

Researcher: Subsequent Package Submission Training Energizer

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



Researcher: Subsequent Package Submission Training Energizer

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.

✓ Note this is the first study package in the sequence.

IRBNet ID: 95621-1 USER PROFILE LOGOUT

IRBNet™

Welcome to IRBNet
Amanda Saunders

Study Manager
Create New Project

Project Administration
[Project Overview](#)
[Designer](#)
[Sign this Package](#)
[Project History](#)
Send Mail

Project Overview

[95621-1] A Phase 3, Randomized, Placebo-Controlled, Blinded, Multicenter Study of the Induction and Maintenance of Clinical Response and Remission by MLN0002 in Patients with Moderate to Severe Crohn's Disease

You have Write access to this project. (Edit)

Research Institution	Metropolitan University, Frederick, MD
Title	A Phase 3, Randomized, Placebo-Controlled, Blinded, Multicenter Study of the Induction and Maintenance of Clinical Response and Remission by MLN0002 in Patients with Moderate to Severe Crohn's Disease
Principal Investigator	Randall, Alice, MD / PhD
Status	Approved
Lock Status	Locked by your Board and not editable
Keywords	Chron, NIH, response
Sponsor	Millennium Pharmaceuticals, Inc.
Internal Reference Number	TRA 124-2008

Documents for this project can be accessed from the **Designer**.

Submitted to:
Metropolitan IRB 09/06/2008 **Approved** 12/01/2006. [Review details.](#)

Shared with the following IRBNet users

IRBNet User	Organization	Access Type
Andrew Olmsted	Metropolitan University, Frederick, MD	Full
Amanda Saunders	Metropolitan University, Frederick, MD	Write
Alice Smith	Metropolitan University, Frederick, MD	Write
Debra Wilson	Metropolitan University, Frederick, MD	Read
Alice Randall	Metropolitan University, Frederick, MD	Write

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


- 1 Designer
- 2 Project History

Researcher: Subsequent Package Submission Training Energizer

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.

1 IRBNet ID: 95621-1 USER PROFILE LOGOUT



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 Maintenance of Remission in Patients with Crohn's Disease

This package is: **Locked**

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.

Documents in this Package:

Document Type	Description	Last Modified	1	3	4
Form	Consent Form	09/06/2008 11:34 AM			
Form	protocol	09/06/2008 11:31 AM			
Application Form	Research Application Form	09/06/2008 11:33 AM			
Study Plan	study plan	09/06/2008 11:33 AM			

1 View
3 Update
4 Delete document

✓ Click "Add New Document" to add documents to next package.

Add New Document

Researcher: Subsequent Package Submission Training Energizer

If you click the Project History button:

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

2

IRBNet ID: 95621-1 USER PROFILE LOGOUT

IRBNet™

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 Maintenance of Remission in Acute Myeloid Leukemia

The following document packages are available in Project History:

Pkg #	Package Type	Status	Create Date	Submission Date	Review Date
1	New Project	Approved	09/06/2008	09/06/2008	12/01/2006

One Package found.

You are currently viewing this package.

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

[Create New Package](#)

✓ Click "Create New package."

Researcher: Subsequent Package Submission

Training Energizer

Revise Your Study As Necessary
It is necessary to create a separate, new package to preserve the audit trail.

The screenshot shows the IRBNet user interface. At the top left, it displays 'IRBNet ID: 95621-1'. At the top right, there are links for 'USER PROFILE' and 'LOGOUT'. The main header features the IRBNet logo and a banner image. On the left side, there is a navigation menu with the following items: 'Study Manager', 'Create New Project', 'Project Administration', 'Project Overview', 'Designer', 'Share this Project', 'Sign this Package', 'Submit this Package', 'Project History', 'Send Mail', and 'Delete this Package'. The main content area displays a message: 'Package is Locked' (circled in red). Below this, it states: '[95621-1] A Phase 3, Randomized, Placebo-Controlled, Blinded, Multicenter Study of the Induction and Maintenance of Remission in Acute Myeloid Leukemia'. The message continues: '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'. At the bottom of the message area, there are two buttons: 'Cancel' and 'Create New Package' (circled in red).

- ✓ 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.

Researcher: Subsequent Package Submission Training Energizer

Revise Your Study As Necessary Creating a second package.

