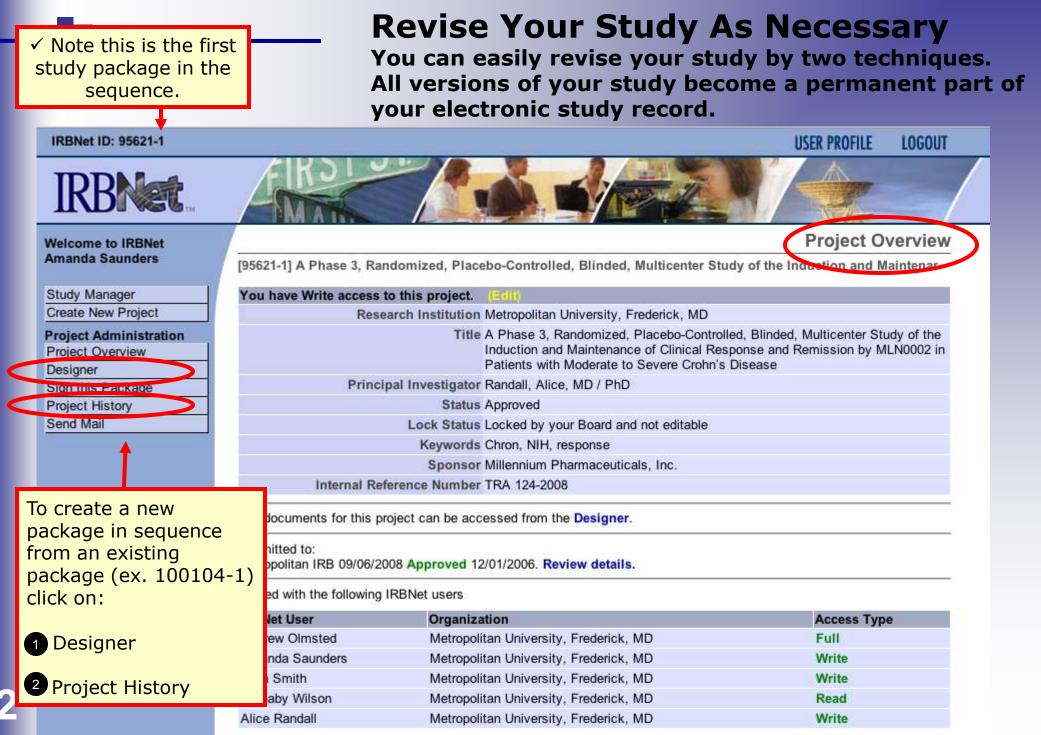


IRBNet provides the research community with an unmatched set of secure, web-based collaboration tools to support the design, management, review and oversight of research involving human subjects.

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





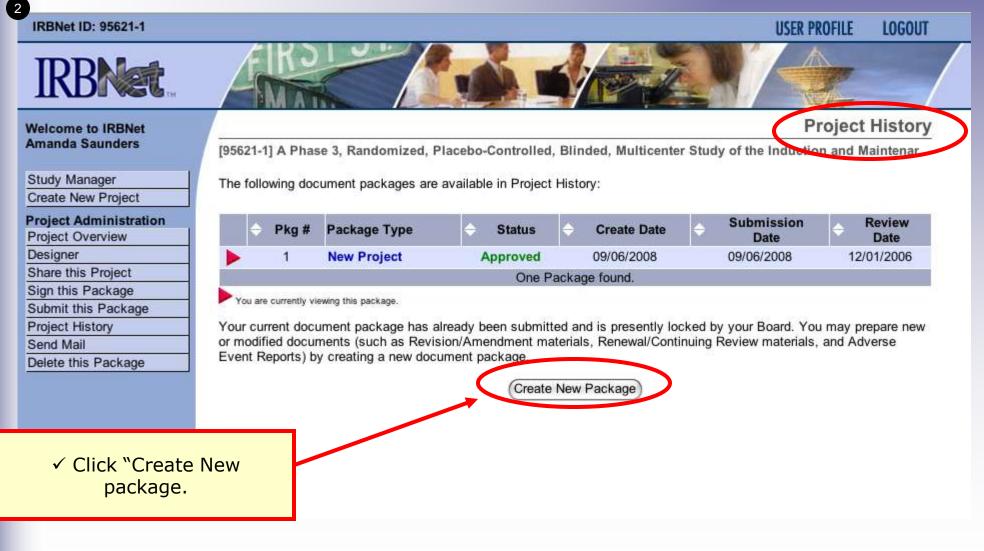
If you clicked the Designer button:

You will be taken to the designer page, and will need to add a new document to create a second package.

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1 · · · · J ·	Study Plan		study plan	09/06/2008 11:33 AM		0	~

If you click the Project History button:

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



Revise Your Study As Necessary

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



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

[95621-1] A Phase 3, Randomized, Placebo-Controlled, Blinded, Multicenter Study of the Induction and Maintenal

Your current document package has already been submitted and is presently locked by your Board.

You may contact your Board and request that they unlock the package. This will allow you to make modifications directly to this package instead of creating a new 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 make changes while also automatically retaining the current versions of all documents as part of your electronic audit trail.

