WESTERN OREGON UNIVERSITY INSTITUTIONAL REVIEW BOARD POLICY (TEMPLATE)

Policy Name:	**Collaborative Research and IRB of Record Policy**					
Policy #:	**002**	**Policy Section:**	Research/Investigator Policies			
Approval Authority:	Chief Academic Officer		**Adopted:**	06.04.2018	**Reviewed:**	
Responsible Party:	Chair, IRB		**Revised:**			
Responsible Office:	Academic Affairs / IRB		**Contact:**	Ethan A. McMahan; mcmahane@wou.edu		

1. **Policy Statement**
   This document describes the Western Oregon University Institutional Review Board (WOU IRB) policy regarding the use of a single IRB (sIRB; i.e., IRB of Record) in situations involving collaborative research between WOU and researchers at other institutions. When engaged in collaborative research, either the WOU IRB or another institution's IRB may serve as the sIRB, provided that the appropriate documentation is completed, submitted, and kept on file by the WOU IRB. When the WOU IRB is serving as the sIRB, the Principal Investigators (PIs) at WOU will be required to submit a completed WOU IRB Authorization Agreement form, identifying the WOU IRB as such, along with all other application materials. When another institution's IRB will serve as the sIRB, the PIs at WOU will also be required to submit a WOU Authorization Agreement, identifying the other institution's IRB as such, along with all other required documentation (described below). Note that as per 45 CFR 46, Subpart A (i.e., the Federal Policy for the Protection of Human Research Subjects), identification of a sIRB is not required unless the project is federally funded, and researchers may choose to have projects reviewed by the IRBs at both institutions.

2. **Reason for Policy**
   In the conduct of cooperative research projects, WOU acknowledges that each institution is responsible for safeguarding the rights and welfare of human subjects and for complying with applicable federal regulations. When a cooperative agreement exists, WOU may enter into a joint review arrangement, relying on the review of another qualified IRB or by serving as the reviewing IRB. This is allowed in order to avoid duplication of effort, as well as to be in compliance with federal regulations regarding the use of an sIRB, where required.
3. **Who Should Read this Policy**
   a. Investigators at Western Oregon University
   b. Non-WOU affiliated Investigators intending to conduct research in collaboration with Western Oregon University
   c. Members of the Western Oregon University Institutional Review Board
   d. Administration at Western Oregon University, including the President, Vice Presidents, Deans, Division Chairs, and Department Heads

4. **Resources**
   a. Western Oregon University Institutional Review Board – www.wou.edu/irb/

5. **Definitions**
   a. Definitions of terms used in this policy are consistent with those applied in 45 CFR 46, Subpart A (Federal Policy for the Protection of Human Subjects, i.e., the Common Rule)

6. **The Policy**
   This policy concerns collaborative research situations in which WOU-affiliated investigators are engaged in human subjects research with qualified individuals at other institutions. In seeking IRB approval for such research, the PIs at all institutions may seek IRB approval through their affiliated IRB. However, in many cases, the identification of an sIRB may be required or preferable. Under such circumstances, the PIs may enter into a collaborative agreement, whereby (1) the WOU IRB will serve as the sIRB and conduct a complete review of the research, or (2) a qualified IRB at the collaborating institution will conduct the review and serve as the sIRB. The required procedures for each of the above options are described in detail below:
   (1) WOU as the sIRB – The following applies to situations in which the WOU IRB will serve as the sIRB for a collaborative research project involving multiple institutions.
      a. The WOU-affiliated PIs must complete and submit all documentation required of a typical IRB application (e.g., application form, project materials, etc.).
      b. The WOU-affiliated PIs must request in writing on the application form or in an application letter that the WOU IRB serve as the sIRB of a multi-site study.
      c. The WOU-affiliated PIs must identify on the application form or in an application letter each collaborating institution and provide the names of all PIs on the project, regardless of institutional affiliation.
      d. Each non-WOU-affiliated PI must complete an Individual Investigator Agreement (IIA) form (see Appendix A), to be submitted with the initial IRB application.
      e. The PIs must submit an IRB Authorization Agreement (IAA) form (see Appendix B) that identifies WOU as the coordinating institution and as providing the sIRB for the study. Each collaborating institution will need to submit a separate IAA form for their institution.
      f. Note that both the IIA and IAA forms must be completed, with the requisite information provided and appropriate signatures obtained, before the WOU IRB will agree to serve as the sIRB and initiate its review.

(2) WOU to cede review – The following applies to situations in which the WOU IRB will cede review to another institution's IRB and rely upon that IRB's determinations regarding initial and continuing review of a collaborative research project.
   a. Prior to engaging in the collaborative research project, the WOU-affiliated PIs must submit an IAA form identifying the reviewing institution's IRB (see Appendix C).
   b. With the IAA form, the WOU-affiliated PIs must submit copies of project materials (e.g., informed consent forms, surveys, etc.) that will be administered by the WOU-affiliated PIs and/or to WOU-affiliated participants.
   c. If approved by the reviewing IRB, the WOU IRB requires a copy of the official approval letter prior to the initiation of the research at WOU.

