**BYLAWS OF THE WOU INSTITUTIONAL REVIEW BOARD**

Approved February 1st, 2019; effective February 1st, 2019

Amended June 6th, 2019; effective June 18th, 2019

Amended February 27th, 2020; effective February 27th, 2020

**PREAMBLE**

The purpose of the review of research involving human participants (in compliance with Title 45, Part 46 of the Code of Federal Regulations for the Department of Health and Human Services, and effective January 18th, 2018, and the Notice of the Secretary of Health, Education and Welfare dated May 20, 1975) is to insure the protection of the human participants in such research. It is the responsibility of Western Oregon University to insure this protection by providing review and approval of each research project prior to the beginning of that activity by an Institutional Review Board (IRB), as well as a continuing review of all research activities as appropriate.

**ARTICLE I**

**Membership of the IRB**

**Section 1. General Membership**

1.1 The IRB shall have at least five members, with varying backgrounds to promote complete and adequate review of research activities commonly conducted by the institution.

1.2 The IRB shall be sufficiently qualified through the experience and expertise of its members (professional competence), and the diversity of its members, including race, gender, and cultural backgrounds and sensitivity to such issues as community attitudes, to promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects.

1.3 The IRB shall be able to ascertain the acceptability of proposed research in terms of institutional commitments (including policies and resources) and regulations, applicable law, and standards of professional conduct and practice. The IRB shall therefore include persons knowledgeable in these areas.

1.4 If an IRB regularly reviews research that involves a category of subjects that is vulnerable to coercion or undue influence, such as children, prisoners, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons, consideration shall be given to the inclusion of one or more individuals who are knowledgeable about and experienced in working with these categories of subjects.

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

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

1.7 Each IRB may, in its discretion, fill up to two non-voting ex officio positions from relevant groups (e.g., programs, administrative offices) at the institution. Ex officio members must be appointed to the IRB, with approval from current membership of the IRB.

1.8 No IRB may have a member participate in the IRB's initial or continuing review of any project in which the member has a conflicting interest, except to provide information requested by the IRB.

1.9 An IRB may, in its discretion, 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.

**Section 2. Selection of IRB Members**

2.1 The IRB and its chair will be elected by the IRB committee for a three-year term. The initial IRB will have members appointed for varied lengths of membership in order to begin a staggered pattern of membership. Members may be re-appointed.

2.2 Each Spring, IRB members indicate to the Chair if they will be able to continue their term of service. The Chair shares this information with the IRB and notifies the Board of how many absences there will be in the coming year. At that point, the Board and the Chair notify the university community about the number of fillable vacancies on the IRB. The Chair will solicit applications for board membership. The application period will be no shorter than ten calendar days and no longer than fourteen calendar days. Interested applicants will submit appropriate and relevant documentation to support their application. Once the Chair has collected all application materials, he/she will share these with the IRB for selection of new members.

2.3 Members are selected by the committee through a voting process. The core goal is to gain diverse representation of perspectives, experiences, research methodologies, epistemologies, special populations served, and other important concerns.

2.4 Membership is not based or intended solely to represent individual university departments or divisions. Thus, when existing IRB members leave, application review is not simply a matter of having someone nominated from that department--a call will be made to the university in general.

2.5 Members are not appointed by division or department chairs or deans. Individuals are nominated or self-nominated. They then apply for membership. The IRB committee reviews all applications through a standardized review process.

**Section 3. Proxies**

3.1 If members are absent, they may not send proxies to vote in their place. However, all efforts will be made so that all votes and decision making can be as accommodating as possible, such as using electronic voting mechanisms, etc.

**Section 4. Board Member Removal**

4.1 Board members can resign at any time. If Board members resign, their place is left empty until annual application/selection cycle each Spring. Exception will occur to maintain general membership compliance with bylaws. In the case that IRB membership drops below five, an immediate recruiting cycle must take place. If the community Board member leaves or is removed, then an immediate search for the community member must be initiated in order to be in compliance with Federal regulations.

4.2 Board members can be removed for (1) failure to complete assigned tasks or (2) three non-professionally related absences from Board meetings; if physical attendance is not possible, Board members are encouraged to attend meetings through virtual means such as phone or videoconference. A majority in-person vote of the IRB is required to remove Board members. Board member removal cannot be proposed and acted on at the same meeting; instead, removal must be proposed at one meeting and then voted on the next month. This provides the member being removed time to prepare for the discussion and vote the following month.

**ARTICLE II**

**IRB Meetings**

**Section 1. Regular Meetings**

1.1 Regular meetings of the IRB are held during each of the following months: October, November, December, January, February, March, April, May, and June. Meetings are held from 9:00 to 10:00 a.m. on the first Friday of each month. The IRB chair may cancel meetings should there be no matters of importance or imminence.

**Section 2. Attendance and Participation**

2.1 Meetings of the IRB are not open to members of the faculty, administration and staff. Each member of the IRB is expected to attend meetings regularly (see Article I, Section 4.2).

