

## Notes for Researchers and Study Coordinators: Submitting a Revised Project Package

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.



 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 4 🔗 🗶 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? Last **Document Type** Description Submission Pkg Status Modified Date Consent Form 09/06/2008 09/06/2008 Consent Form Pending

11:34 AM

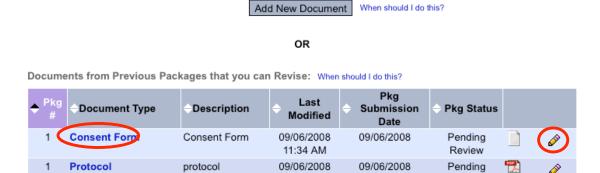
Review



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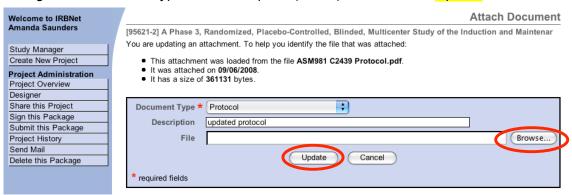
Review

- 2. 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.



11:31 AM

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



 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).

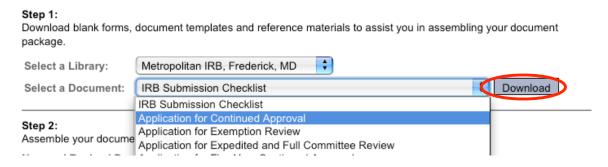
Assemble your document package. New and Revised Documents in this Package: **Last Modified Protocol** updated protocol 07/28/2009 09:02 AM **Document Revision History** Research Pkg Last **Document Type** Description Submission Pkg Status IRBNet al elv new documents Modified Date to your pa Protocol updated protocol 07/28/2009 Work in 09:02 AM progress 09/06/2008 09/06/2008 Protocol protocol Pending 11:31 AM Review



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## Attach a New Document to the Package (Designer)

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



- 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).

Note: If documents are required for committee review then they should be included in the

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

Submit Cancel

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.