff intends to conduct PAM reviews of no less than six protocols per year. Protocols will be selected at random. The IRB also reserves the right to conduct for cause Post Approval Monitoring.

A. Procedures

Upon selection, the IRB will notify the Primary Investigator (PI) of the selection of their protocol for Post Approval Monitoring, provide a timeline for completion of the activities, and as needed, request access to documents, staff, research records, or other relevant information to be provided in a reasonable time and manner. If there is no response by the PI, this would be considered non-compliance and can result in closure of the protocol, a full audit, a processing hold on future submissions, or escalation.

B. Methods

1. Continuing Review

   Continuing Review is conducted annually (or earlier as directed by the Board) for Full Board protocols and Expedited protocols approved prior to January 20, 2019. The PI is required to submit an annual report. Failure to do so results in the automatic closure of the protocol.

2. Status Check

   Status Checks are conducted annually for Expedited protocols approved after January 20, 2019. The PI is requested to send an annual report.
3. Self-Assessment requested by IRB

Self-Assessments that are requested are conducted by random selection from Exempt, Expedited, and Full Board protocols. These will consist of a worksheet and a request for documents.

4. Informed Consent Document Assessment

   Informed consent document assessments are conducted by random selection from Exempt, Expedited, and Full Board protocols. These will consist of a request for documents and a re-review of the documents to ensure the most recently approved versions of consent documents are being used. A worksheet may also be used.

5. Informed Consent Process Assessment/Observation

   Informed consent document assessments are conducted by random selection from Exempt, Expedited, and Full Board protocols. These will consist of a request for documents and a re-review of the documents to ensure the most recently approved versions are being used. ORA staff will also observe the consent process with one or more research participants and may check all consent documents for completion. A worksheet may also be used.

6. Full Assessment

   Full assessments are conducted by random selection from Exempt, Expedited, and Full Board protocols. These will consist of a request for documents and a re-review of the documents to ensure the most recently approved versions are being used. ORA staff will also observe the consent process with one or more research participants and may check all consent and research documents and records for completion. Lab or site visits may be included. A worksheet may also be used.

C. Results

1. Corrective Action

   If reportable events or unanticipated problems are discovered, the PI will be required to submit a report to the IRB. If compliance issues are identified, the ORA staff will consult with the IRB Chair and Director to determine appropriate action.

2. Education

   If an educational opportunity is identified, the ORA staff will provide education to the PI regarding needed improvements. This can include recommendations, tools, or other guidance as to policy and regulations. ORA staff will document the outcome of PAM activities and provide a written report of the results to the IRB.

15. Unanticipated Events, Unanticipated Problems, and Adverse Events

Any unanticipated or adverse events or problems encountered that pose actual or potential risks to subjects must be reported to the IRB immediately but not later than five business days following the event. Such events should be reported in writing to the IRB. The IRB Coordinator or the ORA Director/Associate Vice-President 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.

A. Unanticipated events are generally situations where events that were not articulated in the IRB application or consent form occur during the approved research. Unanticipated events may fall into two categories:
   a. Not serious: those unanticipated events that do not increase the risk to the human participant.
   b. Serious: those unanticipated events that increased the risks to the human participants.

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

C. Unanticipated problems are issues that arise that are unrelated to research, but incidentally create a risk to human subjects.

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.

16. Non-Compliance

Ensuring that human subject research is conducted ethically, as per The Belmont Report, and consistent with federal regulations and University policy for human subject research is a shared responsibility. It is the University's policy that faculty, students, and staff conducting or overseeing human subject research must report any potential instances of noncompliance. Research subjects and individuals not directly involved in conducting or overseeing human subject research are also encouraged to report suspected noncompliance. This document describes the procedures to be followed in addressing allegations of noncompliance and when reporting findings of serious or continuing noncompliance, as required by 45 CFR 46.103(b)(5) and 21 CFR 56.108(b)(2).

A. Definitions

1. Noncompliance – Failure (intentional or unintentional) to comply with applicable federal human subject research regulations, University policy for human subject research, or requirements of or determinations by the IRB. Noncompliance can result from the actions of or omissions by individuals responsible for the conduct

of human subject research. Noncompliance may be non-serious or minor; serious; or continuing.

2. Non-serious or Minor Noncompliance – Noncompliance that does not increase the risk to the research patient, compromise participants' rights or welfare, or affect the integrity of the research/data or the human subject protection program.

Examples of non-serious or minor noncompliance include but are not limited to: failure to obtain IRB certification that research activity is exempt before conducting research that properly qualifies for exemption under federal human subject research regulations; lapse in continuing review by the IRB; implementation of minor changes to or deviations from an approval protocol without IRB approval of the protocol modification.

3. Serious Noncompliance – Noncompliance that has the potential to increase risk to research participants, compromise participants' rights or welfare, or affect the integrity of the research/data or the human subjects' protection program.

Examples of serious noncompliance include but are not limited to: conducting or continuing non-exempt human subject research without IRB approval; failure to obtain adequate and effective informed consent from research participants; failure to report or review serious adverse events or unanticipated problems; failure to obtain IRB approval for substantive changes to an approved research protocol prior to their implementation; inclusion of vulnerable populations in research without IRB approval.

4. Continuing Noncompliance – Noncompliance that has been previously reported, or a pattern of ongoing activities that indicate a lack of understanding of or disinclination to comply with human subject protection requirements, which may, in the absence of intervention by the IRB, affect research participants or the validity of the research and may suggest the potential for future noncompliance.

Examples of continuing noncompliance include but are not limited to: repeated failures to provide or review progress reports resulting in lapses of IRB approval, inadequate continuing review of ongoing research, or repeated failures to respond to or resolve previous allegations or findings of noncompliance.

5. Allegation of Noncompliance – an unconfirmed report of noncompliance

Finding of Noncompliance – a determination that an instance of noncompliance has occurred.

6. Procedures for the Initial Inquiry into an Investigation of Noncompliance Allegations

All allegations of noncompliance, whether these reports arise internally (e.g., from university faculty, staff, students, ORA staff, IRB members, etc.) or externally (e.g., research participants, other institutions cooperating in human subject research, federal agencies, etc.) shall be forwarded to the University Research Assurances Manager in the Office of Research Assurances. Allegations of noncompliance will remain confidential, to the extent permitted by Idaho law and consistent with the need to conduct an adequate investigation of the allegations. Allegations may also be reported anonymously using the University Hotline. The University will take measures to protect from adverse actions or retaliation any person who, in good faith, makes allegations of noncompliance under this policy. (See FSH 3290 and 3810).

