

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 Study Manager 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.

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	Approved	
1	Protocol	protocol	09/06/2008 11:31 AM	09/06/2008	Approved	
1	Research Application Form	Research Application Form	09/06/2008 11:33 AM	09/06/2008	Approved	
1	Study Plan	study plan	09/06/2008 11:33 AM	09/06/2008	Approved	

- 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	
Research Application Form	Research Application Form	07/28/2009 08:52 AM	

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	
1	Consent Form	Consent Form	09/06/2008 11:34 AM	09/06/2008	Pending Review	

- 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.

[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

- Study Manager
- Create New Project
- Project Administration**
- Project Overview
- Designer
- Share this Project
- Sign this Package
- Submit this Package
- Project History
- Send Mail
- Delete this Package

Attach Document

[95621-2] A Phase 3, Randomized, Placebo-Controlled, Blinded, Multicenter Study of the Induction and Maintenance of Remission in Patients with Crohn's Disease

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 **09/06/2008**.
- It has a size of **361131** bytes.

Document Type *

Description

File

* 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	

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: *

- 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: If documents are required for committee review then they should be included in the current package. It is not necessary to attach copies of historical project documents (such the previously approved consent form) unless directed by your local committee for their review. These historical documents will always be available in the Designer for consideration by the committee.