Appendix A

Non-Affiliated Investigator Agreement

Name of Institution with Federalwide Assurance (FWA): Western Oregon University

Applicable FWA#: 00001916

Individual Investigator's Name: _____

Specify Research Covered by this Agreement:

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1. The above-named Individual Investigator has reviewed: 1) *The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research* (or other internationally recognized equivalent; 2) The US Department of Health and Human Services (HHS) regulations for the protection of human subjects at 45 CFR part 46; 3) the FWA and applicable Terms of the FWA for the institution referenced above; and 4) the relevant institutional policies and procedures for the protection of human subjects.
2. The Investigator understands and hereby accepts the responsibility to comply with the standards and requirements stipulated in the above documents and to protect the rights and welfare of human subjects involved in research conducted under this agreement.
3. The Investigator will comply with all other applicable federal, international, state, and local laws, regulations, and policies that may provide additional protection for human subjects participating in research conducted under this agreement.
4. The Investigator will abide by all determinations of the Institutional Review Board (IRB) designated under the above FWA for all data collection conducted at the Institution and will accept the final authority and decisions of the IRB, including but not limited to directives to terminate participation in designated research activities.
5. The Investigator will complete any educational training required by the Institution and/or the IRB prior to initiating research covered under this Agreement.
6. The Investigator will report promptly to the IRB any proposed changes in the research conducted under this Agreement. The Investigator will not initiate changes in research without prior IRB review and approval, except where necessary to eliminate apparent immediate hazards to subjects.

7. The investigator will report immediately to the IRB any unanticipated problems involving risks to subjects or others in research covered under this Agreement.
8. The Investigator, when responsible for enrolling subjects, will obtain, document, and maintain records of informed consent for each such subject or each subject's legally authorized representative as required under HHS regulations 45 CFR part 46 and as stipulated by the IRB.
9. The Investigator acknowledges and agrees to cooperate in the IRB's responsibility for initial and continuing review, record keepings, reporting, and certification for the research referenced above. The investigator will provide all information requested by the IRB in a timely fashion.
10. The Investigator will not enroll subjects in research under this Agreement prior to its review and approval by the IRB.
11. Emergency medical care may be delivered without IRB review and approval to the extent permitted under applicable federal regulations and state law.
12. This Agreement does not preclude the Investigator from taking part in research not covered by this Agreement.
13. The Investigator acknowledges that that they are primarily responsible for safeguarding the rights and welfare of each research subject, and that the subjects' rights and welfare must take precedence over the goals and requirements of the research.

Investigator Signature: _____ Date: _____

Print Full Name: _____ Degree: _____

Telephone: _____ Email: _____

Address: _____

City: _____ State: _____ Zip Code: _____

FWA Institutional Official

Signature of Official (or Designee): _____ Date: _____

Print Full Name: Ethan A. McMahan

Institutional Title: Chair, Institutional Review Board

Telephone: 503.838.9200 Email: irb@mail.wou.edu

Address: 345 N. Monmouth Ave., Institutional Review Board

City: Monmouth State: OR Zip Code: 97361

Appendix B

IRB Authorization Agreement

Instructions: For processing a request for the WOU IRB to serve as the IRB of Record for an external site engaged in research, this form would need to be completed by the WOU internal study team. Once the form is completed, it should be submitted as a separate document with the study application or modification. Please ensure all study information is included for the local and external IRB. Also, the information for the local and external PI should be provided below in the appropriate sections. Any questions can be forwarded to irb@mail.wou.edu.

Name of Institution or Organization Providing IRB Review (Institution A): **Western Oregon University**

IRB Registration #: **IORG0001549**
Federal wide Assurance (FWA) #, if any: **FWA00001916**

Name of Institution Relying on the Designated IRB (Institution B): Please Provide
OHRP Federal wide Assurance (FWA) #: Please Provide

The Officials signing below agree that Institution B may rely on the designated IRB for review and continuing oversight of its human subject research described below: (choose one)

(___) This agreement applies to all human subject research covered by Institution B's FWA.

(_Recommended__) This agreement is limited to the following specific protocol(s):
Name of Research Project: Please Provide
Name of Western Oregon University Principal Investigator: Please Provide
Name of Institution B Principal Investigator: Please Provide
Sponsor or Funding Agency, if any: Please Provide
Award Number, if any: Please Provide

(___) Other (describe):

The Reviewing Institution (Institution A) agrees to the following in regard to the above listed research protocol or activities:

I. Provide initial and continuing review in accordance with 45 CFR 46 and its FWA.
II. Arrange for prompt reporting to the Relying Institution's IRB of any of the following, as defined and determined by the Reviewing Institution's IRB:
    a. Any unanticipated events or problems involving risks to subjects or others.
    b. Any serious or continuing non-compliance.
    c. Any suspension or termination of IRB approval.