Inquiries and, if necessary, further investigation, will be undertaken in response to allegations of noncompliance will be completed in a thorough but expeditious manner, consistent with the circumstances and seriousness of the alleged noncompliance. The Office of Research shall provide the resources and support necessary for the Office of Research Assurances and the IRB to meet its responsibilities with respect to noncompliance review

B. Initial Inquiry into Allegations

Initial inquiries into allegations of noncompliance will be undertaken by the Chair of the IRB, or the Research Assurances Manager acting on behalf of the Chair. The Chair or Manager will contact the complainant to confirm and develop an understanding of the circumstances of the potential instance of noncompliance, unless the complainant has provided sufficient information to proceed without further contact and when the allegation in question is not made anonymously. The Principal Investigator and Co-Investigator(s), or Student Investigator, will be informed of the allegation, will be asked to provide a response to the allegation, and will be required to provide any information deemed necessary by the Chair or Manager to evaluate the allegation and investigator response. The investigator must provide a written response to the inquiry and any requested information within fourteen (14) days after notification of the allegation. When considered necessary, the Chair of the IRB may temporarily suspend portions or all human subject research activity while the initial inquiry proceeds. Initial inquiries will be completed within thirty (30) days after receipt of the allegation of noncompliance.

C. Actions Resulting from Initial Inquiry

- Dismissal of the allegation when the allegation is determined to be unsubstantiated
- Required implementation of corrective actions determined necessary to achieve compliance, when the noncompliance is classified as non-serious or minor
- Determination of non-serious or minor noncompliance, with no further action required
- Determination that review by the convened IRB is required, because information gathered during the initial inquiry indicates that the noncompliance is serious and/or continuing.

D. Conclusion of Initial Inquiry

1. No Violation or Non-Serious Noncompliance

If the Chair or Manager determines that the allegation of noncompliance cannot be substantiated or finds that the noncompliance was non-serious or minor in nature, the Investigator(s), IRB, and the Institutional Official shall be notified in writing within thirty (30) days after receipt of the allegation of noncompliance. [Documentation of the outcome of the initial inquiry shall be placed in the protocol(s) associated with the allegation of noncompliance and noted in the Protocol Database.] If corrective action is required of the Investigator(s) for non-serious noncompliance, this action must be implemented by the Investigator(s) and confirmed by the Chair or Manager before IRB approval(s) can be reinstated. If some or all human research activity was temporarily suspended during the inquiry, notice of lifting of the

suspension and reinstatement of approval(s) will be provided to those entities informed of the suspension, including the Institutional Official, OHRP, and research sponsors.

2. Recommendation of Review by the Convened IRB

If the Chair or Manager determines that the allegation(s) require(s) a more extensive or intensive investigation, because of the complexity of the issues involved or the potentially serious and/or continuing nature of the noncompliance, the matter will be referred to the IRB for its determination.

The Chair or Manager will provide the IRB with a summary of the initial inquiry and supporting documentation including the allegation(s) of noncompliance, and the response of the Investigator(s) to the allegation(s).

The Chair or Manager will notify the complainant and the Investigator(s) of the referral for consideration by the convened IRB and the date of the IRB meeting at which the matter of the alleged noncompliance will be addressed. The Investigator(s) may appear in person at the meeting to respond to the allegation(s) and may be accompanied by a personal advisor or legal counsel, who may not participate in the proceedings. If the investigator intends to appear at the convened meeting, the Chair or Manager must be informed.

If, on review of the initial inquiry materials provided by the Chair or Manager, the IRB determines that further investigation is required prior to the convened meeting, two or more IRB members may be appointed by the Chair to conduct interviews, carry out (with the assistance of ORA staff) an audit of the Investigator(s) research activities, perform literature searches, and consult with experts, as necessary. The results of this investigation, and all other materials to be considered at the convened meeting, will be provided to the IRB seven (7) days before the scheduled meeting. If additional time is required to complete this investigation, the IRB meeting at which the alleged noncompliance was to be considered will be rescheduled and the Investigator(s) notified.

3. Convened IRB Consideration of Allegations

At a convened meeting of the IRB, which fulfills the requirements for quorum, the IRB will consider the allegation(s) of noncompliance. The results of the initial inquiry, and any further investigation, will be considered, along with other relevant materials (e.g., research protocol, consent forms, etc.) by the IRB in determining whether the allegations can be substantiated and, if so, whether the noncompliance involved is serious and/or continuing. As part of its evaluation, the IRB will speak with any Investigator(s) who elect(s) to appear at the meeting to respond to the allegations. The IRB will also discuss corrective action(s) that will be required to remedy any noncompliance and/or to avoid future noncompliance. In closed session and by a majority vote of members at the convened meeting, the IRB will make its final determination concerning the nature of the noncompliance and any corrective action required.

4. Corrective Action Required by the Convened IRB

If the IRB determines that the noncompliance is substantiated and warrants corrective action, the IRB will provide the investigator with a corrective action plan that describes the corrective action(s) that must be performed by the Investigator(s) and the deadline(s) for implementation.

Corrective action(s) required by the IRB will be based, among a number of factors, on the nature of the noncompliance, the degree to which research participants were placed at risk, and the occurrence of previous noncompliance by the same Investigator(s).

Corrective actions required by the convened IRB may include but are not limited to:

- Modification of the research protocol or consent form
- Notification of current and/or past participants
- Re-consent of current research participants, when changes to the research may relate to their willingness to continue in the research
- Required education or mentoring for the Investigator(s) or research staff
- Ongoing monitoring (including audits) of the research or consent process
- Increased frequency of continuing review (i.e., requiring that the research receive continuing
- review more often than once per year)
- Required additional resources to support the research activities
- Limitation of research activities or use of research data
- Suspension of IRB approval for one or more of the Investigator(s)' studies
- Termination of IRB approval for one or more of the Investigator(s)' studies

The Chair or Manager will review the Investigator(s) response to and implementation of the corrective action plan. If the Investigator(s) responsible for implementation do not complete the required corrective actions within the timeframe specified in the corrective action plan, additional action may be required. The Chair or Manager may suspend IRB approval(s) for ongoing human research studies of the Investigator(s); the Chair or Manager may also recommend termination of IRB approval (s) for ongoing human research studies of the Investigator(s). Upon consideration of the circumstances surrounding the failure of the Investigator(s) to timely perform the required corrective action(s), the IRB may formally terminate approval for one or more of the Investigator(s)' studies.

