



Western Oregon University Institutional Review Board

During spring term 2010 the WOU Institutional Review Board revised the Renewal/Continuing Review Policy for research lasting for more than one-year to be in compliance with the Office of Human Research and Protection. The process was piloted and was approved by the IRB during the October 1, 2010 meeting.

Renewal/Continuing Review Policy

The U.S. Department of Health and Human Services (HHS) regulations for the protection of human subjects (45 CFR part 46) has provisions specific to research that continues past the one-year anniversary of IRB approval. Research reviewed and approved by the WOU Institutional Review Board, including multi-year projects, is for one year from the date of approval, and must be renewed for each subsequent year of a continuing research project.

If research is to continue past the date of approval it is the responsibility of the Principal Investigator/s to submit specific documents to the IRB. The renewal documents should be submitted one month prior to the renewal date to allow for adequate time for IRB members to review the documents for continuing approval.

Renewal/Continuing Review Process

The review process for renewal/continuing approval requires the following documentation:

1. Please provide the following information: Research Project Title, identifier # assigned by IRB (found in approval letter), and date of most recent IRB approval.
2. A brief protocol summary. Include in this section information regarding any deviations from the approved protocol since the last approval.
3. A copy of the current informed consent document(s) (i.e., informed consent, parental permission, and children's assent or waiver documents as appropriate).
4. A brief status report including number of participants accrued, summary of unanticipated problems (e.g., withdrawal of subjects), and summary of any new information identified (e.g., risks or benefits) which may affect the willingness of current or future research participants to participate in the study.
5. Evidence of NIH training requirement met for all listed on IRB application if not already on file (including faculty sponsors).

6. The Renewal/Continuing review packet should be submitted to the IRB one month before the end of the initial or previous approval date. Two IRB members will review Expedited or Exempt renewals and at least five IRB members will review Full Board category applications.