The Relying Institution remains responsible for the following:

I. Ensuring research activities at its site are in compliance with the Reviewing IRB's determinations and with the terms of its OHRP-approved Assurance.
II. Adhering to its institutional conflict of interest policies and procedures and providing the Reviewing Institution with any applicable COI management plan related to the study.
III. Ensuring principal investigators and other research personnel involved in the research are appropriately qualified and meet its institutional standards for eligibility to conduct research, including, but is not limited to, having the required professional staff appointments, credentialing, insurance coverage, and background checks for their assigned role in the research and training in the protection of human subjects.

This document must be kept on file at both institutions and provided to OHRP upon request. This agreement will become effective upon the date of the last signature by the institutional officials below and will remain in effect until such time that either institution provides 30 days written notice of termination to the other institution.

Signature of Signatory Official (Institution A):

_____ Date: _____
Print Full Name: **Ethan A. McMahan, PhD**
Institutional Title: **Chair, Institutional Review Board, Western Oregon University**

Signature of Signatory Official (Institution B):

_____ Date: _____
Print Full Name: Please Provide
Institutional Title: Please Provide

Please provide the contact information for the individual at Institution A and Institution B who should be copied on all correspondence regarding the study.

Institution A: **Western Oregon University**

Name: Please Provide

Institutional Title: Please Provide

Address: Please Provide

Email: Please Provide

Phone Number: Please Provide

Institution B: Please Provide

Name: Please Provide

Institutional Title: Please Provide

Address: Please Provide

Email: Please Provide

Phone Number: Please Provide

Appendix C

IRB Authorization Agreement

Instructions: For processing a request for the WOU IRB to cede review to (rely on) an external IRB, this form would need to be completed by the internal WOU study team. Once the form is completed, it should be submitted as a separate document with the IRB application. Any questions can be forwarded to irb@mail.wou.edu.

Name of Institution or Organization Providing IRB Review (Institution A): Please Provide

IRB Registration #: Please Provide
Federal wide Assurance (FWA) #: Please Provide

Name of Institution Relying on the Designated IRB (Institution B): **Western Oregon University**
OHRP Federal wide Assurance (FWA) #: **FWA00001916**

The Officials signing below agree that Institution B may rely on the designated IRB for review and continuing oversight of its human subject research described below:

(___) This agreement applies to all human subject research covered by Institution B's FWA.

(_X_) This agreement is limited to the following specific protocol(s):
Name of Research Project: Please Provide
Name of Western Oregon University Principal Investigator: Please Provide
External IRB Study Number (if any): Please Provide
Sponsor or Funding Agency: Please Provide
Award Number, if any: Please Provide

(___) Other (describe):

The Reviewing Institution (Institution A) agrees to the following in regard to the above listed research protocol or activities:

III. Provide initial and continuing review in accordance with 45 CFR 46 and its FWA.

IV. Arrange for prompt reporting to the Relying Institution's IRB of any of the following, as defined and determined by the Reviewing Institution's IRB:

   a. Any unanticipated events or problems involving risks to subjects or others.

   b. Any serious or continuing non-compliance.

c. Any suspension or termination of IRB approval.

V. Comply will all applicable Federal, State, and Local laws and regulations.

VI. IRB meeting minutes will be made available to the Relying Institution's IRB upon request.

VII. Copy the Relying Institution on all correspondence to regulatory agencies if reporting of an event is required.

The Relying Institution (Institution B) remains responsible for the following:

IV. Ensuring research activities at its site are in compliance with the IRB's determinations and with the terms of its OHRP-approved Assurance.

V. Adhering to its institutional conflict of interest policies and procedures and providing the reviewing Institution with any applicable COI management plan related to the study.

VI. Ensuring principal investigators and other research personnel involved in the research are appropriately qualified and meet its institutional standards for eligibility to conduct research, including but not limited to having the required professional staff appointments, credentialing, insurance coverage, and background checks for their assigned role in the research and training in the protection of human subjects.

This document must be kept on file at both institutions and provided to OHRP upon request. This agreement will become effective upon the date of the last signature by the institutional officials below and will remain in effect until such time that either institution provides 30 days written notice of termination to the other institution.

Signature of Signatory Official (Institution A):

_____ Date: _____

Print Full Name: Please Provide

Institutional Title: Please Provide

Signature of Signatory Official (Institution B):

_____ Date: _____

Print Full Name: **Ethan A. McMahan, PhD**

Institutional Title: **Chair, Institutional Review Board, Western Oregon University**

Please provide the contact information for the individual at Institution A and Institution B who should be copied on all correspondence regarding the study.

Institution A: Please Provide

Name: Please Provide

Institutional Title/Position (e.g., faculty): Please Provide

Address: Please Provide

Email: Please Provide

Phone Number: Please Provide

Institution B: **Western Oregon University**

Name: Please Provide

Institutional Title (e.g., faculty): Please Provide

Address: Please Provide

Email: Please Provide

Phone Number: Please Provide