Suspension or termination, if not previously reported, will be reported to all required parties

E. Appeals

Consistent with federal human subject regulations, research reviewed and approved by the IRB may receive further institutional review. The University may impose additional, institutional conditions for approval or may disapprove the research approved by the IRB. The University may not, however, approve research that has been disapproved by the IRB. (45 CFR 46.112). Determinations by the convened IRB to suspend, terminate, or require corrective action represent disapproval of research that cannot be countermanded by the University. Investigator(s) may, however, petition for reconsideration of determinations of the convened IRB. Such petitions must be made in writing within 30 days of the determination by the convened IRB and submitted to the Vice President for Research and Economic Development, who serves as the Institutional Official. The Institutional Official will convey the petition to the IRB, which will review the request and notify the Investigator(s) within fourteen days of its decision to affirm its previous determination or to reconsider the determination. The decision of the IRB, whether affirming the previous determination or, upon reconsideration, altering its previous determination, is final; no further appeal is permitted. Investigators may also petition for evaluation by the convened IRB of determinations made by the Chair or Manager during the

initial inquiry; determinations by the convened IRB in response to such petitions are not subject to further appeal.

F. Reporting of Serious and/or Continuing Noncompliance, and Suspension or Termination of IRB Approval

Noncompliance that is found by the IRB to be serious and/or continuing shall, within fourteen (14) days of the determination, be reported by the IRB Chair or Manager to the Investigator(s), and the Investigator(s)' Dean and Department Chair. Within thirty (30) days, a determination of serious and/or continuing noncompliance shall be reported to OHRP, FDA (when the noncompliance is related to FDA-regulated research), and any sponsors of the research. Suspension, whether as part of the initial inquiry or the convened IRB review, or termination of IRB approval within fourteen (14) days of the determination, be reported by the IRB Chair or Manager to the Investigator(s), and the Investigator(s)' Dean and Department Chair. Within thirty (30) days, a suspension or termination shall be reported to OHRP, FDA (when the noncompliance is related to FDA-regulated research), and any sponsors of the research.

G. Record Retention for Noncompliance Proceedings

Records related to the review and investigation of noncompliance shall be retained by ORA, on behalf of the IRB, for a minimum of three (3) years after completion of the related research or implementation of required corrective actions, whichever is longer. Copies of determination decisions and corrective action plans, if applicable, shall be filed with the related research protocol(s) and the noncompliance determination shall be entered into the Protocol Database.

45 CFR 46.103(b)(5), 45 CFR 46.111(b)(5), 45 CFR 46.112, 45 CFR 46.113, 45 CFR 46.115, 21 CFR 50.25(b)(5), 21 CFR 56.108(b)(2), 21 CFR 56.112, 21 CFR 56.113, 21 CFR 56.115

17. Protocol Approvals and Renewals

A. Initial Review

Full Board, Expedited, and Exempt protocols are approved after the final re-review and approval is administratively processed.

B. Continuing Reviews

Continuing reviews are conducted annually for all Full Board protocols and for Expedited Protocols approved prior to January 20, 2019. The IRB re-evaluates the research no less than 12 months from the date of the last review. For research that has no more than minimal risk, the approval period is generally one year. For research involving greater than minimal risk, the IRB will determine the appropriate approval period. The approval letter from the IRB will indicate the expiration date. The IRB will attempt to send reminders to investigators prior to the expiration date, but the responsibility of renewing the protocol in a timely manner falls on the investigators.

Continuing Reviews are assigned to the IRB Coordinator for review. The IRB Coordinator may request clarification, changes, or an Amendment to the protocol. The IRB Coordinator may also assign Status Checks to a Designated Member for review.

C. Status Checks

Status checks are conducted annually for all Expedited protocols approved on or after January 20, 2019.

Status Checks are assigned to the IRB Coordinator for review. The IRB Coordinator may request clarification, changes, and an Amendment to the protocol. The IRB Coordinator may also assign Status Checks to a Designated Member for review.

D. Expiration Policy

In order to ensure that approved or certified research protocols are compliant with the most current policies of the Institutional Review Board:

1. Full Board protocols will expire one year from their initial approval date unless a Continuing Review form is approved at a convened Board Meeting for an extension of time equal to or less than one year.

2. Expedited protocols approved on or after January 20, 2019 will expire three years from their initial approval date. Annual status checks will be requested by the IRB.

3. Expedited protocols approved prior to January 19, 2019 expire one year from their rolling anniversary date annually unless a Continuing Review form is approved for an extension of approval for one year.

4. Exempt protocols will expire five years from their initial approval date.

5. Effective July 1, 2021 all currently open Exempt and Expedited protocols will be assigned an expiration date for three or five years as appropriate, based on their next anniversary date.

Examples

- An Exempt protocol was approved on July 11, 2018. After July 1, 2021 a five-year expiration date is assigned for July 11, 2026.
- A Full Board protocol was approved on May 1, 2019. It was approved for renewal on April 3, 2020. It will expire on April 2, 2021 unless an annual Continuing Review is approved.
- An Expedited protocol was approved on February 15, 2017. After a number of annual reviews, it is set to expire on January 12, 2022. After July 1, 2021, it can be renewed for up to three more years. At that time the protocol permanently expires, and a new protocol will need to be submitted.

- An Expedited protocol was approved on February 15, 2019. Status check requests have been sent to the PI, but there has (or has not) been a response. After July 1, 2021, an expiration date will be set for February 14, 2024.

- An Expedited protocol is approved on May 30, 2021. After July 1, 2021, an expiration date will be set for May 29, 2024.

- An Expedited protocol is approved on July 2, 2021. An expiration date is set for July 1, 2024.

E. Notification of Approvals or Renewals

Notifications are sent through the VERAS system to the Primary Investigator and designated Study Contacts. A copy of the notification is also sent to irb@uidaho.edu.

18. Informed Consent

Informed Consent is a process by which an individual participating in human subjects' research has the opportunity to make a fully informed decision. It begins with recruitment, is usually obtained through verbal agreement or a signed document and is a continual process as new information may come to light during the research. The amount of information and the manner of presentation is generally related to the complexity and risk involved in the research study. When a written form is used the subject should receive a copy for their records.

Information must be presented to enable persons to voluntarily decide whether to participate as a research subject. The language and process used in obtaining informed consent should be culturally appropriate and use language the subjects can understand. Informed consent language and its documentation must be written in "lay language", (i.e. understandable to the people being asked to participate). Generally, a 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 participants or their legally authorized representative in a language they understand. The IRB must approve the translated consent form before use and may request that the document be back-translated for accuracy. The written presentation of information is used to document the basis for consent and for the subjects' future reference.

