UNIVERSITY of Western States

Institutional Review Board

MANUAL

University of Western States | 8000 NE Tillamook Street Portland, Oregon 97213

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Contents

Introduction

IRB Policy

This manual establishes the guidelines, responsibilities and procedures for the Institutional Review Board (IRB), which assures the protection of human subjects participating in projects sponsored through University of Western States (UWS). It also serves to implement the specific requirements of the United States Department of Health and Human Services (HHS), Office for Human Research Protections (OHRP), for the protection of human subjects (Code of Federal Regulations, Title 45, Part 46, Protection of Human Subjects). The procedures and guidelines set forth in this policy apply to all activities, irrespective of funding source(s), involving human subjects for whom University of Western States is responsible.

The IRB administrator, with oversight from the vice president for academic affairs, is responsible for preparing and maintaining this policy as well as ensuring associated procedures are developed, documented, and implemented. It will be renewed and updated as indicated by UWS Policy 1001 Policy Development and Publication. A violation of this policy may result in a disciplinary action including temporary or permanent suspension of research activities up to academic dismissal or termination of employment.

UWS makes every effort to protect the rights and welfare of all human subjects who choose to participate in research associated with the university. As a result, the university has an organized and established system for the protection of research subjects that is in line with the principles of the Belmont Report. The university maintains an Institutional Review Board (IRB) registration (IORG #0001188) and a Federal Wide Assurance (FWA) of compliance with the Office for Human Research Protections at the Department of Health and Human Services (FWA #00000851). The IRB administrator will maintain and update the UWS IRB registry annually via the online registration platform through the Office for Human Research Protections. Additionally, the FWA is also updated annually and commits the university to abide by the Code of Federal Regulations title 45, part 46.

Human research protections at UWS encompass faculty, staff and students who conduct human subject research; the Institutional Review Board, which is responsible for reviewing and approving human subject research activities; and the UWS office of research and sponsored programs, which enables faculty and staff development activities related to research, scholarship and sponsored program efforts. The IRB is afforded the independence necessary to carry out its duties. The office of research and sponsored programs also provides an interface between investigators and the IRB as needed to ensure research is conducted with integrity and in compliance with all applicable regulations.

Statement of ethical principles

University of Western States accepts the following as ethical principles:

a. No human being is to be exposed to unreasonable risk to health or well-being;
b. The rights and welfare of all subjects involved in research, training, demonstration, development and other activities who are subject to risk shall be adequately protected;
c. The risks to an individual must be outweighed by the potential benefit to them or by the importance of the knowledge to be gained;
d. Adequate and appropriate informed consent is to be obtained without duress or deception in those cases where human beings will be or are likely to be "at risk;" and
e. Procedures are consistent with sound research design.

All persons involved in initiating, approving, conducting or supervising activities involving human subjects must be aware of their joint responsibility for the welfare of the individuals who serve as subjects.

Prior to proceeding, the principal investigator (PI) must have adequate knowledge of the possible consequences of their research, demonstration, and/or a demonstration directed by them. This is generally substantiated via a review of the relevant literature and is included with the IRB application.

Whenever possible or relevant, any potential hazard to health resulting from procedures using human subjects must be first investigated through animal research.

Whenever operative procedures (e.g., minor surgery) or exposure to hazardous environmental conditions are used (or occur), the activity must be performed under the supervision of licensed health care providers or other qualified personnel.

The nature of the activity, the procedures to be followed, and the possible risks involved must be carefully and fully explained to the subject, parent, or guardian, as appropriate. The explanation must have been fully understood and informed consent obtained as appropriate.

The subject's privacy must be protected and confidentiality maintained in accordance with all applicable laws and regulations.

Any subject may request termination of their participation in an experiment at any time, and this request will be honored promptly and without prejudice.

Remuneration may be offered to a subject as recompense for their time, provided that such remuneration does not constitute an improper inducement, as determined by the IRB.

If participation as a subject is part of the academic work of a student, it must not be a coercive requirement and, as appropriate, informed consent must be obtained. (For example, instructors may not coerce students to serve as models for demonstration or inspection.)

Definitions

Subject: “Human subject” means a living individual about whom an investigator (whether professional or student) conducting research: (1) obtains information or biospecimens through intervention or interaction with the individual and uses, studies or analyzes the information or biospecimens; or (2) obtains, uses, studies, analyzes or generates identifiable private information or identifiable biospecimens. Depending on the circumstances, human subjects could include patients, classroom models, volunteers and students.

The unborn and the dead should be considered subjects to the extent that they have rights that can be exercised by their next of kin or legally authorized representatives.

Principal Investigator (PI): An individual who has full responsibility for the oversight of a human subjects research project; generally, a UWS faculty member, researcher or a staff member or administrator with the appropriate qualifications. UWS EdD students may serve as a PI on projects covered by the UWS IRB with the oversight of their faculty advisor or sponsor who must serve as a co-Principal Investigator. UWS students who are not EdD students may

not serve as a PI on projects covered by the UWS IRB and are required to conduct research under the oversight of a UWS faculty member, research, or authorized staff member or administrator.

Co-investigator: A member of a human subjects research team who plays a major role in one or more aspects of the project (e.g. conceptual design, technical implementation, project administration, statistical analysis, etc.). Students authorized to conduct research to fulfill thesis, practicum or other academic requirements, as well as voluntary research projects, are considered co-investigators, and therefore are required to have a qualified UWS faculty member, researcher or authorized staff member or administrator serve as the study's primary principal investigator. The exception for student researchers is for EdD students, as noted above.

