

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. All versions of your study become a permanent part of your electronic study record.

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

The screenshot shows the IRBNet web application interface. At the top, the IRBNet ID is 100104-1. The user profile is Amanda Saunders. The main navigation menu includes 'Study Manager', 'Create New Study', 'Study Administration', 'Study Overview', 'Study Designer', 'Share this Study', 'Sign Study', 'Submit this Study', 'Study History', 'Send Mail', and 'Delete this Study'. The 'Study Designer' option is circled in red. The main content area displays study details for '[100104-1] Public Acceptance of Dihydrogen Monoxide'. A red circle highlights the 'Study Overview' link in the top right. Below the study title, it states 'You have Full access for this study (Edit)'. The details include: Research Institution (Metropolitan University, Frederick, MD), Study Title (Public Acceptance of Dihydrogen Monoxide), Principal Investigator (Travis, Randy, MD/PhD), Study Status (Approved), Lock Status (Locked by your Board and not editable), Keywords (music), Sponsor (NIH), and Internal Reference Number (dept-08-1101). Below this, it says 'The documents for this study can be accessed from the Study Designer.', with 'Study Designer' circled in red. At the bottom, it shows submission details: 'Submitted to: Metropolitan IRB 11/06/2008 Approved 11/06/2008. Review details.' and a table of users with access types.

IRBNet User	Organization	Access Type
Lawrence Bird	Metropolitan University, Frederick, MD	Read
Amanda Saunders	Metropolitan University, Frederick, MD	Full
John Smith	Metropolitan University, Frederick, MD	Write

✓ To create a new package in sequence from an existing package (ex. 100104-1) click on "Study Designer".

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Revise Your Study As Necessary Add New Document.

The screenshot shows the IRBNet Study Designer interface. On the left is a navigation menu with options like 'Study Manager', 'Create New Study', and 'Study Administration'. The main area shows details for a study package: '[100104-1] Public Acceptance of Dihydrogen Monoxide', which is 'Locked'. It includes 'Step 1' instructions and a 'Step 2' section with a table of documents in the package. A legend on the right explains icons for 'View', 'Update', and 'Delete document'. A callout box points to the 'Add New Document' button at the bottom.

Study Designer

[100104-1] Public Acceptance of Dihydrogen Monoxide

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: 1a.IRBNet_Full_Committee_Submission_Checklist [Down Arrow]

Step 2:
Assemble your document package.

Documents in this Package:

Document Type	Description	Last Modified	1	3	4
Form	My consent form	11/07/2008 10:52 AM			
Director's Brochure	my Brochure	11/06/2008 05:28 PM			
Registration Page	Registration Page	11/06/2008 05:27 PM			

Legend:

- 1 View
- 3 Update
- 4 Delete document

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

Add New Document

Get approval letters and other board documents, and track reviews for this package: [Review details](#).

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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 interface. On the left is a navigation menu with the following items: 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, and Delete this Study. The main content area displays the study title "[100104-1] Public Acceptance of Dihydrogen Monoxide" and a message: "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 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 are two buttons: "Cancel" and "Create New Package". A red circle highlights the "Study is Locked" message, and another red circle highlights the "Create New Package" button.

- ✓ 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.

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Training Energizer

Revise Your Study As Necessary

Creating a second package adds documentation to the Study History.

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

[100104-2] Public Acceptance of Dihydrogen Monoxide

The following document packages are available in Study History:

Pkg #	Package Type	Status	Create Date	Submission Date	Review Date
2	New Document Package	Work in progress	11/06/2008		
1	New Study	Approved	11/06/2008	11/06/2008	11/06/2008

2 Packages found, displaying all Packages.

You are currently viewing this package.

- ✓ Note that a second package is created.
- ✓ The Study History indicates all packages in the study lifecycle.

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 Study

Study Administration

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

Study Designer

[100104-2] Public Acceptance of Dihydrogen Monoxide

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_Submissio

Step 2:

Assemble your document package.

New and Revised Documents in this Package:

There are currently no documents in this package.







✓ 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.

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	My consent form	11/07/2008 10:52 AM	11/06/2008	Approved		
1	Investigator's Brochure	my Brochure	11/06/2008 05:28 PM	11/06/2008	Approved		
1	Registration Page	Registration Page	11/06/2008	11/06/2008	Approved		

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Training Energizer

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 new or updated documents, and attach.

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Document tools

Powerful tools to modify and review documents.

Study Designer

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

[100104-2] Public Acceptance of Dihydrogen Monoxide

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:

Document Type	Description	Last Modified	1	2	3	4
Consent Form	My revised consent form	11/07/2008 10:55 AM				

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

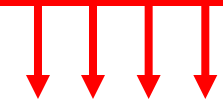
When should I do this?

OR

Documents from Previous Packages that you can Revise: [When should I do this?](#)

Pkg #	Document Type	Description	Last Modified	Pkg Submission Date	Pkg Status	1	2
1	Investigator's Brochure	my Brochure	11/06/2008 05:28 PM	11/06/2008	Approved		
1	Registration Page	Registration Page	11/06/2008 05:27 PM	11/06/2008	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

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Revision History

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

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

Other Tools
Library Manager

Study Designer

[100104-2] Public Acceptance of Dihydrogen Monoxide




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

Step 2:
Assemble your document package.

New and Revised Documents in this Package:

Document Type	Description	Last Modified	
Consent Form	My revised consent form	11/07/2008 10:55 AM	  

Document Revision History

Pkg #	Document Type	Description	Last Modified	Pkg Submission Date	Pkg Status
2	Consent Form	My revised consent form	11/07/2008 10:55 AM		Work in progress
1	Consent Form	My consent form	11/07/2008 10:52 AM	11/06/2008	Approved

IRBNet all to your pa

Document

05:27 PM

✓ 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.

Study Designer

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

Other Tools

Library Manager

[100104-2] Public Acceptance of Dihydrogen Monoxide

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:

Document Type	Description	Last Modified	
Consent Form	My revised consent form	11/07/2008 10:55 AM	   

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?](#)

Pkg #	Document Type	Description	Last Modified	Pkg Submission Date	Pkg Status	
1	Investigator's Brochure	my Brochure	11/06/2008 05:28 PM	11/06/2008	Approved	 
1	Registration Page	Registration Page	11/06/2008 05:27 PM	11/06/2008	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.