Informed consent is used for persons who have reached the age of majority.

Child Assent is used for persons who have not yet reached the age of majority.

Parental Permission/Guardian Permission/Legally Authorized Representative (LAR) Permission is used when a research participant has not yet reached the age of majority or is not capable of making an independent decision.

Assent is 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 treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted. (45 CFR 46 Part D)

The IRB shall determine that adequate provisions have been made for soliciting the assent of children and persons with a guardian or LAR. The IRB will take into consideration the ages, maturity, and psychological state of the persons involved. The assent should include information indicating that the research participant may refuse to assent (participate in the research) even if the parent/guardian/LAR has provided permission. In this way, the research participant is treated as an autonomous agent.

As a general rule, children ages 3 to 6 should be assented verbally and the researcher should provide a verbal assent script along with their IRB application for review. Children ages 7 to 17 should be assented and that assent documented with a written assent form. Lay language should be used that is grade appropriate.

The researcher must provide a copy of consent, permission, and assent documents to the IRB. Changes and updates to these documents must be submitted via Amendment. Templates are available on the IRB website.

There are required elements for informed consent, assent, and permission documents. (45 CFR 46.116) or 21 CFR 50.25. However, The Belmont Principles should also be used when drafting these documents. Specific funding agency requirements must also be met.

A. Requirements

The University of Idaho also requires the following on all consent, assent, and permission documents:

1. Study title and name(s) of researcher(s) at the beginning of the consent form.
2. A statement that the study has been approved for human subject participation by the University of Idaho Institutional Review Board.
3. The language and its documentation (especially explanation of purpose, duration, experimental procedures, alternatives, risks, and benefits) written in simple lay language.
4. A statement that the participant can contact the Primary Investigator and the IRB with any questions or concerns along with contact information.
5. Signature lines include participant, researcher(s), witness if appropriate, and date of signature.
6. When appropriate separate signature or initialing lines to indicate agreement to audio or video recording.
7. The form is free from exculpatory language through which the subject is made to waive, or appear to waive, any of the subject's legal rights.
8. In addition, for most field-based research, informed consent can be obtained in the form of oral agreement. Researchers should provide specific elements in a verbal consent script, which includes concise statements about study purpose, procedures, potential risks, and benefits. A template for verbal consent may be developed by the IRB.

B. Additional Requirements for Assent

1. Explanation that parent, guardian, or legally authorized representative knows the child is being asked to take part.
2. Description of what, if any, information the be shared with shared with the parent, guardian or legally authorized representative.
3. When relevant a statement of any mandatory reporting requirements is included.

C. Additional Requirements for Permission

1. Statement that the researcher is asking for permission and that the person providing assent will also be asked to agree to participate in research.
2. Description of procedures explained in terms of what the research participant will be asked to do.
3. Statement that potential research a participant may choose not to take part even if permission is given.
4. Description of what, if any, data about their child will be shared with the parent, guardian, or representative.
5. When relevant a statement of any mandatory reporting requirements.

D. Documentation of Informed Consent

The IRB will approve procedures for documentation of informed consent in accordance with 45 CFR 46.117 and FDA 21 CFR 50.27.

In most circumstances, the IRB will require that informed consent be documented by the use of a written consent form approved by the IRB and signed and dated by the subject or the subject's legally authorized representative, guardian, or parent. This form may be read to the subject or the subject's legally authorized representative. However, the investigator should allow the subject or the legally authorized representative adequate opportunity to read the consent document before it is signed. A copy of the document should be given to the person signing the form. Subjects who do not speak English should be presented with an informed consent document written in a language understandable to them.

Documentation of Informed Consent does not always necessitate a written signature. In certain scenarios where written consent is not feasible, practical, or needed—for instance, in field-based or telephonic research—the IRB may approve verbal consent or alternative documentation like audio or video recordings of the consent process.

E. Waiver of Documentation of Consent (Signature by Participant)

In some situations (e.g., telephone survey, certain data sets, or certain international research), the IRB may waive the requirement for obtaining a signed informed consent form. (45 CFR 46.117 (C). The regulations state that the IRB may waive the requirement for a signed consent form may be waived if the IRB determines that the research meets one or both of the conditions below:

1. Condition 1: The research involves procedures that involve minimal risk except for the linking of the consent document to private information and; the only record linking the subject and the research would be the consent document, and the principal risk would be potential harm resulting from a breach of confidentiality (i.e., a study that involves subjects who use illegal drugs). Under this condition, each subject must be asked whether he or she wants to sign a consent form; if the subject agrees to sign a consent form, only an IRB approved version should be used. However, this waiver cannot be granted for FDA-regulated research.

2. Condition 2: The research presents no more than minimal risk to the subject and involves no procedures for which written consent is normally required.

The IRB may add an alternative requirement instead such as a recording of the informed consent being read orally and agreed upon, posted notifications, or other possible ways of informing and accepting agreement from potential research participants.

The regulations allow the IRB to grant a waiver of the signed consent document requirement under Condition 1 and Condition 2 scenarios, reinstating that studies determined to be exempt can file a verbal consent script with the IRB without necessitating a written consent document.

F. Waiver of Informed Consent

Some research studies would not be possible if informed consent from participants were required. The IRB may consider waiving the requirements for informed consent (45 CFR 46.116 (d)) when the research meets all of the following conditions (the researcher needs to explain for each condition how it applies to his/her research):

1. The research involves no more than minimal risk to the subject;
2. The rights and welfare of subjects will not be adversely affected;
3. The research could not practicably be carried out without the waiver or alteration; and
4. Whenever relevant, the subject will be provided with additional pertinent information after they have participated in the study.

The IRB cannot approve a 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. The IRB cannot approve a waiver of the consent process for research that is subject to FERPA regulations, unless an exception is met or the information is de-identified or coded with no access to the key prior to receipt.

G. Alteration of Informed Consent Process

Some research studies (i.e., medical record review, deception research, or collection of biological specimens) would not be possible if all of the elements of informed consent from participants were required.

The IRB may consider waiving the requirements for some or all of the informed consent (45 CFR 46.116 (d)) elements when the research meets all of the following conditions (the researcher needs to explain for each condition how it applies to his/her research):

1. The research involves no more than minimal risk to the subject;
2. The rights and welfare of subjects will not be adversely affected;
3. The research could not practicably be carried out without the waiver or alteration; and
4. Whenever relevant the subject will be provided with additional pertinent information after they have participated in the study.

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.