At-Risk: An individual is considered to be "at risk" if one may be exposed to the possibility of any harm—physical, psychological, sociological or other—as a consequence of any activity that goes beyond the application of those established and accepted methods necessary to meet the individual's needs.

Physical risks: Unusual physical activity required of a subject, or the imposition of adverse stimulation or adverse social situation. This includes any activity that might endanger the subject's physical well-being (e.g., taking blood samples or chiropractic adjustments).

Psychological risks: The invasion of a subject's privacy is held to be a "risk." Subject confidentiality must be consistently maintained. Any procedure that may conceivably produce humiliation, embarrassment, loss of self-esteem, feelings of failure or frustration, feelings of anger toward the researcher or others, or even acute boredom can be considered undesirable outcomes of the research and demonstration experience; hence, such procedures are considered as placing the subject "at risk." Any personality change or change in the subject's feelings or motivation that extend beyond a normal debriefing period, must be considered undesirable and possibility of their occurrence constitutes "risk." A subject's personal stimulus value to their peers, such as would be represented by the term "reputation," is of value to them, and the possibility of its being damaged also constitutes "risk."

Social risks: Those procedures that may place the reputation or status of a social group or an institution in jeopardy. Even when procedures do not impinge directly upon a group or institution, it may be derogated or its reputation injured. In evaluating social risk, the investigator should ask how the findings would appear to persons belonging to any identifiable group studied and reported upon.

Minimal risk: The probability and magnitude of harm or discomfort anticipated in the proposed activity are no greater than those encountered in daily life or during the performance of routine physical or psychological examination or tests.

Informed consent: A legally effective agreement obtained from a subject or their authorized representative providing for the subject's participation in a project or activity.

Responsibilities of the IRB

The IRB will review proposals for all university research projects involving human subjects and recommend acceptance, rejection or modification of methodology based upon applicable federal and state laws and University of Western States policies and the IRB's assessment of research design validity, investigator qualification, risk-benefit, voluntary informed consent, protection of privacy, safety assurance and compensation for injury.

No university research project may be conducted and study subjects cannot be recruited without IRB approval [§46.113]. IRB approval does not preclude the necessity for project approval by other institutional authority [§46.112]. PIs must critically evaluate research proposals, utilizing peer review and expert consultation, before submitting proposals for IRB review.

In addition to the review responsibilities set forth in this policy, the IRB also has the following additional responsibilities:

- Make available to investigators federal guidelines regarding requirements for informed consent and criteria for acceptance of proposals.
- Periodically review and update the criteria and process used to evaluate the protection of human subjects.
- Make policy recommendations to the administration regarding protection of human subjects.
- Provide oversight to ensure university-sponsored research upholds with HIPAA and FERPA regulations.
- Prepare and maintain minutes of IRB meetings.
- Maintain appropriate written records: project proposals, consent forms, correspondence, reviews, updates, and subject injury; a list of IRB members including names, degrees, titles and employment status. Records must be kept for three years following project completion [§46.115, §46.117]. All hard copy records will be stored in the office of research and sponsored programs on campus in a secured, locked filing cabinet that is accessible to the IRB administrator. Electronic records will be stored on a secured server in a shared folder accessible to the IRB administrator and IRB chair. IRB minutes are submitted to the university's committee archives and records are accessible for inspection and copying as required by government regulations. The IRB will receive an annual report of open and closed research projects that were sent for full board review (e.g., the IRB board will not receive notice on exempt or expedited research projects).

Membership

The IRB shall consist of not less than five (5) voting members. Appointment of the chair and members of the committee is consistent with the current institutional procedures for committee appointments. Appointment is continuous unless removed. Members must possess varying qualifications, backgrounds and experience that will assure complete and adequate review of projects and activities commonly administered or sponsored by a health science university. The UWS IRB committee ranges between five (5) and eleven (11) members. One (1) member must have primary concerns in the non-scientific profession, one (1) member must have primary concerns in the scientific area, and at least one (1) member must not otherwise be affiliated with UWS through employment or familial relationship. [§46.107]

An IRB member should be considered a non-scientist if that individual's training, background and occupation would incline them to view research activities from a standpoint outside of any

biomedical or behavioral scientific discipline. The membership may not consist solely of members of one profession.

The IRB may establish subcommittees as deemed necessary by workload or other considerations. Such subcommittees, constituted within teaching or research units, are normally chaired by a member of the committee. The functioning of such subcommittees is informal and their main role is to provide a focus of expertise within a specific unit for the rendering of advice and assistance and preliminary review of the adequacy of protocols. In accordance with the Department of Health and Human Services (DHHS) requirements, only the IRB or a quorum thereof may finally review a project involving human subjects and issue certification that the requirements of both university and HHS policy have been satisfied.

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

IRB member responsibilities

1. Execute their responsibilities in accordance with UWS policies and applicable federal, state and local and laws.
2. Complete the required human subjects training and other supplementary training as deemed necessary by the IRB chair and IRB administrator.
3. Ensure that the criteria for IRB approval at 45 CFR 46.111 are met for all review assignments.
4. Maintain confidentiality for all matters before the IRB, all expedited reviews, and IRB consultations.
5. Disclose conflict of interests for a project subject to IRB review at a convened meeting; refrain from the discussion except to provide information requested by the IRB and leave the room during voting.
6. Consider the adequacy of inclusion and exclusion criteria to enroll individuals most likely to benefit from and least likely to be harmed by the research.
7. Determine if the inclusion and exclusion criteria have an ethical basis.
8. Verify the adequacy of the consent document for informing subjects about the research, including risks and benefits.
9. Evaluate the clarity and appropriateness of the information in consent documents with consideration for the sample populations.
10. Verify the consent documents are consistent with IRB protocols.