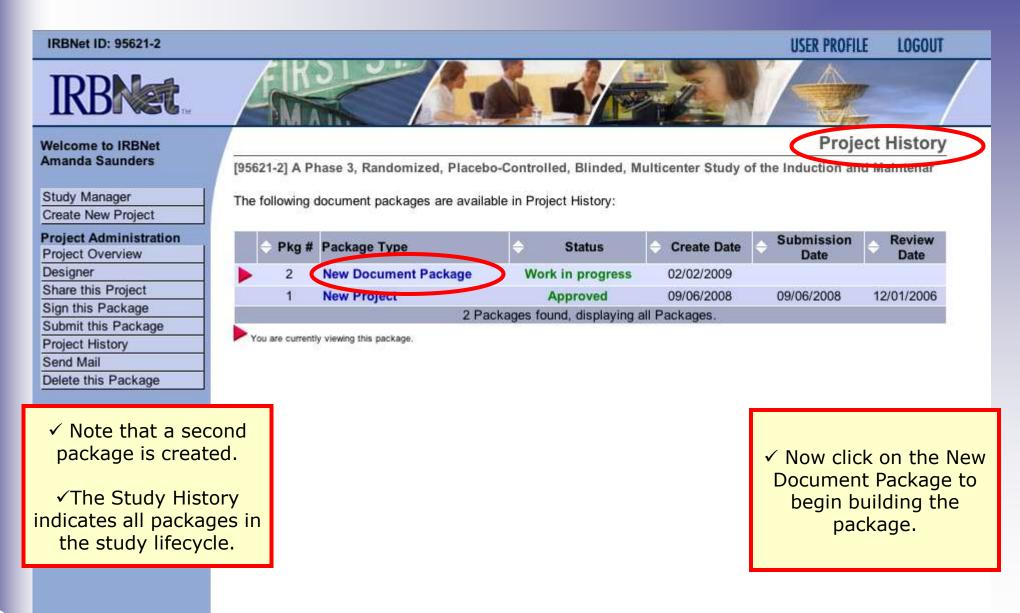


✓ Before you make a new package by clicking "Create New Package", check with your local coordinator for specific local instructions.

✓ 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.



Researcher: Subsequent Package Submission Training Energizer Add or Revise DocumentsBring forward and revise documents previously

submitted, or simply add a new document.

Welcome to IRBNet Amanda Saunders	Designer
Study Manager Create New Project Project Administration Project Overview Designer Share this Project Sign this Package Submit this Package	[95621-2] A Phase 3, Randomized, Placebo-Controlled, Blinded, Multicenter Study of the Induction and Maintenar 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.
Project History Send Mail Delete this Package	New and Revised Documents in this Package: * To add a new document, click * Add new Document".
	 There are currently no documents in this To update an older document: Download the previous version to your computer, modify as required and save. Click on the pencil (update) icon.
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Research Application

Form

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Research Application

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Form

Study Plan

Attach Document

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

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Welcome to IRBNet	Att	tach Document	t
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Project Administration Project Overview	 It was attached on 09/06/2008. It has a size of 361131 bytes. 		
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Document tools

Powerful tools to modify and review documents.

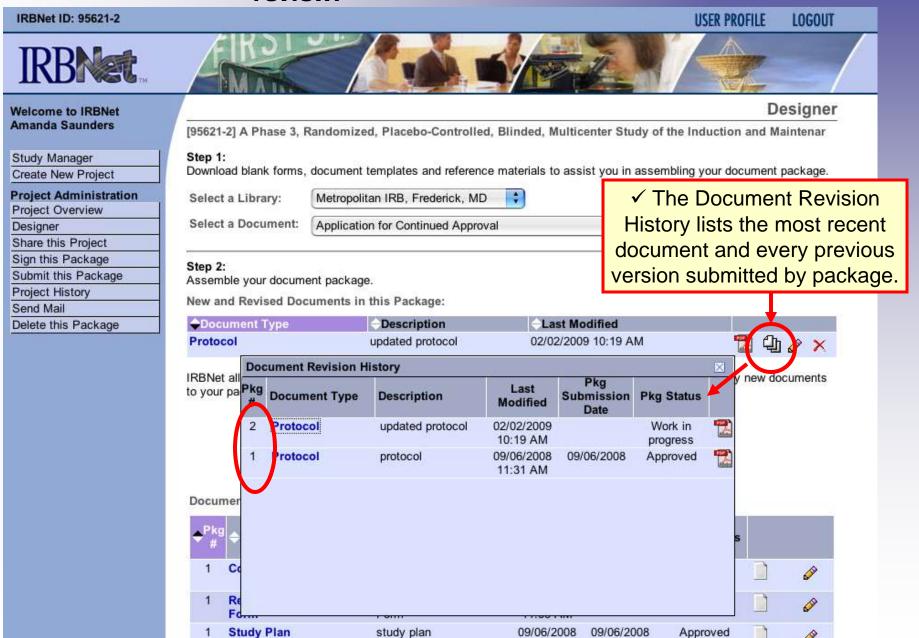
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Documents from Previous Packages that you can Revise: When should I do this?

Pkg #		Description	Last Modified	Pkg Submission Date	Pkg Status	
1	Consent Form	Consent Form	09/06/2008 11:34 AM	09/06/2008	Approved	ø
1	Research Application Form	Research Application Form	09/06/2008 11:33 AM	09/06/2008	Approved	Ø
1	Study Plan	study plan	09/06/2008 11:33 AM	09/06/2008	Approved	ø

Revision History

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



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Submission

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

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or add entirely new docum	ients
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Documents from Previous Packages that you can Revise: When should I do this?

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1	Consent Form	Consent Form	09/06/2008 11:34 AM	09/06/2008	Approved	s in
1	Research Application Form	Research Application Form	09/06/2008 11:33 AM	09/06/2008	Approved	ø
1	Study Plan	study plan	09/06/2008 11:33 AM	09/06/2008	Approved	ø

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.