H. Broad Consent and the Secondary Use of Research Data or Specimens

The secondary use of data or specimens for research purposes may be permitted by the IRB if certain circumstances are met. These may include that the data or specimen has been de-identified to the point that it is no longer considered a "human subject" by legal definition, the data or specimen provider agreed to specific secondary use in the Informed Consent, or other circumstances as permitted by the IRB. In no event should an Investigator make such a determination or use without prior IRB approval.

At this time, the University of Idaho IRB will not allow the use of Broad Consent for specimens or data. The IRB will support investigators in developing an informed consent document and procedures that allow permission for the collection and storage of identifiable private information or biospecimens for future secondary use research.

19. Special Considerations

A. Alcohol

Research on the biological and behavioral effects of the ingestion of ethyl alcohol conforms to the ethical principles that govern all research involving human subjects. These principles are elaborated upon in the National Institute on Alcohol Abuse and Alcoholism (NIAAA) by the National Advisory Council on Alcohol Abuse and Alcoholism's website. The NIAAA website (http://www.niaaa.nih.gov/) provides information on research involving the administration of alcohol and also contains NIAAA guidelines on administering alcohol in human studies (http://www.niaaa.nih.gov/Resources/ResearchResources/job22.htm). The IRB will use the NIAAA guidelines when reviewing research involving alcohol.

Depending on the nature of the research and the perceived risk to the participants the IRB may require frequent blood alcohol level (BAL) measurements, based on time intervals or numbers of participants. The IRB also may approve a limited number of initial human participants and require submission of BAL measurements for review before approving additional participants. The IRB may also require other measures to ensure the safety, health, and welfare of human participants

B. Children

Federal regulations have specific requirements for research involving children. These requirements are found in Subpart D of the DHHS regulations (45 CFR Part 46). "Child" means any person who has not attained the legal age for consent to treatments or procedures involved in research, under the applicable law of the jurisdiction in which the research will be conducted. Children are persons who have not attained the age of majority or are not emancipated minors. The age of majority varies, and researchers should verify what the age of majority is in the area where they will conduct research.

Subpart D contains many specific requirements for research involving children and should be reviewed by the researcher and applied in the protocol. The IRB is responsible for ensuring that the proposed research plan addresses the requirements in Subpart D.

45 CFR 46 Subpart D states that in general assent and parental or guardian permission be obtained. The IRB requires that parents provide permission prior to children being asked to participate in research. Children of three years of age or older should be asked to provide their assent, either in verbal (for illiterate children) or in writing (for children who have achieved literacy). Consent forms are used when a child who is enrolled in a study reaches the age of majority and will need to be consented to continue participation in the research. The researcher should provide the IRB with a verbal script, written assent, parental permission, and consent form for review as appropriate for the research.

There are some exceptions to the permission, assent, and consent requirements that the IRB may grant.

- When research is approved under Exemption 2, and the research involves observation of public behavior and the investigator does not participate in the activities being observed, no parental permission or child assent is required, but the IRB may request public notification, especially if recording is involved.
- If the research involves direct benefit to the subject child, or if the research does not directly benefit the subject child but is likely to yield generalizable knowledge of the subject child's disorder or condition, the IRB may allow permission from only one parent or guardian. The IRB may also choose to waive some or all of the assent.
- The IRB may waive permission if it is not a reasonable requirement to protect the child subjects (e.g., neglected or abused children) and a reasonable protective mechanism is substituted.
- The only record linking the child subject and the research would be permission and/or assent documents and the principal risk of harm would be from breach of confidentiality.

- The research presents no more than minimal risk of harm to child subjects, and it involves no procedures for which written consent is normally required outside of the research context. If the IRB determines that such research meets this standard, the IRB will also require the PI to state why it is not practicable to obtain permission and/or assent. The IRB may also require different methods of permission and/or assent or may waive only some elements or may substitute an appropriate mechanism such as a child advocate.
- Assent may be waived if the capability of the children is so limited that they cannot reasonably be consulted.
- If the intervention or procedure holds out the prospect of direct benefit to the health or well-being of the children and is available only in the context of the research.

If the child is a ward of the state, an agency, or an institution, the research must either be related to the childrens' status as wards or is conducted in a school, camp, hospital, institution, or similar setting in which the majority of the children are not wards. Each child must be appointed an appropriate advocate in addition to any other individual acting as the child's guardian or in loco parentis.

Subpart D contains specific requirements and documentation as protections for children who are research subjects. Research involving greater than minimal risk must have written documentation and can be approved only if one of the following conditions is met.

- Research involving greater than minimal risk but presenting the prospect of direct benefit to the subject children.
- Research involving greater than minimal risk and no prospect of direct benefit to the subject children, but likely to yield generalizable knowledge about the children's disorder or condition.
- Research not otherwise approvable that presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children. If this research is proposed, the Secretary of the HHS will need to approve the research after consultation with experts and an opportunity for public review and comment.

C. Confidentiality Agreements

Depending on the confidentiality of the material being collected, the IRB may request signed confidentiality agreements with certain study personnel (depending on their role in the research). Individuals with limited involvement (e.g., transcriptionist, translator, specific data analyses duties, etc.) may be asked to sign confidentiality agreements.

The IRB does not require confidentiality agreements in all situations except when the confidentiality (sensitivity of the material) warrants such consideration.

D. Locations outside of the University of Idaho

If research will be conducted off-campus, researchers are required to provide documentation that the proposed site location has agreed to allow research to occur on its premises.

Research that will 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. The IRB will also request that the researchers meet with the University of Idaho Tribal Relations Office prior to beginning research, or prior to IRB approval.

Research occurring outside of the United States should be considered under “International Research” in this manual.

(Model Tribal Research Code, 1999)

E. Genetic Research

The IRB will follow OHRP, FDA, and other sources for advice and guidance as ethics and research in this area is rapidly evolving.

In general, genetic research will require detailed and specific disclosure in the informed consent documents and the application. Information that should be disclosed in the application and consent forms include considerations as to whether:

- Samples are identified, confidential, or anonymous.
- Tests and analyses will be done on the material are appropriate.
- Samples will be destroyed at a certain time, or whether samples will be stored for future use.
- Samples are stored for future use what type of use researchers anticipate. At this time the University of Idaho does not allow “broad consent”. Future research uses must be specified and/or samples must be de-identified.
- Samples that will be stored for future use (data repository) have additional information on how will samples or identities be protected.
- Participants will be informed of any test results, and if so, which ones and how. CLIA certified lab testing is considered to be scientifically valid and confirmed, while some research labs may only be able to recommend follow-up testing.
- If a discovery is made (incidental finding) that pertains to a subject’s previously unknown physical or psychological condition, how the discovery will be handled and/or disclosed to the subject. The subject should have the right to not know as well.
- Research subjects may be re-contacted and whether this is disclosed in the consent.
- There is a risk of psychological or social harm from disclosure whether deliberate or inadvertent.
- Data, lab, and other security.