Attendance requirements

1. Attend at least 75% of scheduled IRB meetings.
2. Arrive promptly and stay at convened meetings until all committee business and training has been completed.
3. Review the entire study protocol, including recruitment and consent materials, for all projects on the agenda for IRB meetings.
4. Participate in IRB discussions of protocols.

Meeting requirements

An IRB meeting cannot occur unless a quorum, consisting of the majority of the members, is participating and least one member is participating whose primary concerns are in non-scientific areas.

Any or all members may participate by teleconference, videoconference or similar technology, but only when it can be documented in the meeting minutes that those members received all pertinent materials before the meeting and were able to actively and equally participate in all discussions.

Additional responsibilities of the IRB chair

1. Maintain compliance with regulatory requirements, the Belmont Report, state laws and university policies.
2. Ensure the criteria for IRB approval and other relevant requirements (e.g., consent waivers/alterations, waivers of signed consent, determinations for vulnerable populations) are met before projects/packages are approved.
3. Ensure a determination is made and voting takes place for each action item on the agenda.
4. Inform PI of the status of their research protocol.
5. The IRB chairperson received specific IRB chair training through the Collaborative Institutional Training Initiative (CITI). All IRB members including the IRB chairperson, as well as administrative support staff and investigators receive training through the National Institutes of Health (NIH) on protecting human research participants via an online module.

Term of service

Committee and chairmanship appointments range from one to three years and are renewable at the mutual agreement of the university president and the appointee. It is recommended that the chair has at least one year of membership experience on the UWS IRB prior to accepting this appointment.

1. An IRB member conflict of interest is defined as those circumstances in which an IRB member's personal interest conflicts with, may affect, or has the appearance of affecting human subjects or the integrity of human subject research. This includes the interest of an IRB member and his or her immediate family (i.e., spouse, children, persons with whom he or she maintains living arrangements that approximate a family relationship) which may affect, or has the appearance of affecting the human subjects or the integrity of human subject research.

   A conflict of interest for the IRB chairperson, members, alternate members and investigators include:
   a. Financial stake in the sponsorship of research or other type of personal or professional stake in the study.
   b. Financial interest of any business transaction(s) involving the study sponsor, affiliated entities, or any organization or enterprise that has done or is doing business with the study sponsor.
   c. Financial stake or interest in the outcome of the research study.
   d. Academic/intellectual bias that may interfere with the research process for the purpose of intangible personal gain.
   e. Personal beliefs or moral conflicts of interest.

No IRB member with a declared conflict of interest may participate in the review. IRB members who realize they have a conflicting interest must notify the chair immediately. The chair will begin each meeting with a reminder that each member must disclose any conflicting interest and recuse him or herself from the vote on the project by leaving the room. If the chair has a conflict, they may not chair the meeting involving the proposal with which the chair has a conflict of interest.

Types of review

Criteria for exempt review

Exempt research includes:

1. Research only conducted in established or commonly accepted educational settings involving normal education practices (45 CFR 46.101(b)(1)).
2. Research involving the use of educational tests, survey procedures, interview procedures and/or observation of public behavior (45 CFR 46.101(b)(2)).
3. Research involving collection or study of existing data, documents, records or pathological and/or diagnostic specimens (45 CFR 46.101(b)(4)).
4. Research studying, evaluating, and/or examining public benefit or service programs (45 CFR 46.101(b)(5)).
5. Research involving taste and food quality evaluation and/or consumer acceptance studies (45 CFR 46.101(b)(6)).
6. Research that has been previously reviewed and approved by the committee that is up for annual or continued renewal with no substantive changes to the protocol or study population, including no more than minimal risk to the study population.

Criteria for expedited review

An expedited review may be conducted for proposals with minimal risk or for minor changes in previously approved projects.

Either the chair or an assigned reviewer will conduct the review. Documents that the study staff will have available to the chair or assigned IRB members include, as applicable: complete study protocol; proposed consent, assent, or HIPAA documents; proposed consent or assent scripts; recruitment materials; participant contact materials; any relevant grant applications; PI's brochure or other study product information; and disclosures of financial and other conflicts of interest.

While the chair or assigned reviewer can approve a proposal through expedited review, no proposal may be disapproved without a vote at a convened meeting of the board. [§46.110(b)].

A list of proposals that underwent expedited review will be listed in the meeting agenda of the IRB meeting that most closely follows the time of expedited review. Any member can request to review the record associated with proposals that underwent expedited review.

Not research or not human subjects research

1. The IRB has determined the proposed activities do not meet the definition of research under 45 CFR 46.102(i) or do not involve human subjects as defined in 45 CFR 46.102(e)(1).
2. All studies conducted at University of Western States are subject to IRB review.

Review of documents

For each item to be considered by a convened IRB, all committee members will conduct a comprehensive review of all submitted materials for the assigned item prior to the meeting, present findings resulting from that review, provide an assessment of the criteria for approval, and recommend specific actions to the IRB.

New applications

All faculty, staff, and students conducting research at UWS must apply to the IRB and receive approval before any research is conducted. Faculty members who have a primary appointment with UWS will submit their research materials to the UWS IRB. If more than one school is involved in the proposed research, the investigators will apply to the PI's institution IRB as well as the other investigator's IRBs. The PI's institution can determine whether to oversee or default responsibility to another institution.

