4-34.b Institutional Review Board and Human Subjects

1. General Information
	1. The Institutional Review Board (IRB) at Weber State University (WSU) is a committee designated to review and approve research involving human participants prior to the initiation of such research, and to conduct periodic reviews of such research. Federal regulations require that any institution requesting and receiving funds from a federal department or agency for research involving human subjects must assure that such research is reviewed and approved by the WSU’s Institutional Review Board (IRB).

The IRB operates according to Title 45 Code of Federal Regulations (CFR) part 46, Federal and State guidelines, and the Belmont Report. International studies involve the use and guidance of the International Code of Harmonization.

* 1. The Office of Sponsored Projects (OSP), in coordination with the IRB will keep WSU in good standing with the Office of Human Research Protections (OHRP). OSP will also maintain current roster information reported to the OHRP. These tasks will be accomplished by the OSP IRB Representative.
	2. Detailed institutional standard operating procedures (including definitions, forms, procedures, and references) for conducting research involving human subjects are provided in expanded description in a manual entitled “WSU Policies and Procedures for Research Involving Human Subjects.” This document is available from the OSP office(electronic or Hard copy).
1. Policy
	1. IRB Authority
		* 1. WSU recognizes the IRB as the leader of the institution’s human subjects’ protection program and as having full jurisdiction over all research conducted with human subjects by WSU faculty, staff, or students, whether funded or unfunded. The IRB has full authority to disapprove, modify, or approve studies in keeping with ethical and sound research design and in adherence to the guiding principles of the IRB. The IRB can implement or modify policies and procedures only by a vote of the Board at a convened meeting. New policies and policy modifications adopted by the IRB also must be approved by the Provost. The IRB must disseminate modified policies and procedures to the university community.
			2. Principal investigators (PIs) who propose human subject research must follow the guidelines for preparing and submitting proposals to the IRB outlined by the WSU IRB. This includes all research activities that involve human participants in any manner or that involve records about human subjects.
2. IRB Meetings
	1. WSU’s IRB is convened by the Chair, or the Chair’s designee, at a minimum of two times per year. Additional meetings may be convened, as appropriate, provided that the IRB Chair provides sufficient notification 48 hours prior to such meeting to the IRB Committee.
	2. No member of the IRB may participate in the review and approval process for any project in which he or she has an actual or potential conflict of interest.
3. External Experts

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

1. IRB Lead Reviewers

In order to facilitate the review of new protocols at convened meetings of the board, whenever possible lead reviewers from the college will be assigned to each new protocol or continuing review in advance of the convened meeting at which that protocol is to be discussed. The Chair, at his/her discretion may appoint lead reviewers for amendments to protocols. Each individual will be responsible for advanced review of the submission, noting areas requiring further inquiry or that may require revision. When necessary, lead reviewers will communicate with the principal investigator, either directly or via the IRB Chair, to secure information to facilitate the review of the protocol. The reviewers will submit their analysis of the proposed research to the IRB in writing sufficiently in advance of the convened meeting to allow for dissemination.

1. Levels of Review and Decisions
2. Types of Review
3. College-Level Review

This level of review is reserved for research that represents no more than minimal risks to participants and does not involve subjects who are vulnerable to coercion or undue influence. This level of review is conducted by the college level representative (CR). The CR from the college determines if the protocol does not warrant an expedited or full review( is exempt from further review). These protocols are to be reviewed by the IRB Chair or a designee from the IRB determined by the IRB Chair. The CR reports the recommendation that the study is exempt from further review to the IRB. The IRB Chair may review the college level representative’s determination and may require a higher level of review.

1. Expedited Review

This category is reserved for studies that exceed what is permissible as exempted research, but also do not represent more than a minimal risk to the subjects involved. The CR reviews the study and recommends this level of review. At the discretion of the IRB Chair or Chair’s Designee, a protocol may be elevated from expedited to full review. The expedited review is typically conducted by the IRB Chair; however, the IRB Chair (or the IRB designee in the absence of the IRB Chair) may assign an experienced IRB member to conduct the expedited review.