- Material Transfer Agreements and Data Transfer and Use Agreements are sufficient.
- Genetic counseling is advised.
- Withdrawal of participation is allowed and what can be withdrawn.
- Ownership of the genetic material and any discoveries.
- There should be special considerations for vulnerable persons.
- Re-identification is possible and how this can be limited.

[National Institutes of Health – National Human Genome Research Institute]

F. Graduate Student Research

IRB review and final approval should take place during the proposal stage of a dissertation or thesis. Graduate students should refer to the qualifications to be a Primary Investigator and choose an appropriate advisor for such a role.

G. Health Insurance Portability and Accountability Act (HIPAA) and Privacy BoardThe Privacy Rule regulates the way covered entities under the Rule, handle, secure, and disclose individually identifiable health information known as Protected Health Information (PHI). It also establishes the conditions under which covered entities can use or disclose PHI for many purposes, including for research. When needed the IRB will also serve as an ad hoc Privacy Board for HIPAA waivers.

H. Internet-based research (social media)

The PI must follow the policies and terms of the platform. If the online source requires a login or account or registration, it is considered private and informed consent must be obtained. If researchers plan to quote from online social media sources or support groups, the individual should be contacted to receive direct permission, even if the quoted individual is using a persona.

Additional guidance can be found in SACHRP's "Considerations and Recommendations Concerning Internet Research and Human Subjects Research Regulations, with Revisions" of March 12-13, 2013.

I. Oral History

The Oral History Association (https://oralhistory.org/information-about-irbs/) has information available to members to help determine whether oral history research and activities require IRB review.

45 CFR 46.102(l) deems the following not to be research “Scholarly and journalistic activities (e.g. oral history, journalism, biography, literary criticism, legal research, and historical scholarship), including the collection and use of information, that focus directly on the specific individuals about whom the information is collected.)”

Primary Investigators and researchers should consult with the IRB to ensure that their research meets this exclusion. Primary Investigators and researchers who will need a formal determination of “Not Human Subjects Research” must submit an IRB application.

J. Pregnant women, fetuses, and neonates

The federal regulations have specific requirements for research involving pregnant women, human fetuses, and neonates. The IRB will adhere to the regulations set forth and may apply additional requirements to ensure the safety of participants. These requirements are found in Subpart B of the DHHS regulations (45 CFR Part 46).

K. Prisoners

The federal regulations have specific requirements for research involving prisoners. “Prisoner” means any individual involuntarily confined or detained in a penal institution and encompasses 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. These requirements are found in Subpart C of the DHHS regulations (45 CFR Part 46).

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.

L. Recording (photographs, audio, video)

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. Researchers should also provide human subjects with information regarding any software Terms of Service or Privacy Policies that apply to the recording, storage, or transcription.

M. Suicide/Depression

Research involving depression indexes and scales can reveal information or disclosures that carry additional responsibilities for the researchers. Studies with suicide or suicidal ideation related questions also require additional safeguards and responsibilities on the part of the researcher. The consent document will also need to contain specific information regarding the risks, resources for counseling, and reportability of certain information. Researchers should

provide information in their IRB application regarding if an identifiable participant expresses the potential to harm themselves or others and how the situation will be handled.

N. General Data Protection Regulation

The General Data Protection Regulation (GDPR) applies to countries within the European Union and some that have adopted the same or similar requirements for data security. While the IRB can provide some guidance on the GDPR, it is ultimately the Primary Investigator's responsibility to ensure that applicable data security and disclosures are conducted.

The IRB may require that additional data security measures and additions to the informed consent documents are provided to subjects participating in research while present in a GDPR-covered country. The IRB may also request that IP addresses of participants be restricted to those currently residing in the United States.

O. International Research

Human subjects research performed outside of the U.S. should meet the same level of protection of human subjects are given inside of the U.S. The research must also take into account the laws, culture, and customs of the international institution/site. Approval by the site location and local government is also required.

Regardless of funding sources, PI should ensure that the protocol is reviewed by a local IRB and approved prior to the conduct of research activities. This approval will precede approval from the University of Idaho IRB. However, if no local IRB exists and/or national security situation, the University of Idaho IRB will serve as the IRB of record. The university recognizes that the procedures normally followed in foreign countries may differ from those set forth in U.S. federal regulation.

All applicable IRB policies and procedures that are applied to research conducted domestically are also applied to research conducted in other countries, with reasonable and justifiable modifications to be addressed by the IRB. If the research is federally funded, the site location or collaborating institution will be required to have a Federalwide Assurance (FWA) with OHRP as well as local IRB approval.

When the research is not federally funded, the non-U.S. location is not required to have a FWA, however, the local IRB should be registered with the U.S. Department of Health and Human Services (DHHS) OHRP. Registration is the responsibility of the local IRB.

The PI is responsible for ensuring that non-affiliated local personnel are properly listed on the protocol and receive appropriate training for their roles. Individual Investigator Agreements and Data or Material Transfer Agreements should be utilized as needed. Additional data security measures may need to be undertaken, and these are also the responsibility of the PI.

The PI is responsible for communication and coordination with the local IRB for the non-U.S. institution/site. The PI and IRB should also consult the OHRP's International Compilation of Human Research Standards for both Region-Specific Compilations and Country-specific laws and regulations.

All applicable ethical standards and regulations are applied consistently to all human research, regardless of whether it is conducted domestically or in another country, including in line with US and International Conference on Harmonization and Good Clinical Practice (ICH-GCP):

1) Confirming the qualifications of investigators for conducting the research
2) Conducting initial review, continuing review, and review of modifications to previously approved research
3) Post-approval monitoring; quality assurance
4) Handling of complaints, non-compliance, and unanticipated problems involving risks to subjects or others
5) Consent process.
6) Ensuring all necessary approvals are met.
7) Coordination and communication with local IRBs.

P. Protection of Pupil Rights Amendment

The Protection of Pupil Rights Amendment (PPRA) governs the administration to students of surveys, analysis, and evaluations. Certain areas of student and family information are protected including asking questions regarding political affiliations, mental or psychological issues, sex behavior or attitudes, illegal, anti-social, self-incriminating, or demeaning behavior, critical appraisals of close relationships, religious practices, and income. While this applies to Department of Education funded research, the IRB reserves the right to consider this for all research conducted with minors.