Current students of UWS who propose research outside of class assignments must apply to and receive approval from the UWS IRB prior to conducting research. In addition, class research assignments that include human interaction and intervention must also apply to and receive approval from the UWS IRB. All students must have a designated a faculty member to oversee the project. The faculty member will serve as the project PI, except in the case of EdD students who will serve as project PI and have their faculty sponsor or advisor as a co-Principal Investigator.

All UWS employees and students can refer to the IRB administrator and/or the research and sponsored programs office for more information.

Documents that the study staff will have available to the assigned reviewers include, as applicable: complete IRB application and study protocol; proposed consent, assent or HIPAA documents; proposed consent or assent scripts; recruitment materials; participant contact materials; any relevant grant applications; investigator's brochure or other study product information; Disclosures of Financial Interest and other conflict of interest materials, including the Conflict of Interest Statement; certificate of completion for CITI training (EdD students only); appropriate Vulnerable Populations Worksheet (as necessary); and reviews by other committees. If the study involves institutional data from UWS, there should be a letter from the campus provider of the data, approving use of data and timeline need.

When a member of the IRB is not an assigned reviewer, the member is to review, at a minimum, the following materials to prepare for active participation in the discussions and the vote.

1. The full protocol, application, or a summary of sufficient detail to make the determinations required under HHS regulations at 45 CFR 46.111
2. Proposed consent, assent, or HIPAA documents
3. Proposed consent or assent scripts
4. Any recruitment materials

IRB members will present findings and recommendations during the convened IRB meeting.

Modifications to previously approved research

1. All IRB members shall review the revised materials. Assigned reviewers will conduct a review of the request for modifications in accordance with the criteria for approval and assess whether the proposed modifications are consistent with ensuring the continued protection of subjects. In addition, assigned reviewers will consider whether:
    a. Any new significant findings have arisen that may impact the subject's willingness to continue participation.
    b. Any new information resulting from the modification or from other sources necessitates an adjustment to the IRB's prior determination(s), such as inclusion of protected or vulnerable populations and findings regarding FDA-regulated products.
    c. The proposed modifications to the research require revision of the consent document(s), and if so, whether the revised consent documents are accurate and understandable to the subject population.
    d. The modifications warrant re-consenting of currently enrolled subjects or notification of subjects who have completed research interventions.
    e. Continuing review should occur more frequently than previously determined.
    f. Assigned reviewers will present findings and recommendations during the convened IRB meeting.

Actions by the IRB

After reviewing the materials and considering assigned reviewers' findings and recommendations, the IRB will make one of the following determinations:

1. Approved
   The IRB has determined research activity and submitted materials meet the criteria for approval set forth in 45 CFR 46.111 (and 21 CFR 56.111 and/or 32 CFR 219.111, when applicable). The IRB will issue an approval only if a majority of the members participating in the meeting vote to approve [45 CFR 46.108].

2. Deferred
   The IRB has determined that modifications or actions by the PI are required for the research activity and the materials to meet approval criteria.

3. Disapproved
   The IRB has determined that the research activity and submitted materials do not meet the criteria for approval and substantial revisions will be required.

4. Exempt
   The IRB has determined the proposed activities meet the criteria for exemption set forth in 45 CFR 46.104.

Submission procedures

New applications

Determining that the criteria for IRB approval of research are met

To approve a research proposal, the IRB must determine that all of the following requirements are satisfied:

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

Overview of IRB process

1. The PI and co-investigators are responsible for reviewing and completing all required and supporting documents available in Udocs, under the Institutional Review Board header.
2. The PI will send materials to the irb@uws.edu to be evaluated for completeness. Suggestions may be made, and additional materials or edits may be requested.
3. The PI will make the necessary edits and electronically submit all IRB forms and protocols to irb@uws.edu.
4. The IRB chair or IRB committee will make a determination of the status of the research proposal. The application will either be approved, disapproved, or sent back for further revisions.
5. The PI will be notified of the status of their proposal and any necessary edits.
    a. Approval status: The PI can start conducting proposed research.
    b. Needs revisions: The PI revises the protocol and addresses IRB committee concerns, then resubmits their protocol for review.

c. Disapproval: The PI reviews the IRB's comments and reasons for disapproval. The PI can file a grievance via email and request further information and/or a meeting with the IRB chair regarding their proposed research project.

Collaborative Research

Collaborative research projects are those projects that involve more than one institution. In the conduct of collaborative research projects, each institution is responsible for safeguarding the rights and welfare of human subjects.

Principal investigators may conduct cooperative research with individuals at organizations or institutions that are not owned or operated by UWS. If the collaborating researcher's institution has an IRB, the study team must submit the required documents and receive approval from every participating institution's IRB prior to conducting the research project. At its discretion, the UWS IRB may decide to share oversight of the project or defer to collaborating IRB(s).

In addition, PIs must provide the UWS IRB with information regarding the facility and population targeted in the research. A letter of support from the site where the research will be conducted is required by the IRB. A letter of support is also required of an organization providing the PI with private information (e.g. contact information) about their employees, students, etc. for recruitment purposes.

PIs are responsible for ensuring the administrator signing the letter of support understands the IRB's expectations of the PI and has the authority to make those assurances. Letters of support must be printed on the facility's letterhead, signed by the administrator, and include the following:

- A statement that the site administrator has reviewed the research and has found it appropriate for the population of that facility;
- A statement allowing the PI to conduct the research activities on site and if applicable, indicating there are appropriate resources available to conduct the research;
- Contact information for an individual who will represent the facility in matters related to the conduct of human subjects research; and
- A statement that based on the risks associated with the research, there are adequate provisions to handle unanticipated problems and/or adverse events as applicable.