**Section 3. Order of Business**

3.1 At regular meetings the business of the IRB shall be conducted in the following order:

 Call to order

 Corrections to and approval of minutes from previous meeting(s)

 Updates from the IRB chair

 Consideration of old business

 Consideration of new business

 Informational presentations

 Adjournment

**ARTICLE III**

**IRB Chair**

**Section 1. Duties/Responsibilities of IRB Chair.**

1.1 The Chair shall, subject to the control of the Board, have responsibility for the supervision, direction, and control of all IRB-related operations and business at Western Oregon University. In this capacity, the Chair is responsible for the following:

Coordinating and presiding over regular IRB meetings.

Serving as the primary liaison between the IRB, administrative staff, investigators, and all academic bodies/groups of the institution.

Coordination of the recruitment, orientation, retention, and dismissal of IRB members.

Coordinating the maintenance of IRB records and documents.

Reviewing current IRB policies and procedures for currency, accuracy, and consistency.

Providing oversight for the development and implementation of appropriate policies, procedures, and guidelines directed at human subjects research protections.

Providing direct supervision of IRB administrative staff.

Coordinating the review of all applications submitted to the IRB.

Representing the interests of the IRB and facilitating and promoting ethical human subject research activities at the institution.

Ensuring that the institution is compliant with all federal guidelines regarding the conduct of human subjects research.

1.2 The Chair is nominated and appointed by the IRB and will serve in the above capacity for a term of three years. Individuals may not serve as IRB chair in two concurrent terms. Upon completion of a three year term as Chair, the individual may serve an additional one year term as Past Chair with all the same rights as a regular committee member with the Committee’s approval. Assumption of the Past Chair position does not need approval from current IRB membership. In lieu of the Past Chair position, the individual may seek an additional three-year term, as a standard IRB committee member, after a ballot-based vote approval by current IRB membership.

**ARTICLE IV**

**Review Policies**

**Section 1. Duties/Responsibilities**

1.1 The IRB will be responsible for the following

Implementing WOU's policy for the protection of human participants in a manner as supportive as possible to research at WOU.

Informing research investigators of WOU's policies and procedures for the protection of human participants.

Reviewing research requests, approving, requiring modifications in, or rejecting requests based on risk of injury to participants.

1.2 For purposes of conducting review, the WOU IRB shall make the following determinations:

Broad consent for storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens is obtained.

Broad consent is appropriately documented or waiver of documentation is appropriate, and if there is a change made for research purposes in the way the identifiable private information or identifiable biospecimens are stored or maintained, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

When some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as children, prisoners, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons, additional safeguards have been included in the study to protect the rights and welfare of these subjects.

1.3 The WOU IRB will notify the investigator(s) of action taken on requests and the rationale for any action.

1.4 The WOU IRB will prepare and maintain adequate documentation of IRB activities, including:

Copies of all research proposals reviewed, scientific evaluations, if any, that accompany the proposals, approved sample consent forms, progress reports submitted by investigators, and reports of injuries to subjects.

Minutes of IRB meetings which shall be in sufficient detail to show attendance at the meetings; actions taken by the IRB; the vote on these actions including the number of members voting for, against, and abstaining; the basis for requiring changes in or disapproving research; and a written summary of the discussion of controverted issues and their resolution.

Records of continuing review activities, including the rationale for conducting continuing review of research that otherwise would not require continuing review.

A list of IRB members.

Copies of all correspondence between the WOU IRB and the investigators.

Written procedures for the IRB in the same detail. This includes but is not limited to this IRB Procedures manual.

Statements of significant new findings provided to subjects.

The rationale for an expedited reviewer's determination that research appearing on the expedited review list is more than minimal risk.

Documentation specifying the responsibilities that WOU, as the organization operating this IRB, will undertake to ensure compliance with the requirements of this policy.

The records required by this policy shall be retained for at least 5 years, and records relating to research conducted shall be retained for at least 3 years after completion of the research. The institution or the WOU IRB may maintain the records in printed form, or electronically. All records shall be accessible for inspection and copying by authorized representatives of the department or agency at reasonable times and in a reasonable manner.

1.5 The IRB has the responsibility to report to the chief academic officer (CAO) any unanticipated problem identified to the IRB involving injury to participants or others, including adverse psychological or medical complications. (Note - it is the responsibility of the principal investigator to report promptly in writing any proposed changes in the research activity that increases risk of injury and unanticipated problems involving injury to participants or others. It is then the IRB's responsibility to re-evaluate the project for risk of injury.)

1.6 It is appropriate for individual members of the IRB to be supportive to the investigator by interpreting WOU’s policy for the protection of human participants and by assisting investigators in the preparation of materials for IRB review.

