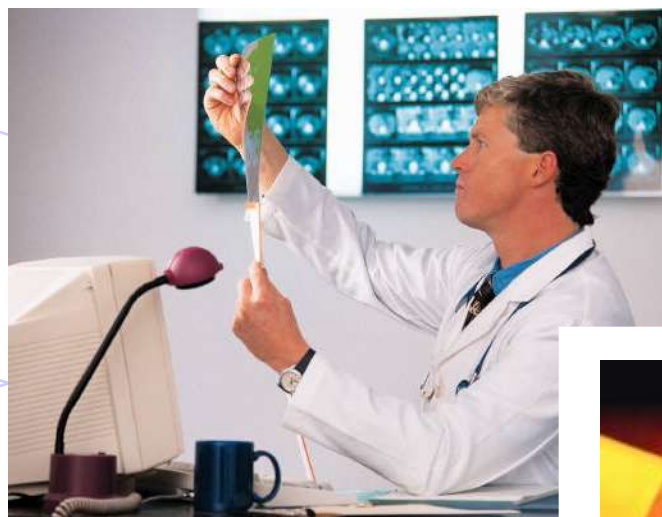




# Researcher: Subsequent Package Submission

## Training Energizer



# **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 interface. At the top, the IRBNet ID is 100104-1. The user profile is Amanda Saunders. The main navigation menu includes 'Study Overview' (circled in red), 'Study Designer' (circled in red), and other options. The study details section shows that the user has full access to the study. The study title is 'Public Acceptance of Dihydrogen Monoxide', and the principal investigator is Travis, Randy, MD/PhD. The study status is 'Approved' and the lock status is 'Locked by your Board and not editable'. The keywords are 'music' and the sponsor is 'NIH'. The internal reference number is 'dept-08-1101'. Below the study details, there is a table of users who have access to the study documents, with 'Study Designer' circled in red.

IRBNet ID: 100104-1

USER PROFILE LOGOUT

IRBNet™

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

[100104-1] Public Acceptance of Dihydrogen Monoxide

You have Full access for this study (Edit)

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
Internal Reference Number	dept-08-1101

The documents for this study can be accessed from the Study Designer.

Submitted to:  
Metropolitan IRB 11/06/2008 **Approved** 11/06/2008. [Review details.](#)

Shared with the following IRBNet users

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".



# Researcher: Subsequent Package Submission Training Energizer

## 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 displays 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](#).

# 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 interface. On the left is a navigation menu with options like 'Study Manager', 'Create New Study', and 'Study Administration'. The main content area displays a message for study '[100104-1] Public Acceptance of Dihydrogen Monoxide'. A red circle highlights the text 'Study is Locked' in the top right corner. Below the message, there are two buttons: 'Cancel' and 'Create New Package', with the latter also circled in red.

- ✓ 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.

# Researcher: Subsequent Package Submission

## 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		



# 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..

✓ Browse your hard drive for new or updated documents, and attach.



# Researcher: Subsequent Package Submission Training Energizer

## Document tools

Powerful tools to modify and review documents.

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

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

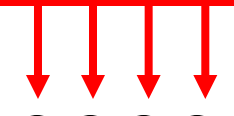
When should I do this?

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

# Researcher: Subsequent Package Submission Training Energizer

## 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 package

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:

Select a Document:

**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.](#)

[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.