Deviations from approved protocols

When a protocol deviation occurs, the PI must report the deviation to the IRB administrator and the IRB chair regardless of whether the incident is minor, serious, or continuing.

Resubmission procedures

Changes to approved research (include verification regarding material changes and reviewing changes in research)

The IRB will inform investigators that they may not initiate changes to research without prior IRB review and approval except when necessary to eliminate apparent immediate hazards to subjects (e.g., through training programs, materials for investigators, specific directives included in approval letters to investigators). The IRB will require investigators to notify the IRB of any changes made to eliminate apparent immediate hazards to subjects that did not have prior IRB approval.

The IRB will perform random audits of research records to ensure that changes in research are being reported to the IRB before they are initiated.

Upon learning of changes in research, the IRB will:

1. Determine the level of review required for the proposed changes.
2. Review the proposed changes in accordance with approval criteria and determine whether the changes are consistent with ensuring the subject's continued protection.
3. Review changes initiated without prior IRB approval that eliminate apparent immediate hazards to the human subjects and determine whether each change was consistent with ensuring the participant's continued welfare.
4. Determine that any new significant findings arising from the review process, and possibly impacting the subject's willingness to continue participation are provided to the subject.
5. Determine if any new information resulting from the change or from other sources necessitates an adjustment to the IRB's prior determination.
6. Determine if the proposed changes to the research require revision of the consent document(s).
7. Determine if the modifications warrant re-consenting or notification of subjects including those who have completed research interventions.
8. Consider whether the interval for continuing review as last determined by the IRB should be adjusted based on the modifications.
9. Determine whether the modifications to the research activity may require verification from sources other than the investigator that no material changes have occurred.

The IRB will report its findings and actions for changes in research to the PI and the University of Western States office of research and sponsored programs. The IRB will communicate in writing any modifications or clarifications required by the IRB as a condition of approval. The IRB will review and act on the PI's response to any required modifications or clarifications required by the IRB as a condition of approval. A letter of disapproval must include an explanation. The PI has the right to respond to the IRB in person or in writing [§46.109(d)] and to file a grievance.

Closing out an approved study

The Principal Investigator must formally close their IRB-approved study when (1) they are leaving the university, including graduating from the University, or (2) when the research study is complete. Completion is defined as "data collection has ceased, participants are no longer being enrolled, no follows-ups with participants are planned, and activities (e.g. data analysis, manuscript preparation) that require use of personal identifiable information are complete."

The closure of a study is a change in activity for a research project, which must be reported to the IRB under federal regulations. The key document related to the closure of a research project is the IRB Study and Closure Report. All PIs must submit a closure form when a research project is completed or otherwise closed. This form not only formalizes and documents the closure of a study file, but also

provides the IRB with information pertinent to its review and approval of similar or related studies. Failure to submit a closure form for all closed studies, including those that have expired or lapsed, may cause the IRB to postpone the review and approval of future research protocols.

PIs can find the IRB Study and Closure Report in UDocs, under the Institutional Review Board header.

Criteria for approval

Informed consent

The IRB will review the informed consent form and the informed consent process. Applicants should use one of the informed consent templates that are available on UDocs to ensure that all basic elements are addressed. The template choice is based on (1) how researchers will be obtaining informed consent (signed forms; electronic form with check-box selected) and (2) on the participant population (adults; consent form for parents of minor children, plus assent form for minor children).

During its review of the consent document, the IRB will confirm that the basic elements are addressed. The basic elements of informed consent are:

1. A statement that the study involves research, an explanation of the purpose(s) of the research, the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental;
2. A description of any reasonably foreseeable risks or discomforts to the subject;
3. A description of any benefits to the subject or to others which may reasonably be expected from the research;
4. A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;
5. A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained;
6. For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained;
7. An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights and whom to contact in the event of a research-related injury to the subject;
8. A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled; and
9. One of the following statements about any research that involves the collection of identifiable private information or identifiable biospecimens:
    a. A statement that identifiers might be removed from the identifiable private information or identifiable biospecimens and that, after such removal, the information or biospecimens could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from the subject or the legally authorized representative, if this might be a possibility; or
    b. A statement that the subject's information or biospecimens collected as part of the research, even if identifiers are removed, will not be used or distributed for future research studies.

The IRB will also consider whether additional elements should be incorporated or whether some of the basic elements can be waived or altered, according to regulation [§ 46.116].

The IRB will review the document to confirm that it does not include any exculpatory language through which the subject is made to waive, or to appear to waive, any of their legal rights or to release University of Western States or its agents from liability for negligence.

The IRB will also consider, as applicable: translation of the informed consent form for non-English speaking subjects; a waiver or alteration of the consent procedure; and a waiver of documentation of consent. [§46.116].

The IRB may also review studies requesting an exception from informed consent requirements for emergency research, consistent with HHS guidelines.

Subjects vulnerable to coercion or undue influence

Coercion occurs when an overt or implicit threat of harm is intentionally presented by one person to another in order to obtain compliance. For example, an investigator might tell a prospective subject that he or she will lose access to needed health services if he or she does not participate in the research.