**Section 2. General Procedures**

2.1 The WOU IRB chair will distribute promptly to all IRB members copies of all completed requests that do not meet the conditions for exempt or expedited review (i.e., requests that need a full board review). The IRB chair or designee will review requests for exemption to ensure that identified projects meet all criteria for exemption from IRB oversight. Requests that meet criteria for expedited review will be forwarded to two committee members for review. Members will respond promptly to the chair by completing requisite review documentation within established timelines and indicating:

Classification of proposed project as exempt, expedited, or full.

Approval or disapproval based on the policy for the protection of human participants.

Deferral based on inadequate information.

Deferral based on specified conditions that must be met

**Section 3. IRB Notifications**

3.1 The WOU IRB will notify, in writing, the principal investigator of its decisions regarding the research activities it reviews. The IRB will attach to its notification a copy of the record of the IRB’s review of the research activity and a summary of reviewer concerns.

3.2 If the research activity is approved, a copy of the IRB’s letter of approval will be attached to the notification. The IRB will also identify the date by which the next continuing review must take place.

3.3 If the activity is approved subject to modifications, the IRB will explain the required modifications and the basis for them.

3.4 If the activity is disapproved, the IRB will provide a statement of the reasons for its decision, and will offer the investigator an opportunity to respond in person or in writing.

3.5 The IRB will also provide investigators with written instructions directing them to report promptly to the IRB any unanticipated problems involving risks to subjects or others, or any serious or continuing noncompliance with the Final Common Rule or the WOU IRB’s requirements.

3.6 The IRB will promptly notify investigators, appropriate institutional officials in the CAO office, and the IRB office, of any unanticipated problems involving risks to subjects or others, or any serious or continuing noncompliance with the Final Common Rule or the IRB’s determinations of which it becomes aware.

3.7 If the research is suspended or terminated by the IRB, the IRB shall state the reasons for its action and shall report its action in writing to the investigator, the appropriate institutional officials in the CAO office, and the department, division, or agency head.

3.8 The IRB will report promptly to investigators and institutional officials any findings or actions not pertaining exclusively to any one particular research activity, as appropriate.

**Section 4. Continuing review**

4.1 The IRB will conduct continuing review of research requiring review by the convened IRB at intervals appropriate to the degree of risk, not more than once per year.

4.2 The IRB may be called into an interim review session by the IRB chair at the request of any IRB member or any university institutional official to consider any matter concerning the rights or welfare of any subject.

4.3 The IRB will use the same criteria to make decisions about continuing reviews as it does for initial reviews. It will make continuing review decisions using the material submitted for the initial review, the records of the IRB’s initial review, and any new information relevant to the research activity and the IRB’s criteria for approval:

At the request of any member.

At the request of a principal investigator for a formal hearing following disapproval or suspension by the IRB.

When any member classifies a project as full.

For other IRB business including proposed policy changes.

4.4 Unless the IRB determines otherwise, a five-year continuing review cycle, rather than an annual continuing review cycle will be used under the following circumstances:

The research is eligible for expedited review

The research is reviewed by the IRB in accordance with the limited IRB review or the research has progressed to the point that it involves only one or both of the following, which are part of the IRB-approved study: data analysis, including analysis of identifiable private information or identifiable biospecimens; or accessing follow-up clinical data from procedures that subjects would undergo as part of clinical care.

**Section 5. Exempt or expedited review**

5.1 If a research request is clearly exempt or expedited (see Classification of Proposed Research—Section VI.), the chair or designee has the authority to expedite the process by assigning exempt or expedited status to the project without the necessity of full committee review. Records of the request and its disposition should be maintained by the IRB regardless of whether the request has received full committee or expedited review.

**Section 6. Student-initiated research**

6.1 The role of the WOU IRB is to ensure that research projects involving human subjects are conducted in accordance with accepted ethical and governmental standards related to the protection of human subjects. Although the IRB requires that a faculty member supervise all student research projects, direct IRB review of student projects is only necessary under the following circumstances:

The student class assignment is intended to collect information that will contribute to generalizable knowledge;

If there is any chance of publication beyond WOU;

If a faculty member believes that there is any potential for dissemination of class project activities beyond WOU (for example if there is the potential for students to present research at a local, state or national conference, as a result of research activities conducted within a course);

The project poses more than minimal risk to participants; or

When some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as children, prisoners, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons.

6.2 Student theses, honors projects, and independent study projects are by their nature intended to add to generalizable knowledge and not contained within the formal classroom environment. These projects, if they involve human subjects, are always subject to IRB oversight. All such projects must involve a sponsoring/supervising faculty member who must carefully review, approve and sign the IRB application before forwarding it to the IRB.

6.3 IRB review is not necessary if student class projects are not systematic data collection efforts involving human subjects that are intended to develop or contribute to generalizable knowledge and thus do not meet the federal regulatory definition of research, if they involve minimal risk to human participants and do not involve members of vulnerable populations, they do not fall under the jurisdiction of the IRB and DO NOT require IRB application, approval, or oversight. These include Academic Excellence Showcase projects that pose minimal risk, do not involve vulnerable populations, and are not intended for dissemination beyond WOU.