



Western Oregon UNIVERSITY

WESTERN OREGON UNIVERSITY INSTITUTIONAL REVIEW BOARD POLICY

Policy Name:	Continuing Review Policy				
Policy #:	001	Policy Section:	Review Procedures		
Approval Authority:	Chief Academic Officer	Adopted:	11/03/2017	Reviewed:	
Responsible Party:	Chair, IRB	Revised:			
Responsible Office:	Academic Affairs / IRB	Contact:	Ethan A. McMahan; mcmahane@wou.edu		

1. Policy Statement

This policy eliminates the requirement of continuing annual review for minimal risk studies that are approved via exempt, expedited, or limited review. Additionally, this policy eliminates the requirement that studies approved prior to the adoption of this policy continue to undergo continuing annual review.

2. Reason for Policy

The Final Rule to update the current regulations at 45 CFR 46, Subpart A – “Federal Policy for the Protection of Human Subjects (Common Rule)” includes a number of significant changes that affect research institutions, Institutional Review Boards (IRBs), and investigators. One of these changes is the elimination of continuing review for minimal risk research, unless the reviewer explicitly justifies why continuing review is necessary (see subsection 46.109[f][1][i]). The WOU IRB will be required to comply with this change in regulations by the Final Rule compliance date (01/19/2018), but can implement changes earlier by formally adding a requirement to our policies that applies the Final Rule (or a modified version thereof) to both (1) studies reviewed prior to the compliance date and (2) those approved prior to the adoption of this policy.

Although the Final Rule allows for the complete elimination of continuing review for minimal risk studies, institutions may require an alternative method of accounting for ongoing research and establish their own requirements, policies, and procedures regarding continuing review. Accordingly,

Note. All policies are subject to amendment.

to account for research conducted over extended periods, the WOU IRB will require that studies engage in continuing review every five years following their date of approval. If approved, this policy will go into effect on 01/01/2018.

Summary: This policy adopts the regulations regarding continuing annual review detailed in the Final Rule, and states that previously approved studies meeting the criteria for the elimination of continuing annual review (i.e., those that pose only minimal risk) are no longer required to engage in continuing annual review. However, the WOU IRB will require continuing review of studies every five years following their date of approval. Thus, ongoing research conducted over extended periods will need to periodically submit requests for continuation of approval to the WOU IRB.

3. Who Should Read this Policy

- a. Investigators at Western Oregon University
- b. Members of the Western Oregon University Institutional Review Board
- c. Administration at Western Oregon University, including the President, Vice Presidents, Deans, Division Chairs, and Department Heads

4. Resources

- a. Office for Human Research Protections – Copy and explanation of Final Rule:
<https://www.hhs.gov/ohrp/regulations-and-policy/regulations/finalized-revisions-common-rule/index.html>

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 (Common Rule)”

6. The Policy

Consistent with upcoming modifications to 45 CFR 46, Subpart A – “Federal Policy for the Protection of Human Subjects” associated with the Final Rule, the WOU IRB will no longer require continuing annual review for all minimal risk studies. For some studies, the reviewer(s) may request continuing annual review, which will be granted provided that the reviewer(s) provides explicit and clear rationale for the necessity for annual review. Additionally, ongoing research that was approved prior to the adoption of this policy is no longer required to engage in continuing annual review. However, the WOU IRB maintains accounting for ongoing research and retains a more limited form of continuing review, such that ongoing research conducted over extended periods is required to submit a formal request for continuation of approval every five years.

This policy applies to the following forms of minimal risk research:

- Research that is exempt from IRB review.
- Research that is exempt but is deemed to require limited review.
- Research that undergoes expedited review.
- Research that has completed interventions and is merely analyzing data or involve only observational follow up in conjunction with standard clinical care.

If approved, this policy will go into effect on 01/01/2018. For studies approved prior to 01/01/2018, continuing review will be scheduled for five years from the most recent approval or renewal.