Undue influence, by contrast, often occurs through an offer of an excessive or inappropriate reward or other overture in order to obtain compliance. For example, an investigator might promise a student extra credit if they participate in the research. If that is the only way a student can earn extra credit, then the investigator is unduly influencing potential subjects. If, however, she offers comparable non-research alternatives for earning extra credit, the possibility of undue influence is minimized.

In addition to undue influence that can arise with the offering of rewards, undue influence also can be subtle. For example, patients might feel obligated to participate in research if their physician is also the investigator, or students might feel pressure to participate in research if everyone else in the class is doing so.

The IRB will consider whether the circumstances proposed give rise to influence. The IRB will consider, among other things, whether the informed consent process will take place at an appropriate time and in an appropriate setting, and whether the prospective subject may feel pressured into acting quickly or be discouraged from seeking advice from others

The IRB will also carefully review the information to be disclosed to potential subjects to ensure that the incentives and how they will be provided are clearly described. The IRB will require known benefits to be stated accurately but not exaggerated, and potential or uncertain benefits to be stated as such, with clear language indicating how much is known about the uncertainty or likelihood of these potential benefits.

The IRB will consider whether restrictions on the levels of financial or nonfinancial incentives for participation are necessary.

If the IRB determines that the proposal involves subjects that are likely to be vulnerable to coercion or undue influence, the committee will consider whether additional safeguards have been included to protect the rights and welfare of the subjects.

Research involving children

The IRB may approve three of the four categories of human research involving children. The four categories differ from one another according to the level of risk involved, the prospect of direct benefit to the research subjects, and the anticipated research findings.

For all four categories, the IRB will assure the proposed research activity satisfies the requirements for parental or guardian permission and child assent.

The three categories of research involving children approvable by an IRB are research proposals that the IRB finds that:

1. The risks of the research are no more than minimal;
2. More than minimal risk to children is presented by an intervention or procedure that holds out the prospect of direct benefit for the individual subject or by a monitoring procedure that is likely to contribute to the subject's well-being; the risk is justified by the anticipated benefit to the subjects; and, the relation of the anticipated benefit to the risk is at least as favorable to the subjects as that presented by available alternative approaches; and
3. More than minimal risk to children is presented by an intervention or procedure that does not hold out the prospect of direct benefit for the individual subject, or by a monitoring procedure that is not likely to contribute to the well-being of the child; the risk represents a minor increase over minimal risk; the intervention or procedure presents experiences to subjects that are reasonably commensurate with those inherent in their actual or expected medical, dental, psychological, social or educational situations; and, the intervention or procedure is likely to yield generalizable knowledge about the subjects' disorder or condition which is of vital importance for the understanding or amelioration of the subjects' disorder or condition.

The IRB will refer HHS-conducted or -funded research to the HHS secretary for consideration if the IRB finds that the research does not meet the conditions for approval under the other three categories of research involving children.

To determine that a research activity presents no more than minimal risk, the IRB will compare the possible harms or discomforts experienced in normal daily life or during routine physical or psychological examinations or tests with the possible harms or discomforts that will be faced by subjects as a consequence of research participation. The IRB will also consider the nature of the harms or discomforts (e.g., physical, psychological, legal), as well as the chances that they will occur and the seriousness of their impact if they were to happen.

Reviewing the qualifications of the study staff

Principal Investigator

The Principal Investigator (PI) is ultimately responsible for assuring compliance with applicable university IRB policies and procedures, DHHS Federal Policy Regulations, FDA regulations, applicable state regulations, and for the oversight of the research study and the informed

consent process. Although the PI may delegate tasks to members of the research team, the PI retains the ultimate responsibility for the conduct of the study.

Generally, the PI must be a current employee of the university because the PI responsibilities involve direct interaction and supervision of the research team. Current EdD students may serve as PIs, with their faculty sponsor or advisor as co-PI. PIs leaving the institution are responsible for notifying the IRB well in advance of their departure so that the IRB can make arrangements to either close the study or name another appropriately qualified individual currently at the institution to serve as the PI (See Appendix A for a list of authorized personnel by category).

Faculty members

All full-time faculty members, including residents and fellows, may serve as a PI. Part-time or adjunct faculty of the university are not permitted to serve as a PI unless they are serving as a faculty mentor in the oversight of student research and/or have permission from the dean of their college to conduct human subject research.

Authorized staff and administrators

Other university staff and administrators may serve in this role if they have appropriate qualifications to conduct the research and if they have obtained approval to conduct the research from their immediate supervisor.

General responsibilities of Principal Investigators

As a general condition for the approval of a research study, the IRB holds the PI of the study responsible for:

1. Minimizing risks to research subjects by executing procedures that are consistent with sound research design and not unnecessarily exposing the subjects to risk.
2. Ensuring risks to human research subjects are reasonable in relation to the anticipated benefits (if any) to the individual and the importance of the knowledge that may be expected to result.
3. Selecting and recruiting human subjects and patients for research participation in an equitable manner.
4. Informing individuals of the risks and benefits of research participation and the procedures that will be involved in the study.
5. Obtaining informed consent from each human research subject, or their legally authorized representative, in advance of research participation.
6. Upholding and protecting the privacy of human research subjects and maintaining the confidentiality of data.
7. Implementing appropriate safeguards within the study to protect the rights of human research subjects who are likely to be vulnerable to coercion or undue influence (e.g., children, prisoners, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons).

General responsibilities of the co-investigators and/or research staff

The IRB holds the co-investigator of the study and/or research staff responsible for:

1. Completing the required institutional training related to research and human subjects research.

2. Adhering to the federal and state regulations and institutional policies and procedures surrounding the safety and protection of human research subjects.
3. Assuring participant privacy and confidentiality according to FERPA guidelines, HIPAA guidelines, and institutional policies and procedures.

