**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. 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 “Study Designer”.

Note this is the first study package in the sequence.
Welcome to IRBNet
Amanda Saunders

Study Manager
Create New Study

Study Administration
Study Overview
Study Designer
Share this Study
Sign Study
Submit this Study
Study History
Send Mail
Delete this Study

Researcher: Subsequent Package Submission
Training Energizer

Revise Your Study As Necessary
Add New Document.

1. View
2. Update
3. Delete document

- Click “Add New Document” to add documents to next package.

[Table]

<table>
<thead>
<tr>
<th>Document Type</th>
<th>Description</th>
<th>Last Modified</th>
</tr>
</thead>
<tbody>
<tr>
<td>Form</td>
<td>My consent form</td>
<td>11/07/2008 10:52 AM</td>
</tr>
<tr>
<td>Informed Consent</td>
<td>my Brochure</td>
<td>11/06/2008 05:28 PM</td>
</tr>
<tr>
<td>Registration Page</td>
<td>Registration Page</td>
<td>11/06/2008 05:27 PM</td>
</tr>
</tbody>
</table>

Get approval letters and other board documents, and track reviews for this package: Review details.
Revise Your Study As Necessary

It is necessary to create a separate, new package to preserve the audit trail.

Your current document package has already been submitted and your study is presently locked by your Board. You may contact your Board and request that they unlock the study. This will allow you to make modifications to this study without creating a new document package.

You may prepare new or modified documents (such as Revision/Amendment materials, Renewal/Continuing Review materials, and Adverse Event Reports) by creating a new document package for this study. Creating a new document package will allow you to make changes while also automatically retaining the current versions of all documents as part of your electronic audit trail.

Before you make a new package by clicking “Create New Package”, check with your local coordinator for specific local SOPs and 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 adds documentation to the Study History.

The following document packages are available in Study History:

<table>
<thead>
<tr>
<th>Pkg #</th>
<th>Package Type</th>
<th>Status</th>
<th>Create Date</th>
<th>Submission Date</th>
<th>Review Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>New Document Package</td>
<td>Work in progress</td>
<td>11/06/2008</td>
<td>11/06/2008</td>
<td>11/06/2008</td>
</tr>
<tr>
<td>1</td>
<td>New Study</td>
<td>Approved</td>
<td>11/06/2008</td>
<td>11/06/2008</td>
<td>11/06/2008</td>
</tr>
</tbody>
</table>

2 Packages found, displaying all Packages.

✓ Note that a second package is created.
✓ The Study History indicates all packages in the study lifecycle.
Add or Revise Documents
Bring forward and revise documents previously submitted, or simply add a new document.

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

Documents from the previous submitted package are referenced.
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.
Attach Document

Browse and locate the revised or new document on your computer, and attach by clicking the Update button.

- This attachment was loaded from the file Consent Form - Spinal Motion.doc.
- It was attached on 11/07/2008.
- It has a size of 93184 bytes.

To Update this attachment:

1. Choose document type to attach from drop down menu.
2. Provide study-specific information in description field.
3. If you wish to update the document then click Browse to find the document in your computer files.
4. Click Update to complete.

Browse your hard drive for new or updated documents, and attach.
Document tools
Powerful tools to modify and review documents.

Step 1:
Download blank forms, document templates and reference materials to assist you in assembling a new package.

Select a Library: Metropolitan IRB, Frederick, MD
Select a Document: 1a.IRBNet_Full_Committee_Submission_Checklist

Step 2:
Assemble your document package.

New and Revised Documents in this Package:

<table>
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<tr>
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<th>Pkg Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Consent Form</td>
<td>My revised consent form</td>
<td>11/07/2008 10:55 AM</td>
<td></td>
<td></td>
</tr>
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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?

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<tr>
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<tbody>
<tr>
<td>1</td>
<td>Investigator’s Brochure</td>
<td>my Brochure</td>
<td>11/06/2008 05:28 PM</td>
<td>11/06/2008</td>
<td>Approved</td>
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<td>1</td>
<td>Registration Page</td>
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<td>11/06/2008 05:27 PM</td>
<td>11/06/2008</td>
<td>Approved</td>
</tr>
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</table>

Note that after revising, the document is removed from the visible list of documents from previous packages.
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.
Subsequent Package Submission

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

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: 1a.IRBNet_Full_Committee_Submission_Checklist  Download

Step 2:
Assemble your document package.

New and Revised Documents in this Package:

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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.