Q. DXA – Bone Density Scan (DEXA)

Primary Investigators should include the following information with their IRB application:

- The rem dose equivalent of each scan
- The total amount of scans the participant will undergo
- A screening form that removes participants who have undergone more than four scans in a single calendar year, or those who are pregnant

R. Novel Research for the University of Idaho

When research is new or novel to the University of Idaho IRB, additional time may be needed for the IRB to consult with experts, other IRBs, counsel, or other sources of information in order to make the best decision to protect the health, welfare, and safety of participants.

S. Re-Consent or Notification of Significant New Findings or Results During the Course of Research

Principal Investigators and researchers may need to re-consent or provide notification of significant new findings or individual results during the course of research. The Principal Investigator is responsible for submitting an IRB Amendment form within five business days of such an event and prior to continuing research if the change is likely to have an impact on any

subject's willingness to continue in the study. The IRB may require notification or re-consent of subjects.

T. Research Participants of Limited Capacity

If the potential human subject's capacity to consent is impaired, researchers may need to provide the IRB with additional information as to how the ability to consent will be assessed. Impairment can be permanent or transient and may be dependent on education or situational events. If the potential participant is determined to be impaired, then a Legally Authorized Representative or Guardian should be consented on their behalf.

U. Safeguarding Confidentiality and Record Storage

Data and Biospecimen confidentiality, security, and destruction are the responsibility of the Primary Investigator. The IRB can provide some guidance, but researchers should consider utilizing other resources such as IT, librarians, statistical experts, campus security, or other experts in data security. Adequate policies, procedures, and safeguards should be in place and align with the University of Idaho's Information Technology, sponsor, and administrative requirements among others.

When reviewing protocols, the IRB will check to ensure that the minimum amount of information is being obtained, de-identification occurs when possible, informed consent allows participants to know how their information is stored, that appropriate security measures are undertaken, and a data storage timeline is in place. The IRB will consider whether other methods for ensuring confidentiality can be undertaken such as confidential coding or statistical scrambling for data sets or cloud storage for field work.

The IRB will generally defer to ITS policies for electronic data and administrative policies for data retention and storage of paper archives. Lab security procedures should be undertaken for biospecimens and other materials with a human subjects' research component.

When appropriate, researchers must be aware and communicate to subjects that federal officials have the right to inspect and copy research records, including consent forms and individual medical records, to ensure compliance with the rules and standards of their programs. Subjects must be informed of the extent to which confidentiality of research records will be maintained. The FDA requires that information regarding this authority be included in the consent information for FDA-regulated research. Identifiable information obtained by Federal officials during such inspections is protected by the provisions of the Privacy Act of 1974.

Primary Investigators should consider whether additional documents for researchers or third parties should be used, such as Confidentiality Agreements, Data or Material Transfer agreements, Non-Disclosure Agreements, or other contracts should be utilized to protect the University's interests and the confidentiality of collected data.

[University of Idaho – IT Data Classification Standards, ITS Approved Storage Locations, APM 65.02, FSH 5700, APM 30.11]
[45 CFR 46, 21 CFR 50]

V. Research Involving Deception or Withholding Information

Deception research or research in which information is withheld from the participant must have sufficient justification that it is necessary. When appropriate the participant should be debriefed or provided the information afterwards in a timely manner. The IRB will also take into account that the subject population is suitable.

The IRB will need to consider a partial or full waiver of consent and will adhere to the requirements in 45 CFR 46 as to when this is legally and ethically permissible.

W. Research with Data Sets

When data sets are publicly available, which is defined by the IRB as open access with no credential or fee requirements, and available to the general public, the IRB will generally allow such usage. If sensitive or identifying information is part of the data set the IRB will take this into account when requesting information regarding the investigators' plans for data security.

When data sets are not publicly available, the IRB will take into consideration the original informed consent that such subjects agreed to and whether the research is permissible under that informed consent. The IRB may utilize options to waive consent or to invoke a Privacy Board for HIPAA waivers. At other times the IRB may determine that the researchers must obtain or use data sets that remove specific codes or identifiers or destroy those upon receipt within a designated period of time. This can involve the permanent removal of such fields so that re-identification by both the provider and recipient is impossible. Other options the IRB may take into consideration are other techniques for de-identification such as data scrambling, or other statistical interventions.

X. Research Using Data or Tissue Repositories

The IRB will approve protocols in part after review of the Data Transfer and Use or Material Transfer Agreement. This may also include requiring the Primary Investigator to provide information regarding the release of identifiers, use of HIPAA data enclaves or other IT systems requirements, and an agreement that the researchers will use the data only for the purposes specified and that data will be destroyed at appropriate intervals. The researchers may also be required to agree not to attempt to re-identify or contact subjects.

The IRB will evaluate the possible risks as well as benefits of the data or biospecimens stored in the repository. When the University of Idaho is obtaining data or biospecimens for a repository the IRB will work to ensure that HIPAA, Privacy Regulations, and other considerations are effectively managed. An IRB protocol will be approved with the required minimum security requirements for such a repository.

The Principal Investigator will be responsible for ensuring that informed consent, HIPAA disclosures, and other agreements are properly administered to subjects and signatures are obtained and stored for required time periods. The Principal Investigator will further ensure that the Protected Health Information (PHI) is properly secured and that the collection, storage, use and distribution follow all legal requirements.

Y. Single IRB Review (sIRB)

When possible, the IRB will use the SMART IRB common reliance agreement platform to enter into a reliance agreement and determine the IRB of Record. The IRB reserves the right to decline entering into a reliance agreement or terminating an existing agreement for proposed study for any reason including, but not limited to, the type of research, the risk of the research,

the qualifications of the study staff, the resources required to conduct the research. The IRB will take other factors into account when entering into a reliance agreement including whether the other IRB has current FWA, IORG, and IRB numbers with OHRP, other accreditations, a requirement by a funding agency to use a single IRB, and whether warning letters or other sanctions have been imposed on the other institution.

Z. Clinical Trials and ClinicalTrials.gov

Primary Investigators are responsible for completing the requirements of their funding agencies. IRB approval does not invest the responsibility for posting required documents to ClinicalTrials.gov to the University of Idaho. The IRB will assist in providing guidance to investigators, but it is the responsibility of the Primary Investigator on a research protocol to ensure that all deadlines and responsibilities are met.

