

II5 GD2 Document Management: IRB Protocols

Overview

To facilitate efforts to respond to investigator's questions, process renewals, amendment requests, and routine or for-cause file audits, the University of Nevada, Reno (the University) Human Research Protection Program (i.e., the Office of Human Research Protection (OHRP) and Institutional Review Boards (IRB)) has adopted a systemic procedure for managing protocol files.

Files are organized to allow immediate access to (1) the complete, approved version of the protocol (including all attachments) and (2) all documents and correspondence associated with each completed or pending protocol event (i.e., submission).

II5A1 Protocol File Document Management

II5A1a Documents for Protocol Events

Events are placed in the protocol file in descending order of receipt, with all event-related documents and correspondence placed within the event, also in descending order of receipt. Each element of the submission is clipped together or stapled to maintain a separate set of materials for each step of the review process. Materials for all submissions, whether for a new protocol, modification, renewal, or reportable event, will vary for each submission and may include the following:

1. original submission from the investigator, stamped with the receipt date (e.g., new protocol application, protocol modification, and renewal forms) and event-related attachments such as
 - a. recruitment and informed consent, parent permission and assent materials;
 - b. HIPAA authorization or waiver of authorization;
 - c. assessment instruments, questionnaires, and data collection logs;
 - d. debriefing statement (for research involving incomplete disclosure or deception);
 - e. intervention materials (e.g., scenarios, screen shots for computerized research);
 - f. site permission letters;
 - g. approval letters or forms from external committees and IRBs at collaborating institutions;
 - h. verification of human subjects research training for collaborating investigators;

- i. for FDA-regulated research (e.g., investigational drugs or devices), documentation of FDA approval for the proposed use of the drug or other relevant documents; and
 - j. for funded research, grant application, scope of work or contract (with budget);
2. screen feedback (e.g., email correspondence, file notes summarizing telephone discussions);
3. investigator response to screen feedback, including revised documents;
4. complete set of materials forwarded for review;
5. completed and signed reviewer checklists, as appropriate for the submission type and review;
6. IRB Review Report, email or file note summarizing telephone discussion communicating review results and requested revisions;
7. final versions of revised and updated documents submitted in response to the reviewer's comments and questions;
8. primary and video informed consent, permission and assent forms stamped with the approval date (note: information sheets are not date-stamped); and
9. Certifications of Approval for the event and HIPAA waiver of authorization (as applicable).

I15A1b Approved Versions of Protocol Documents

Following approval of a new protocol and all subsequent events, the IRB Coordinator or Program Manager will prepare or update the approved versions of all documents for the protocol, in the following order:

1. protocol application,
2. performance site permission letters,
3. recruitment materials,
4. date-stamped consent, permission, and assent forms,
5. information sheets,
6. research instruments and intervention materials, and
7. grant application, or scope of work or contract.

Signed originals will remain with the event materials. The IRB Coordinator or Program Manager will photocopy the approved documents and when updating the protocol following certification of approval of an event, will discard all versions being replaced.

I15A2 IRBManager Electronic Document Management

If the investigator provides electronic versions of the documents for a new submission, whether for a new protocol, protocol modification, continuing review or reportable event, the IRB Coordinator or Program Manager overseeing the event will attach the electronic documents to the event in IRBManager. If no e-copies are provided with the initial submission, she or he may request e-copies of the documents or may wait until the investigator submits revised versions following screen feedback or IRB review.

Following the screen or IRB review, the IRB Coordinator or Program Manager will ask the investigators to submit all revised or requested documents in electronic format. Documents that may require additional revisions (e.g., application, recruitment or consent materials) will be submitted in MSWord or equivalent word-processing format. All other documents (e.g., site permission letters, grant applications) may be submitted as Adobe pdfs. Upon receipt, the coordinator or program manager will attach the e-documents to the related event in IRBManager, placing the version date in the file name to facilitate tracking and identification of versions. If subsequent versions of one document are required (e.g., additional changes are needed), these will be attached to the same “document.”

After approval for the event has been certified, the IRB Coordinator or Program Manager will attach (for new protocol events) or update (for modifications and renewals) the approved versions of the protocol application and each of the protocol-related documents to the home page of the protocol in IRBManager. As with the paper files, protocols in IRBManager will always contain a complete copy of the approved protocol.