PI and co-PI conflict of interest

All PI and co-PIs must submit a Conflict of Interest (COI) Disclosure Form to the IRB administrator on an annual basis.

Communicating the IRB's findings and actions

The IRB will report the IRB's decision to the PI and university in writing.

The IRB will communicate in writing any modifications or clarifications required by the IRB as a condition of approval. The IRB will review and act upon the PI's response to any required modifications or clarifications [§46.109(d)].

A letter of disapproval will include an explanation. The PI has the right to respond to the IRB in person or in writing [§46.109(d)] and to file a grievance.

Grievance procedure

The IRB's grievance procedure is as follows:

1. The aggrieved PI will discuss his concerns with the chair of the IRB within ten (10) business days of receiving the written notice from the IRB. The IRB chair will issue a decision letter by email or mail.
2. If the PI is not satisfied with the chair's determination, the PI may submit a written description of the grievance to the executive vice president within ten (10) business days of receiving the IRB chair's determination. Upon receipt of the grievance, the executive vice president will appoint an ad hoc committee to include three to five individuals comprised of faculty and administrative representatives who do not have an interest in the outcome to review the grievance and make a recommendation.
3. Based on the recommendations from the ad hoc committee, the UWS president will make a final decision, no later than thirty (30) business days following the PI's submission of the grievance to the president. The president will issue a written decision to the PI by email or mail.

In case of litigation, members of the IRB are to be considered employees within the scope of university liability coverage or legal protection.

Frequency of IRB review

Ongoing projects will be reviewed at least once a year [§46.109(e)] or when any change in the protocol involving human subjects is to be implemented [§46.103(b)(4)].

The IRB will determine the approval period/continuing review interval of the proposed research, taking into account the nature of the study and risks posed by the study, the degree of uncertainty regarding the risks involved, the vulnerability of the subject population, the

experience of the investigator, the IRB's previous experience with the investigator and/or sponsor, the projected rate of enrollment, and whether the study involves novel therapies).

The IRB will document the approval period or continuing review interval in the meeting minutes. Additionally, the PI will receive notification via email.

The IRB will communicate its determinations regarding the approval period/continuing review interval to the PI. The PI will receive notification of the IRB's determination regarding the approval period/continuing review intervals via email.

Reporting of unanticipated problems/adverse events, noncompliance, and suspension or termination of IRB approval

The IRB administrator will promptly notify the IRB, appropriate institutional officials and, as applicable, any department or agency head, OHRP, and/or FDA of any:

1. Unanticipated problems involving risks to human subjects or others.
2. Serious or continuing noncompliance.
3. Suspension or termination of IRB approval.

Unanticipated problems/adverse events

The information that is to be included in reports of unanticipated problems:

1. Severity (e.g., mild, moderate, severe, serious, unanticipated).
2. Definition (e.g., minimal symptoms, symptomatic, incapacitating, life threatening, change in activity level).
3. Relatedness of event to research participation (e.g., unrelated, unlikely, possible, probably, definite).
4. The IRB incident report form.

To determine whether an adverse event is an unanticipated problem involving risks to human subjects or others, the IRB will consider and answer the following questions:

1. Is the adverse event unexpected?
2. Is the adverse event related or possibly related to participation in the research?
3. Does the adverse event suggest that the research places subjects or others at a greater risk of harm than was previously known or recognized?

An unexpected adverse event is any adverse event occurring in one or more subjects participating in a research protocol, the nature, severity or frequency of which is not consistent with either:

1. The known or foreseeable risk of adverse events associated with the procedures involved in the research that are described in (a) the protocol-related documents, such as the IRB-approved research protocol, any applicable investigator brochure, and the current IRB-approved informed consent document, and (b) other relevant sources of information, such as product labeling and package inserts; or
2. The expected natural progression of any underlying disease, disorder or condition of the subject(s) experiencing the adverse event and the subject's predisposing risk factor profile for the adverse event.

Adverse events may be caused by one or more of the following:

1. The procedures involved in the research;
2. An underlying disease, disorder or condition of the subject; or
3. Other circumstances unrelated to either the research or any underlying disease, disorder or condition of the subject.

In general, adverse events that are determined to be at least partially caused by (1) would be considered related to participation in the research, whereas adverse events determined to be solely caused by (2) or (3) would be considered unrelated to participation in the research.

The first step in assessing whether an adverse event meets the third criterion for an unanticipated problem is to determine whether the adverse event is serious. A serious adverse event is any adverse event that:

1. Results in death;
2. Is life-threatening (places the subject at immediate risk of death from the event as it occurred);
3. Results in in-patient hospitalization or prolongation of existing hospitalization;
4. Results in a persistent or significant disability or incapacity;
5. Results in a congenital anomaly or birth defect; or
6. Based upon appropriate medical judgment, may jeopardize the subject's health and may require medical or surgical intervention to prevent one of the other outcomes listed above.

When reviewing a report of an unanticipated problem, the IRB will consider whether the affected research protocol still satisfies the requirements for IRB approval [§46.111]. In particular, the IRB will consider whether risks to subjects are still minimized and reasonable in relation to the anticipated benefits, if any, to the subjects and the importance of the knowledge that may reasonably be expected to result.