The screenshot shows the IRBNet web application interface. At the top left, the IRBNet ID is 95621-2. At the top right, there are links for 'USER PROFILE' and 'LOGOUT'. The main header features the IRBNet logo and a banner image. On the left side, there is a navigation menu with options like 'Study Manager', 'Create New Project', 'Project Administration', 'Project Overview', 'Designer', 'Share this Project', 'Sign this Package', 'Submit this Package', 'Project History', 'Send Mail', and 'Delete this Package'. The main content area displays the project title '[95621-2] A Phase 3, Randomized, Placebo-Controlled, Blinded, Multicenter Study of the Induction and Maintenance' and a 'Project History' link circled in red. Below this, it states 'The following document packages are available in Project History:' and shows a table of packages. The table has columns for Pkg #, Package Type, Status, Create Date, Submission Date, and Review Date. Two packages are listed: Pkg # 2, 'New Document Package' (circled in red), with status 'Work in progress' and create date '02/02/2009'; and Pkg # 1, 'New Project', with status 'Approved', create date '09/06/2008', submission date '09/06/2008', and review date '12/01/2006'. Below the table, it says '2 Packages found, displaying all Packages.' and 'You are currently viewing this package.'

Pkg #	Package Type	Status	Create Date	Submission Date	Review Date
2	New Document Package	Work in progress	02/02/2009		
1	New Project	Approved	09/06/2008	09/06/2008	12/01/2006

✓ 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.

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

Designer

[95621-2] A Phase 3, Randomized, Placebo-Controlled, Blinded, Multicenter Study of the Induction and Maintenan

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 version control for your package. [Learn more.](#)

Add New Document

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	2
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		

- ✓ 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.



Researcher: Subsequent Package Submission

Training Energizer

Attach Document

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

IRBNet ID: 95621-2 USER PROFILE LOGOUT

IRBNet

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

[95621-2] A Phase 3, Randomized, Placebo-Controlled, Blinded, Multicenter Study of the Induction and Maintenance of Remission in Patients with Acute Myeloid Leukemia

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 * Protocol

Description updated protocol

File Browse...

Update Cancel

- ✓ 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.

Researcher: Subsequent Package Submission Training Energizer

Document tools

Powerful tools to modify and review documents.

IRBNet ID: 95621-2 USER PROFILE LOGOUT

IRBNet

Welcome to IRBNet
Amanda Saunders

Project Administration

- Study Manager
- Create New Project
- Project Overview
- Designer
- Share this Project
- Sign this Package
- Submit this Package
- Project History

Designer

[95621-2] A Phase 3, Randomized, Placebo-Controlled, Blinded, Multicenter Study

Step 1:
Download blank forms, document templates and reference materials to assist you in as

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:

Document Type	Description	Last Modified	1	2	3	4
Protocol	updated protocol	02/02/2009 10:19 AM				

IRBNet allows you to revise your existing project documents and maintain version history, or add entirely new documents to your package. [Learn more.](#)

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	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		

- 1 View
- 2 View revision history
- 3 Update
- 4 Delete document



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

Researcher: Subsequent Package Submission Training Energizer

Revision History

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

The screenshot shows the IRBNet web application interface. At the top, the IRBNet ID is 95621-2, and there are links for USER PROFILE and LOGOUT. The user is identified as Amanda Saunders, a Designer. The main content area shows the details for a Phase 3 study package. A callout box highlights the Document Revision History table, which lists two versions of the protocol document. The most recent version (Pkg # 2) is highlighted with a red circle, and an arrow points from the callout box to it.

IRBNet ID: 95621-2 USER PROFILE LOGOUT

IRBNet

Welcome to IRBNet
Amanda Saunders Designer

[95621-2] A Phase 3, Randomized, Placebo-Controlled, Blinded, Multicenter Study of the Induction and Maintenan

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:

Document Type	Description	Last Modified	
Protocol	updated protocol	02/02/2009 10:19 AM	

Document Revision History

Pkg #	Document Type	Description	Last Modified	Pkg Submission Date	Pkg Status	
2	Protocol	updated protocol	02/02/2009 10:19 AM		Work in progress	
1	Protocol	protocol	09/06/2008 11:31 AM	09/06/2008	Approved	

Document

Pkg #	
1	Co
1	Re
1	Stu

✓ The Document Revision History lists the most recent document and every previous version submitted by package.

Researcher: Subsequent Package Submission

Training Energizer

Submission

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

IRBNet ID: 95621-2
USER PROFILE LOGOUT

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Study Manager
Create New Project

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Designer

[95621-2] A Phase 3, Randomized, Placebo-Controlled, Blinded, Multicenter Study of the Induction and Maintenan

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

Select a Library:

Select a Document:

Step 2:
Assemble your document package.

New and Revised Documents in this Package:

Document Type	Description	Last Modified	
Protocol	updated protocol	02/02/2009 10:19 AM	

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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	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	

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.