IRBNet provides the research community with an unmatched set of secure, web-based collaboration tools to support the design, management, review and oversight of research involving human subjects.

This Energizer covers advanced submission topics for Researchers, Research Managers or Research Coordinators. This Energizer will illustrate:

- Creating a second package
- Adding and revising documents for a second package
Revise Your Study As Necessary
You can easily revise your study by two techniques. All versions of your study become a permanent part of your electronic study record.

To create a new package in sequence from an existing package (ex. 100104-1) click on:

1. Designer
2. Project History

Note this is the first study package in the sequence.
If you clicked the Designer button:
You will be taken to the designer page, and will need to add a new document to create a second package.

- Click "Add New Document" to add documents to next package.
If you click the Project History button:

You will be taken to the Project History page and will need to add a second package.

✓ Click “Create New package.”
Revise Your Study As Necessary
It is necessary to create a separate, new package to preserve the audit trail.

Before you make a new package by clicking “Create New Package”, check with your local coordinator for specific local instructions.

This will save time and effort for all parties and result in more efficient processing of your submission.
Revise Your Study As Necessary
Creating a second package.

- Note that a second package is created.
- The Study History indicates all packages in the study lifecycle.
- Now click on the New Document Package to begin building the package.
**Researcher: Subsequent Package Submission**

**Training Energizer**

Add or Revise Documents

Bring forward and revise documents previously submitted, or simply add a new document.

---

**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:** Application for Continued Approval

**Step 2:**
Assemble your document package.

New and Revised Documents in this Package:

*There are currently no documents in this package.*

IRBNet allows you to revise your existing project documents and maintain versions control to your package. Learn more.

- **Add New Document**

OR

Documents from the previous submitted package are referenced.

- To add a new document, click “Add new Document”.

- To update an older document:
  1. Download the previous version to your computer, modify as required and save.
  2. Click on the pencil (update) icon.

---

Documents from Previous Packages that you can Revise:

<table>
<thead>
<tr>
<th>Pkg #</th>
<th>Document Type</th>
<th>Description</th>
<th>Last Modified</th>
<th>Pkg Submission Date</th>
<th>Pkg Status</th>
<th>1</th>
<th>2</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Consent Form</td>
<td>Consent Form</td>
<td>09/06/2008 11:34 AM</td>
<td>09/06/2008</td>
<td>Approved</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>Protocol</td>
<td>protocol</td>
<td>09/06/2008 11:31 AM</td>
<td>09/06/2008</td>
<td>Approved</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>Research Application Form</td>
<td>Research Application Form</td>
<td>09/06/2008 11:33 AM</td>
<td>09/06/2008</td>
<td>Approved</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>Study Plan</td>
<td>study plan</td>
<td>09/06/2008 11:33 AM</td>
<td>09/06/2008</td>
<td>Approved</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

---

*When should I do this?*
Attach Document
Browse and locate the revised or new document on your computer, and attach by clicking the Update button.

- Browse your hard drive for documents, and attach.
- This view is for updating a document from package 1. The view for attaching a new document is similar.
Document tools
Powerful tools to modify and review documents.

- View
- View revision history
- Update
- Delete document

- Note that after revising, the document is removed from the visible list of documents from previous packages
Revision History

The revision history, by study package, is available for review.

The Document Revision History lists the most recent document and every previous version submitted by package.
Researcher: Subsequent Package Submission

When the study documentation is complete, sign and submit according to your institution’s SOPs.

[IRBNet ID: 95621-2] A Phase 3, Randomized, Placebo-Controlled, Blinded, Multicenter Study of the Induction and Maintenance

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: Application for Continued Approval

Step 2:
Assemble your document package.

New and Revised Documents in this Package:

<table>
<thead>
<tr>
<th>Document Type</th>
<th>Description</th>
<th>Last Modified</th>
</tr>
</thead>
<tbody>
<tr>
<td>Protocol</td>
<td>updated protocol</td>
<td>02/02/2009 10:19 AM</td>
</tr>
</tbody>
</table>

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

OR

Documents from Previous Packages that you can Revise:

<table>
<thead>
<tr>
<th>Pkg #</th>
<th>Document Type</th>
<th>Description</th>
<th>Last Modified</th>
<th>Pkg Submission Date</th>
<th>Pkg Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Consent Form</td>
<td>Consent Form</td>
<td>09/06/2006 11:34 AM</td>
<td>09/06/2006</td>
<td>Approved</td>
</tr>
<tr>
<td>1</td>
<td>Research Application Form</td>
<td>Research Application Form</td>
<td>09/06/2006 11:33 AM</td>
<td>09/06/2006</td>
<td>Approved</td>
</tr>
<tr>
<td>1</td>
<td>Study Plan</td>
<td>study plan</td>
<td>09/06/2006 11:33 AM</td>
<td>09/06/2006</td>
<td>Approved</td>
</tr>
</tbody>
</table>
Where to Get Help...

Your IRB Office can offer you assistance and training on IRBNet as well as advice on how to comply with important policies and standards as you use IRBNet.