



# Western Oregon UNIVERSITY

## WESTERN OREGON UNIVERSITY INSTITUTIONAL REVIEW BOARD POLICY

<b>Policy Name:</b>	<b>Policy for Research Conducted by Third-Party, Non-Affiliated Investigators</b>				
<b>Policy #:</b>	001	<b>Policy Section:</b>	Research/Investigator Policies		
<b>Approval Authority:</b>	Chief Academic Officer	<b>Adopted:</b>		<b>Reviewed:</b>	
<b>Responsible Party:</b>	Chair, IRB	<b>Revised:</b>			
<b>Responsible Office:</b>	Academic Affairs / IRB	<b>Contact:</b>	Ethan A. McMahan; mcmahane@wou.edu		

### 1. Policy Statement

This policy addresses the Western Oregon University Institutional Review Board (WOU IRB) requirement that all third-party, non-affiliated investigators (i.e., an investigator not affiliated with WOU as faculty, staff, etc.) who wish to conduct human subjects research at WOU, whether in collaboration with a WOU-affiliated investigator or not, provide all requested project documentation to the WOU IRB as outlined below and complete an “Individual Investigator Agreement” form (see Appendix) prior to initiating such research.

### 2. Reason for Policy

The WOU IRB regularly and frequently entertains inquiries from outside institutions and non-WOU affiliated individuals who wish to conduct research and collect some or all of their data at WOU. While we wish to encourage and facilitate such research, the requirements outlined in this policy document must be met prior to initiating any projects in order to ensure effective communication between participants, project staff, and WOU, as well as to ensure that WOU IRB policies are being followed during the conduct said research.

### 3. Who Should Read this Policy

- a. Investigators at Western Oregon University
- b. Third-party, non-WOU affiliated Investigators intending to conduct research at 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/](http://www.wou.edu/irb/)
- b. Office for Human Research Protections (OHRP) - <https://www.hhs.gov/ohrp/>
- c. 45 CFR 46, Subpart A (Federal Policy for the Protection of Human Subjects, i.e., the Common Rule) - <https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html>
- d. Non-Affiliated Investigator Agreement Form – LINK TO GO HERE

#### 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 applies to human subjects research conducted, at least in part, by a third party (e.g., an investigator from an outside institution) where some or all of data collection will be at WOU and/or conducted in collaboration with WOU. The WOU IRB requires that that all third-party, non-affiliated investigators (i.e., an investigator not affiliated with WOU as faculty, staff, etc.) who wish to conduct human subjects research at WOU, whether in collaboration with a WOU-affiliated investigator or not, provide all requested project documentation (see below) to the WOU IRB and complete an “Individual Investigator Agreement” form (see Appendix) prior to initiating such research.

- a. If research initiated by a third-party has not already received IRB approval elsewhere, that party may submit an application to the WOU IRB for consideration for approval provided that the following conditions are met:
  - i. All investigators listed on the project, regardless of affiliation, have met all WOU IRB requirements for the conduct of human subjects research at WOU (e.g., holding a valid CITI certification); and
  - ii. The third-party investigator(s) completes in full and submits a WOU IRB application and any associated project documentation; and
  - iii. The third-party investigator(s) completes and submits an “Individual Investigator Agreement” form along with their IRB application and any other documents requested by the IRB prior to initiating research at WOU.
- b. If research initiated by a third-party already has IRB approval from an outside institution, the WOU IRB will maintain reciprocity with that approval, provided that the following conditions are met:
  - i. A copy of the IRB approval letter from the outside institution is provided; and
  - ii. The Federal-wide Assurance Number of the outside institution is provided; and
  - iii. A copy of the original application approved by the outside institution is provided, or a completed WOU IRB application and associated documentation is provided; and
  - iv. All investigators on the project, regardless of affiliation, have met all WOU IRB requirements for the conduct of human subjects research at WOU (e.g., holding a valid CITI certification); and
  - v. The third-party investigator(s) completes and submits an “Individual Investigator Agreement” form and any other documents requested by the IRB prior to initiating research at WOU.

Although every attempt will be made to accommodate the review and conduct of non-affiliated research at WOU, the WOU IRB reserves the right to deny both review and approval of any such research without specified cause.