1. Full Review

Full review by the entire IRB is intended for research that does not meet the college-level review or expedited levels of review, studies that have more than minimal potential risk to human subjects, and/or involve certain vulnerable populations including, but not limited to, prisoners, children, pregnant women, neonates, fetuses, fetal material, and students.

1. Appeal of IRB Actions and Determinations

a. WSU will allow the PI to appeal decisions of the convened IRB. In keeping with federal regulations and institution policy, research may only be disapproved by the IRB at a convened meeting and no external body, institutional official, or other individual may approve research that has not received approval of the IRB or has been disapproved by the IRB.

b. If the PI wishes to appeal a decision of the full IRB board, the researcher may submit in writing an appeal to the Provost and to the Chair of the IRB. The investigator’s statement must outline the reasons for the appeal. Appeals to the IRB must be made within 30 days of the date the investigators received notification of the IRB’s decision. The Provost and IRB chair will then review the appeal, the minutes of the respective IRB meeting(s), the IRB file, and other documentation. If the Provost and the Chair feel the protocol should be considered by the board again, it will be placed on the agenda for the next IRB meeting. The board may invite the investigator to attend the meeting of the IRB to provide additional information if necessary. The investigator may not be present for any discussion or voting conducted by the IRB.

c. If the PI wishes to appeal a decision made by the CR or the Chair, following expedited or college level review, he/she may submit in writing the appeal, and request that the protocol be reviewed at the expedited level (if the PI is appealing a college level decision) or full (if the PI is appealing an expedited decision).

1. Monitoring of Approved Research, Approval Duration, and Continuing Review

It is the responsibility of the IRB to govern research that has been approved to ensure that research is conducted in accordance with governmental guidelines and regulations and with IRB requirements.

1. Suspension and Termination of Research

The IRB has authority to suspend or terminate research that is not being conducted in accordance with the IRB’s requirements, other institutional and federal requirements, or has been associated with any unexpected serious harm to subjects.

1. Unanticipated Problems, Adverse Event, and Investigational New Drug (IND) Safety Reporting

The investigator must promptly report any unanticipated problems or adverse events to the chair of the IRB. The investigator must also report the adverse event to a study sponsor (via the sponsor’s adverse reporting system) or the Food and Drug Administration, if applicable. Investigators must also report to the IRB any IND safety reports received by the last business day of the month in which the report was received. IND safety reports must be accompanied by investigator attestation that he or she has reviewed the IND safety report.

1. Amendments to Research

It is within the responsibility of the IRB to govern research that has been approved to ensure that research is conducted in accordance with governmental guidelines and regulations and with IRB requirements. In order to effectively do this, the IRB must review amendments (researcher-initiated revisions) to previously approved research prior to their implementation except when immediate implementation is necessary due to apparent hazard to subjects.

1. Verification of Compliance with Approved Protocols from Sources Other than Investigators

In keeping with the IRB’s responsibility to conduct ongoing monitoring of approved research, the IRB may, as appropriate, independently inquire into allegation of non-compliance and verify that research is being conducted in accordance with approved protocols and/or that study procedures are not harming subjects.

1. Responsibilities of a Researcher
2. Information the principal investigator (PI) provides to the IRB.
	1. The PI provides study-related information to the IRB using the appropriate forms - New Protocol Form (Submission Form for Initial Review), Submission Form for Continuing Review of IRB Approved Studies, or Submission Form for Amendment of IRB Approved Studies.
	2. Investigators also provide copies of the proposed informed consents/assents . Investigators should review the Informed Consent policy for more information as to informed consent requirements. Once the consent forms are approved, the IRB provides researchers with copies that are stamped “approved” and indicate the date of approval of the document and the date of continuing review of the research.
	3. For federally funded studies, the investigator must also provide the IRB with a copy of the funded proposal.
	4. As noted in the Adverse Event/Unanticipated Problems policy, investigators must report adverse events, unanticipated problems, or safety reports to the IRB.
	5. As noted in the Monitoring of Approved Research, Approval Duration, and Continuing Review policy, investigators must report to the IRB information related to the study during continuing review periods.
	6. For all studies approved at the expedited or full review levels the PI are requested to provide a closing report within 30 days of the completion of the study, with one copy to the IRB Chair and one copy to the OSP IRB Representative.
3. Ensuring prompt reporting to the IRB of changes (amendments) in research activities

An investigator must notify the IRB of any proposed changes in the protocol or consent forms prior to the initiation of these changes.