The IRB Coordinator is able to access Protocol Registration and Results on behalf of the University of Idaho and will assist Primary Investigators in obtaining and maintaining their account. The IRB Coordinator will also assist in updating Primary Investigators of notifications or alerts placed on their ClinicalTrials.gov accounts. However, neither the Coordinator nor other University of Idaho administrative personnel has the ability to update records on behalf of the Primary Investigator.

It is the Primary Investigators responsibility to record an IRB protocol's information on ClinicalTrials.gov and keep such records up to date by submitting required information prior to any deadlines. While the IRB may assist with providing notification or guidance, the IRB and the University of Idaho are not the responsible parties for ensuring the records are kept up to date.

AA. Data and Safety Monitoring Plan

If a Primary Investigator is using an experimental drug or device or is using an FDA-approved drug or device that has the potential for significant risk, or the research is greater than minimal risk, the PI is expected to have a Data Safety and Monitoring Plan. The Board may request regular reports from the Primary Investigator regarding that DSMP at intervals to be determined.

Data and safety monitoring provides a clinical investigation with a system for appropriate oversight and attention to the protection of human subjects by the investigator, research team, or an independent reviewer. A Data and Safety Monitoring Plan is a quality assurance plan for a research study. A DSMP prospectively identifies and documents monitoring activities intended to protect the safety of the subjects, the validity of the data and the integrity of the research study. The DSMP may also identify when to terminate a subject's participation (i.e., individual stopping rules) and/or the appropriate termination of a study (i.e. study stopping rules). The IRB may request an appropriate DSMP be developed and adhered to as part of a protocol regardless of the research risk level. A DSMP may also be required by certain funding agencies or sponsors.

BB. Data Sharing Plans and Repositories

The National Institutes of Health and other federal funding agencies may require that data and results from funded protocols be placed in accessible data repositories. It is the responsibility of the Primary Investigator to ensure that such information is posted within the designated timeframes. The IRB should be consulted prior to agreeing to a data sharing plan with a funding

agency to ensure that the proposed data-sharing plan is likely to be approved by the IRB.

Information in the data sharing plan must match the informed consent so that research participants are aware of how their data will be shared.

CC. Local Context

The Primary Investigator and researchers must provide local context for research when requested by the IRB. This may include additional information on the subject population, as well as relevant geographic, cultural, or social information and norms. This may be useful to determine privacy, consent, compensation, or other issues related to IRB review. The IRB may request or utilize additional sources of information other than those provided by the Primary Investigator or researchers.

DD. Translated Information

The IRB may require that the Primary Investigator and researchers translate and back-translate copies of documents that will be used in the research or provided to subjects who speak a non-English language. This can include recruitment, consent, and relevant documents that are useful for the subject populations' understanding of the research.

EE. Research on Vulnerable Participants

The IRB may require additional protections for those it deems particularly vulnerable. This will assist researchers in ensuring that participants are not coerced, unduly influenced, or have their legal or ethical rights violated. There may be specific instances in which persons who are minorities, non-English speaking, economically disadvantaged, or subject to other disadvantages will require special protections or enhanced protocols.

FF. Researchers Recruiting from Their Own Course

In order to avoid undue influence, imbalances in power dynamics, or the perception of ethical concerns by students, the IRB will carefully review any request for an instructor to conduct research on their own students. It is preferred that such research be conducted with students from a class other than one being taught by the researchers. If such research is permitted, the Primary Investigator and researchers are expected to minimize potential concerns. Strategies for minimization can include blinding the researchers to participant identity until grades are finalized, having a non-researcher collect and de-identify data, providing alternative equivalent assignments for extra credit, and assuring students that participation will have no outcome of their course grade or evaluations, among others.

GG. SONA

The IRB allows the use of SONA credits for participation in Psychology research. Participants should be given the opportunity to complete an alternate but equivalent study or assignment in order to receive credits as no person can be compelled to participate in research.

HH. Investigational Devices

Investigational Devices must follow the FDA guidelines (21 CFR). Permission from the Vice President of Research must be granted prior to using FDA-regulated devices. (See FSH 1640.54). Once this permission has been received, then the IRB will be able to issue a final

approval to an IRB protocol. The IRB may make and document a significant/nonsignificant risk (SR/NSR) determination as needed.

II. Investigational Drugs

Investigational Drugs must follow FDA guidelines (21 CFR). Permission from the Vice President of Research must be granted prior to using FDA-regulated drugs. (See FSH 1640.54). Once this permission has been received, then the IRB will be able to issue a final approval to an IRB protocol.

JJ. FERPA

The Family Educational Rights and Privacy Act (34 CFR 99) protects educational records of students who receive funds from certain programs of the U.S. Department of Education. It regulates the disclosure of Personally Identifiable Information and records such as course grades, coursework, transcripts, student financial information, schedules, and other materials.

When accessing FERPA protected records for research, either written permission must be given by the student and/or guardian, or the researcher and IRB must determine if the use of the records meets an exception, or whether identifiers will be removed prior to receipt of the data (although coded data can be obtained so long as the code is not received).

KK. Data Repositories and Publication

For federally funded research, or in order to meet sponsor requirements, Primary Investigators are expected to find and submit the required information to an appropriate repository. If a plan is required to be submitted as part of a funding agency proposal, it is the Primary Investigator's responsibility to ensure that such a data sharing plan will meet IRB requirements. These requirements will include, but are not limited to, the following:

- No usage of "broad consent"
- Appropriate methods of de-identification
- Informed Consent documents that reflect the Data Sharing Plan
- Appropriate Data Security

LL. Tracking Devices, Wearables, and Smart Devices

Research using these devices must comply with the End User License Agreement (EULA) and Terms of Service (TOS). If consent to an EULA or TOS is required, the subject must be given this information in the Informed Consent documents, along with a link to these contracts.

Collection of data for research from these devices should be limited to the minimum necessary with justifications submitted within the IRB application. Additionally, the PI must clearly explain in the consent form what loss of privacy will occur with the collection of the data, as well as what risks might be incurred. Human subjects should be provided with simple and concise information as to exactly what data is being collected, when, and how. Data security should also be clearly addressed in the application and consent form.

If subjects are required to download required software or provide their own devices for use in the research, or are responsible for maintaining researcher-owned equipment, it should be clearly explained how privacy, and loss or damage, will or will not be compensated in the application and consent. Consent forms should cover the use of the device, how to remove it or any software, and how the return of researcher-owned equipment should be completed.

Additional guidance is available from SACHRP's Recommendations "Attachment B-Clarifying Requirements in Digital Health Technologies Research".