

OHSU Policy on Research Protocol Revisions and Amendments

Once the IRB has reviewed and approved a research protocol and the various forms (consent, assent, data collection) and letters that may be associated with the protocol, no changes may be implemented without prospective review and approval by the IRB. The Project Revision/Amendment Form (PRAF) is designed to summarize any proposed changes and must be submitted with any request for protocol or forms revisions.

Whenever a PRAF is submitted that incorporates a change to the protocol, the investigator must submit a new protocol with the revision incorporated and highlighted in the document. The document will be dated and indicated as a revision in the ORIO file and will replace prior versions of the protocol. If the revision affects only selected and discreet pages of a multi-page protocol, the investigator may forward copies of the revised pages, clearly marked as to which existing pages they replace and clearly marked as to the date of the revision. The IRB staff will incorporate these revised pages into the complete protocol and stamp the correct revision number and date on the cover page. If the investigator or sponsor does not indicate a revision number, one will be assigned by the IRB.