

You may be asked to submit a revised project package with updated information for your local committee. Examples include: a continuing review, modifications required for approval, changes to the study team, or another reason. The following steps will help ensure a smooth submission.

Create a New Package for an Existing Project in IRBNet

1. In your My Projects page click on the title of the project to go to the Project Overview page.
2. Click the Project History button to the left.
3. Click the Create New Package button in the middle of the page.
4. Click the Designer button to work on documents for the new package via two methods:
 - Revise a previously submitted document; or
 - Attach a new document to the package.

Revise or Submit a Previously Submitted Document for Review (Designer page)

Refer to the 'Documents from Previous Packages' section at the bottom of the Designer page.

1. To revise or include a **Document Wizard** from a previous package for committee review:
 - Click on the pencil icon for the online Document Wizard document to be revised.

The screenshot shows the 'Documents from Previous Packages that you can Revise' section. At the top, there is a button 'Add New Document' and a link 'When should I do this?'. Below this, the text 'OR' is centered. The main section is titled 'Documents from Previous Packages that you can Revise: When should I do this?'. It contains a table with the following data:

Pkg #	Document Type	Description	Last Modified	Pkg Submission Date	Pkg Status	Actions
1	Consent Form	Consent Form	09/06/2008 11:34 AM	09/06/2008	Approved	[Pencil icon]
1	Protocol	protocol	09/06/2008 11:31 AM	09/06/2008	Approved	[Pencil icon]
1	Research Application Form	Research Application Form	09/06/2008 11:33 AM	09/06/2008	Approved	[Pencil icon]
1	Study Plan	study plan	09/06/2008 11:33 AM	09/06/2008	Approved	[Pencil icon]

In the original image, the pencil icon for the 'Research Application Form' row is circled in red.

- Make any necessary changes to previously entered information and save. The document will move to the 'New and Revised Documents in this Package' section.

New and Revised Documents in this Package:

Document Type	Description	Last Modified	Actions
Research Application Form	Research Application Form	07/28/2009 08:52 AM	[Pencil icon] [X icon]

IRBNet allows you to revise your existing project documents and maintain version history, or add entirely new documents to your package. [Learn more.](#)

Add New Document [When should I do this?](#)

OR

Documents from Previous Packages that you can Revise: [When should I do this?](#)

Pkg #	Document Type	Description	Last Modified	Pkg Submission Date	Pkg Status	Actions
1	Consent Form	Consent Form	09/06/2008 11:34 AM	09/06/2008	Pending Review	[Pencil icon]

- To revise an **uploaded document** (.doc, .xls, .pdf, etc.) in a previous package:
 - First download the document by clicking on Document Type or the paper icon.
 - Make necessary changes and **save** the revised document to your computer.
 - Click on the pencil icon for that document in the Designer.

[Add New Document](#) [When should I do this?](#)

OR

Documents from Previous Packages that you can Revise: [When should I do this?](#)

Pkg #	Document Type	Description	Last Modified	Pkg Submission Date	Pkg Status	
1	Consent Form	Consent Form	09/06/2008 11:34 AM	09/06/2008	Pending Review	
1	Protocol	protocol	09/06/2008 11:31 AM	09/06/2008	Pending Review	

- Browse** your computer, select your revised document to upload, make necessary changes to Document Type and Description (below), and click the **Update** button.

Welcome to IRBNet
Amanda Saunders

My Projects
Create New Project
My Reminders (2)

Project Administration
Project Overview
Designer
Share this Project
Sign this Package
Submit this Package
Delete this Package
Send Project Mail
Reviews
Project History

Attach Document

[95621-2] A Phase 3, Randomized, Placebo-Controlled, Blinded, Multicenter Study of the Induction and Mainten
You are updating an attachment. To help you identify the file that was attached:

- This attachment was loaded from the file **ASM981 C2439 Protocol.pdf**.
- It was attached on **10/22/2009**.
- It has a size of **361131** bytes.

Document Type * Protocol

Description updated protocol

File * **Browse...**

Update **Cancel**

* required fields

- When you click Update, the revised document will appear in the current document package ('New and Revised Documents in this Package') with a revision history that reflects versions from previous packages (see below).

Step 2:

Assemble your document package.

New and Revised Documents in this Package:

Document Type	Description	Last Modified				
Protocol	updated protocol	07/28/2009 09:02 AM				
Research	Document Revision History					
Pkg #	Document Type	Description	Last Modified	Pkg Submission Date	Pkg Status	
2	Protocol	updated protocol	07/28/2009 09:02 AM		Work in progress	
1	Protocol	protocol	09/06/2008 11:31 AM	09/06/2008	Pending Review	

Attach a New Document to the Package (Designer)

1. **Download** the document template and related instructions from the Document Library.

Step 1:

Download blank forms, document templates and reference materials to assist you in assembling your document package.

Select a Library: Metropolitan IRB, Frederick, MD

Select a Document: IRB Submission Checklist **Download**

IRB Submission Checklist
Application for Continued Approval
Application for Exemption Review
Application for Expedited and Full Committee Review

Step 2:

Assemble your document

2. Complete downloaded forms or create documents to be submitted.
3. Use the Add New Document button to upload the document into the current package. The document will not have a revision history (stack of paper icon) at this time as it is new.

Points to Remember

When you have attached all the required documents, please remember to **sign** the package as instructed by your committee.

Submit the revised package to your local committee. Be sure to indicate the appropriate Submission Type (image to right).

The following IRBNet users at Gotham IRB will be automatically notified of your submission:
Administrator, Tanya

Submission Type: *

You may also specify additional comments to

Your Comments:

- Adverse Event
- Close/Final Report
- Continuing Review/Renewal
- Modification/Amendment
- New Project
- Other
- Publication
- Reportable Event (Non-AE)
- Response/Follow-Up
- Revision

Submit Cancel

Note: All documents required for committee review should be included in the current package. It is not necessary to attach copies of historical, unchanged project documents (such as the previously approved consent form) unless directed by your local committee for their review purposes. These historical documents will always be available in the Designer for consideration by the committee.