When reviewing a particular incident, experience or outcome reported as an unanticipated problem by the investigator, the IRB may determine that the incident, experience or outcome does not meet all three criteria for an unanticipated problem. In such cases, further reporting to appropriate institutional and regulatory officials would not be required.

However, if the IRB determines there is an unanticipated problem involving risks to human subjects, it will review and report on the problem as required by law [§46.103(b)(5)].

The IRB has authority to require, as a condition of continued approval by the IRB, submission of more detailed information by the investigator(s), the sponsor or the study coordinating center about any adverse event or unanticipated problem occurring in a research protocol [§46.109(a)].

Any proposed changes to a research study in response to an unanticipated problem must be reviewed and approved by the IRB before being implemented, except when necessary to eliminate apparent immediate hazards to subjects.

Noncompliance

Noncompliance is defined as the failure to comply with federal regulations, UWS policies and procedures, and/or the UWS requirements and determinations of the IRB.

Serious noncompliance is defined as noncompliance which significantly increases risk to participants, significantly decreases potential benefits or compromises the integrity of the Human Research Protection Program (HRPP), as determined by the IRB. Multiple instances of noncompliance that are deemed not-serious individually may constitute serious noncompliance when considered collectively.

Continuing noncompliance is defined as a pattern of non-compliance that indicates a lack of understanding or disregard for the regulations or institutional requirements that protect the rights and welfare of participants and others, compromises the scientific integrity of a study such that important conclusions can no longer be reached, suggests a likelihood that noncompliance will continue without intervention, or involves frequent instances of minor noncompliance. Continuing noncompliance may also include failure to respond to a request from the IRB to resolve an episode of noncompliance or a pattern of minor noncompliance.

The following information will be included in an incident report submitted to the IRB regarding serious or continuing noncompliance:

1. Name of the institution conducting the research;
2. Title of the research project and/or grant proposal in which the noncompliance occurred, or, for IRB or institutional noncompliance, the IRB or institution involved;
3. Name of the PI on the protocol, if applicable;
4. Number of the research project assigned by the IRB and the number of any applicable federal award(s) (grant, contract, or cooperative agreement);
5. A detailed description of the noncompliance; and
6. Actions the institution is taking or plans to take to address the noncompliance (e.g., educate the investigator, educate all research staff, educate the IRB or institutional official, develop or revise IRB written procedures, suspend the protocol, suspend the investigator, conduct random audits of the investigator or all investigators, etc.).

A full board review will be required to determine serious and continuous noncompliance. In the event that the IRB finds there to be serious and/or continuous noncompliance, a decision on the future of the project will be determined (e.g., continued with stringent oversight and monitoring, project termination). This will be evaluated on a case-by-case basis.

Suspension or termination of IRB approval

The IRB has the authority to suspend or terminate IRB approval of research that is not being conducted in accordance with regulations or IRB requirements, or that has been associated with unexpected serious harm to human subjects, or where suspension or termination has been initiated by a sponsor or other outside entity. Any suspension or termination of IRB approval of research for cause, including a statement of the reason for the IRB's action, shall be reported promptly to the PI, the institutional official, and for federally-funded research, also to the Office for Human Research Protection (OHRP) and other federal agencies as appropriate [§46.113].

In the event that IRB terminates study approval, the PI will:

1. Cease research activities as specified in the IRB suspension notification until notified that the IRB has granted approval for resumption of the research activities, or in the case of termination, cease all research activities.
2. Notify subjects of the suspension or termination, as directed by the IRB.
3. Report to the IRB any adverse event or unanticipated problems involving risk to subjects or others that occur while the research activities are suspended.
4. Comply with all corrective action(s) as directed by the IRB.
5. Facilitate prompt actions to protect the rights and welfare of study subjects; for example, arranging for medical care outside of the study or transferring subjects to another study.
6. Compile all research records and not apply any modifications or omissions to record content.

The IRB will:

1. Review any suspension or termination initiated by the sponsor or other outside entity.
2. Notify the PI that research activities have been suspended or terminated and provide the rationale for their action.
3. Direct the PI to undertake corrective action as appropriate.
4. Direct the PI to notify subjects of the suspension or termination as appropriate.
5. Review reports of unanticipated problems involving risks to subjects or others during the time in which research is suspended for cause.
6. Report any suspension for cause or termination for cause to the institutional official and for federally funded research, also to regulatory agencies, as appropriate.

Appendix A: Role and investigator status

Position/Role	Can this position/role serve as PI?	Co-investigator?
Professor	Yes	Yes
Associate Professor	Yes	Yes
Assistant Professor	Yes	Yes
Adjunct Faculty	Yes, if the adjunct faculty member is serving as a faculty mentor on a thesis, dissertation, or practicum, or has approval from their college dean.	Yes
Postdoctoral Scholars or Fellows	Yes	Yes
Researcher	Yes	Yes
Librarian	Yes	Yes
Staff	Yes, if the individual has appropriate qualifications to conduct the research and if they have obtained approval to conduct the research from their immediate supervisor.	Yes
Administrator	Yes, if the individual has appropriate qualifications to conduct the research and if they have obtained approval to conduct the research from their immediate supervisor.	Yes
EdD Student	Yes. EdD students conducting research to fulfill dissertation requirements may serve as PI. They must have a faculty sponsor or advisor on the project as a co-Principal Investigator.	Yes
Student	No. Students conducting research to fulfill thesis, practicum, or academic requirements are assigned a faculty mentor to serve as the PI to provide oversight of all research activities.	Yes
Non-UWS Personnel	No	Yes, if collaborating with UWS personnel on a research project.