How to Respond to a Human Subject IRB Protocol Application that Requires Modifications to Secure an Approval Determination

This help document is related to the Human Subjects module in the InfoEd Electronic Research Administration (eRA) portal. If the IRB determines that your protocol requires modifications to secure approval, the IRB will send a determination letter to the principal investigator (PI) outlining the necessary changes. After receiving this notice, log into InfoEd and open the protocol that requires modifications. Refer the “how to” guides on showing or listing human subjects IRB protocols or searching for an existing human subjects IRB protocol, if necessary, for instructions on locating and opening an existing protocol within InfoEd.

1. Once you have opened the protocol, select the “Respond” hyperlink next to the Requires Modifications to Secure Approval Status on the submissions page to begin modifying your submission. If you click the “Open” folder icon by mistake, just click the “Submissions” folder link in the left hand navigational side bar area on the screen to return to the screen shown below.

2. Select the type of revision that corresponds with the original protocol submission from the drop down menu and click the Save button. Note: This example shows a Revision to an Initial Review, but the procedures are the same if revisions are required for other submission types. Be sure to correct type of revision that corresponds with your submission.

3. You will be presented with the “Components for Revision” page. Notice that all of the forms and supporting documents initially submitted are listed by default. The determination letter from the IRB indicating that modifications are required may also be listed. The system assumes that all documents require revision; however, you should resubmit only those documents that were actually revised and delete all others (see Step 7). Make the required revisions to each document requiring revision per the IRB determination letter and click the relevant “Replace” icon to upload and replace the previous version. Note: you should upload the “clean” version of the document without highlights or track changes here. Refer to step 4 on how to add a highlighted or track change version of previously submitted documents.

4. If you made changes to any previously submitted document (e.g. protocol, consent forms, recruitment materials, survey instruments, medical history forms, interview guides, etc.), upload the highlighted or track-change version of the revised
documents as a new supporting document using the miscellaneous document category using the Add Institution Forms/Supporting Documents hyperlink. For the name of the revised document, please use the same name as the clean copy of the document and append “track-change copy” without the quotes as the full name of the document. Refer to the how to guide on adding supporting documents, if you need specific instructions.

5. If you need to add a new document that was missing from your submission per the IRB determination letter, add the new supporting document using the Add Institutional Forms/Supporting Documents hyperlink. Refer to the how to guide on adding supporting documents, if you need specific instructions.

6. If you need to modify the study protocol application eForm, click the Edit icon on the “Components for Revision” page next to your protocol application. Once the form is open, you will need to uncheck the box next to complete at the top of the form to be able to edit it. Make the required changes to the application and check the complete box to finish editing the form.

7. Delete any documents that were not revised by clicking the remove icon. IMPORTANT: Please leave the IRB application e-form as part of your revision submission package, even if you didn’t need to modify it. Do not remove it.

8. When finished making all your modifications and revisions to your submission, click the icon to send the revised documents to the IRB office.

Note: Student protocols must be re-sent to the faculty advisor for internal review and approval prior to submission to the IRB. Faculty Principal Investigators may resubmit the protocol directly to the IRB office unless department head approval is specifically required per the determination letter. In the latter case, the revisions must be resubmitted to each person who reviewed the initial submission. Refer to the how to guide on submitting an IRB protocol for internal review and approval for instructions on adding additional persons to the internal review and approval route, if required.