1. Equitable Subject Selection

Subject selection must be equitable. In making this assessment, the IRB will need to take into account the purposes of the research and the setting in which the research will be conducted and will be particularly cognizant of the special problems of research involving vulnerable populations, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons.

1. Professional Qualifications to Conduct Research

An investigator must demonstrate to the IRB that he/she is qualified to conduct the research. Additionally, as noted in the Human Subjects Research Training policy, the investigators must demonstrate completion of the CITI training.

1. Federal/State Regulations

An investigator must follow all federal and state regulations when he/she conducts research.

1. Audit/Review

Investigators conducting research approved by the WSU IRB agree to onsite audit by individuals identified by the WSU IRB and/or the Provost.

1. Communication from Regulatory Agencies

Investigators conducting research approved by the WSU IRB agree to notify the WSU IRB Chair and the OSP IRB Representative of any communications received from regulatory agencies, including but not limited to, the Food and Drug Administration (FDA) and the Office for Human Research Protections (OHRP).

1. Non-Compliance

The IRB encourages those who are aware of, or concerned about the potential misconduct by researchers, to report their concerns to the IRB Chair or the Provost. University employees and students are required to report their concerns promptly. The IRB will maintain a climate that fairly evaluates reports of potential misconduct, and protects the “whistleblower” from retaliation.

1. Informed Consent
2. General Items

The Principal Investigator (PI) is required to submit informed consent forms in keeping with WSU requirements and federal regulations. An Informed Consent Form Checklist and model consent and assent forms are provided to assist researchers in completing consent forms that are in keeping with WSU requirements.

2. The IRB may, at its discretion, require elements in the informed consent that exceed the requirements of the OHRP and the FDA.

1. Researchers conducting human-subjects research outside of the state of Utah shall review and adhere to applicable law, particularly those regulations that apply to wards and minors. The IRB may require researchers to provide documentation with respect to local laws and may also conduct information searches to determine appropriate local laws.
2. Cooperative Research: For studies conducted at cooperative research sites where another IRB exists, the PI should contact that IRB to discuss its consent form requirements.
3. Individuals under 18 years of age cannot serve as research subjects unless their parents or legal guardians have given written consent for them to participate. Passive consent, or an opt-out, is not consistent with federal regulations noted in 45 CFR 46.116.
4. Training for Individuals Involved in Human Subject Research
5. To meet federal requirements on investigator training for those conducting human subjects research and the desire of WSU to ensure that our research meets the highest ethical standards in the protection of human subjects, WSU requires all individuals involved in human subjects research to satisfactorily complete (with at least a 90% passing score) the CITI (Cooperative IRB Training Initiative) program on human subjects research. This includes all studies that involve human subjects in any manner as well as research on medical, psychological, educational, or other records derived from individuals.
6. The principal investigator and all co-investigators must have documented CITI course completion before their IRB proposal will be reviewed. All members of the research team involved in human subjects testing (e.g. staff, students, volunteers) must achieve CITI certification before participating in the research project. Individuals participating in the research who will not have any contact with human subjects or subject identifiable data are exempt from this policy.

The IRB will make CITI training available to everyone at WSU at no cost to individuals.

Individuals conducting research must maintain their CITI training certification which expires every three years.

