Submitting Modifications or Updated Documents to IRB Net

1. Log into IRBNet.
2. Click on the Submission Manager tab in the navigation bar on the left side of the screen. Select the title of the study that is undergoing continuing review.
3. In the navigation bar on the left, select 'Project History'.
   a. A list of all "packages" that have been submitted as part of the study will be displayed.
4. Your original submission package will be listed as package number ######### - 1, and any modifications, amendments or unanticipated adverse events will each be listed as separate "packages." The last digit of the protocol number will change accordingly (to -2, -3, etc.) as modifications/resubmissions are made.
   b. The information provided in the Project History page includes the type of package submitted, the date of submission, and the status of each submitted package (approved, pending review, etc.).
5. Select the Create New Package button at the bottom of the Study History page. A new package will be added to your Project History page, named "new document package." The status of this package will be shown as "work in progress." The "work in progress" status will be displayed in the status column until the Amendment/Modification package is submitted.
6. Click on the blue 'New Document Package' text. If you are submitting a new application form (e.g., changing your submission from an Exempt form to the Expedited/Full form), use the dropdown menu to download the appropriate forms. After the forms are completed, upload any other documents required for your study's Amendment/ Modification application (e.g., consent form, revised consent form, revised protocol, survey or interview documentation, recruitment materials, new advertisements, etc.)
7. Select the 'Sign Study' button from the navigation menu on the left side of the screen. The PI or the PI's designee MUST sign the study before it is submitted.
8. Once you have attached all the required documents and signed the study, it can be submitted to the IRB Office. Select 'Submit this Project' from the navigation panel on the left side of the screen.
   b. Under 'Submission Type' use the drop down menu to select 'Amendment/Modification'. If you have any comments for the IRB office to accompany the submission, include them in the comment box. Select the 'Submit' button.

c. You will receive a confirmation message that your amendment/modification package has been submitted. An email message will be sent to you when there is activity required on your part or a decision letter has been issued.

Additional Instructions from IRBNet:

Your project documents are managed on the Designer, where you can assemble your documents into "packages" for submission to your board.

The Package Navigator is accessible by clicking on the blue arrow just above the Package Notes. Using the Package Navigator you can quickly create a new package, switch between packages, or view all of the project documents in a single list to quickly find the most recent version of any document.

When assembling your documents into a package for submission to your board, you can add entirely new documents to your package, or you can "revise" project documents that have already been submitted. "Revising" a document will create a new version of the document while maintaining prior versions in the Document Revision History.

Keeping documents properly maintained in the Document Revision History helps to organize your project, makes it easier to see the evolution of important documents over time, and helps you find the most recent version of each document you need. If you find that you haven't organized your documents correctly, you can simply drag and drop a document into, or out of, a Document Revision History.

Revise an Existing Document. Use the "revise" option when you want to add or create a new version of a project document that has already been submitted. IRBNet creates a new version of your document and retains all historical versions as part of your Document Revision History. You can view the historical versions of any document by clicking on the Document Revision History icon.

Add a New Document. Use the "Attach New Document" or "Start a Wizard" (if available) option when the document you are adding is <u>not</u> a revised or updated version of an existing project document. The "new" document will not be tied to the Document Revision History of any existing document. Instead, it will have a new Document Revision History of its own.

When using the "Attach" option, you can attach multiple documents at the same time simply by selecting them in the browse window, and you can even drag and drop documents directly into your package.

What about copies of existing documents? Committee members and administrators often need to access copies of previously submitted project documents, such as a previously approved Consent Form, when reviewing your new or revised documents. Committee members and administrators can automatically access these older documents as needed from the "Documents from Previous Packages" list. If you are unsure about the documents you are required to submit, you should contact your local administrator for more information.

Examples:

1. You have a modified Consent Form that replaces the current version of your Consent Form from a previous package.

   What To Do: Locate your Consent Form in the "Documents from Previous Packages" list and click the "Revise this Document" icon . This will allow you to create a new version of your document in your current package while retaining your complete Document Revision History.

2. You have a completely new document that is not a revised or updated version of any existing project document.

   What To Do: Click the "Attach New Document" button. This will allow you to add the new document to your current package. This new document will have a new Document Revision History of its own.

3. You need to update a Wizard document that you previously submitted.

   What To Do: Locate the Wizard document that you previously submitted in the "Documents from Previous Packages" list and click the "Revise this Document" icon . This will allow you to create a new version of your Wizard document in your current package. The new version will automatically retain all of the information previously entered into the Wizard so you only need to update the information that has changed. The new version of your Wizard document will be automatically added to your complete Document Revision History.

4. You want to start a completely new Wizard document that is not a revised or updated version of any existing Wizard in your project.

   What To Do: Click the "Start a Wizard" button. This will allow you to add the new Wizard document to your current package. This new Wizard will have a new Document Revision History of its own.

5. The committee requires a copy of a previously submitted project document to complete the review.

   What To Do: Committee members and administrators can automatically access previously submitted project documents as needed from the "Documents from Previous Packages" list. If you are unsure about the documents you are required to submit, you should contact your local administrator for more information.

6. You want to combine documents into the same Document Revision History.

What To Do: Simply drag any document into a Document Revision History, or over a Document Revision History icon, to add the document to that Document Revision History.

7. You want to remove a document from a Document Revision History.

   What To Do: Simply click the Document Revision History icon to open that document's Document Revision History, and then drag the document out of the Document Revision History to remove it. The document will then have a new Document Revision History of its own. You can also add the document to a different Document Revision History by dragging it into the new one.