1. All individuals who are members of WSU’s IRB must complete all training modules (for all disciplines) and maintain their training certification which expires every five years.
2. Research With Children

Research involving children is permitted in certain instances if adequate provisions are made for soliciting the assent of the children and the permission of parents or guardians. Detailed institutional procedures for conducting research involving research with children are provided in expanded description in a manual entitled “WSU Policies and Procedures for Research Involving Human Subjects” This document is available at the Institutional Review Board’s OSP office

1. Research With Prisoners

Because prisoners may be under constraints due to their incarceration that could affect their ability to make a truly voluntary and un-coerced decision about whether or not to participate as subjects in research, researchers must adhere to additional safeguards for the protection of prisoners. Detailed institutional procedures for conducting research involving research with prisoners are provided in expanded description in a manual entitled “WSU Policies and Procedures for Research Involving Human Subjects” This document is available at the Institutional Review Board’s OSP office

1. Research with Pregnant Women, Neonates, Fetuses, and Fetal Material
	1. Studies that do not place the mother or fetus at greater than minimal risk and are reviewed and determined as exempt at the center level (as allowed by 45 CFR 46.101(b)(1)-(6)) may include pregnant women as subjects. Routine exclusion of women who are or may be pregnant reduces research generalizability and is not recommended; however, when there are risks, or the risks are unknown or there is concern for liability, the researcher may be justified or may be required to use pregnancy or potential for pregnancy as exclusionary criteria.
	2. Detailed institutional procedures for conducting research involving research with Pregnant Women, Neonates, Fetuses and Fetal Material are provided in expanded description in a manual entitled “WSU Policies and Procedures for Research Involving Human Subjects” This document is available at the Institutional Review Board’s OSP office
2. Student Research

1. Assignments for Class:Research conducted by students, graduate or undergraduate, as a part of classroom assignments does not usually fall under the federal regulation of research because it is not intended to or likely to lead to generalizable results. Rather, the activities are resources of teaching which facilitate learning of concepts and the opportunity to practice various procedures, including research methods (interviewing, observation and survey techniques, as well as data analysis). While most assignments for class do not require IRB review, some do as a result of the vulnerability of subjects or the potential risk to subjects including:

1. Studies in which children will be interviewed or surveyed.
2. Studies in which children are being observed, and data collected, where the investigator is also a part of the activities being observed.
3. Studies involving prisoners, the mentally disabled, or pregnant women.
4. Studies that ask subjects about illegal activities and which place the data at risk for subpoena and/or the subject at risk for loss of civil liberties.
5. Studies in which subjects are at risk of breach of confidentiality, such as ones that ask sensitive or intrusive questions about behaviors.
6. Studies that place subjects at risk due to emotionally charged subject matter.
7. Instructors are advised to discuss these issues with their students and clarify the role of the IRB should the student be interested in pursuing a research activity that might necessitate IRB review. Instructors should contact their IRB College Representative for more information.
8. Instructors are expected to review the proposed research to determine if it meets the definition of student research and is permissible under these guidelines. In instances where a class of students will be conducting group or individual research projects as a part of the classroom instruction, and the instructor believes that, under WSU-IRB guidelines, IRB approval is required, the instructor shall present for IRB approval one application setting forth the information requested within IRB documents.
9. Student researchers should also note that if there is any likelihood that the results of the project might later be used for research that does lend to generalizable knowledge (for example, within a dissertation or a presentation to a group other than the class), IRB approval must be secured prior to conducting the research activities.
10. IRB approval cannot be granted retroactively. It is expected that any data collected as a class project will be destroyed after the grading of the project has been completed.
11. Theses and projects involving human subjects are considered research as defined by 45 CFR 46 and require review by the IRB (beginning with the College Representative of the researcher’s college/school).
12. Research Conducted With Students as Subjects
13. Extra Credit/Credit**:** The Institutional Review Board (IRB) does permit giving extra credit/credit to students who participate in research only when alternative means of obtaining credit are available to students who do not wish to volunteer for research. The extra credit/credit must be calculated and announced to the class within the syllabus, in advance. Additionally, the non-research extra credit activities must be comparable in time/commitment as the research activities. The IRB will likely consider non-research activities that are not comparable to the proposed research activities as coercive. In order to maintain the voluntary nature of participation in research, students should also be able to elect to leave the research activity at any time and complete one of the other non-research extra credit activities to be able to still earn the credit.
14. Informed consent must be done in writing for all student participants.