



Researcher 2: Post-Submission Advanced Topics

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, animal models, recombinant DNA, and more.

This Energizer covers advanced submission topics for Researchers, Research Managers, or Research Coordinators. This Energizer will illustrate how to:

- Manage My Reminders
- Review Project Messages & Alerts
- Create a Subsequent Package
- Add and Revise Documents
- Complete and Submit Subsequent Package



Did you submit an incomplete package?

If you have forgotten to add a necessary document or need to make a quick change to a recently submitted project package,
CONTACT YOUR LOCAL BOARD COORDINATOR.

Responses to board requests and normal actions in the project life cycle (reportable events, continuing reviews, adverse events, study team changes, investigator - and sponsor - initiated modifications, etc.) require the creation of subsequent packages in a project.
CONTACT YOUR LOCAL BOARD COORDINATOR if you have questions.

Receiving Notifications

Once the committee has rendered a decision you will receive an automatic e-mail notification. That notification can be found in My Reminders.

The screenshot shows the IRBNet user interface. On the left, a navigation menu includes 'My Projects', 'Create New Project', 'My Reminders (4)', and 'Other Tools'. The main content area displays a table of projects. The first project, 'A Phase 3, Randomized, Placebo-Controlle...', has a red flag icon in the first column, indicating an active reminder. A yellow callout box points to this flag with the text: '✓ The flag indicates an active Reminder for this project.' Another yellow callout box points to the 'My Reminders (4)' link in the navigation menu with the text: '✓ Click My Reminders to view all active notifications sent to you concerning any of your projects.' The 'My Projects' link in the top right corner is also circled in red.

USER PROFILE LOGOUT

IRBNet™

Welcome to IRBNet
John Researcher

My Projects
Create New Project
My Reminders (4)
Other Tools
Forms and Templates

My Projects

Projects that you have created or that have been shared with you:

Search: Search Clear

1 - 3 of 3 10

IRBNet ID	Project Title	Principal Investigator	Submission Type	Status	Effective Date	
137618-1	Motivations of Research Subjects: A Mixe...	Researcher	New Project	Modifications Required	10/05/2009	
108459-3	Double-Blind, Multicenter Phase 3 Study ...	Researcher	Adverse Event	Acknowledged	09/21/2009	
07645-1	A Phase 3, Randomized, Placebo-Controlle...	Bird	New Project	Approved	05/28/2009	

1 - 3 of 3 10

My Reminders

All notifications sent to you across all of your projects will appear here. An e-mail will be sent to your registered e-mail address.

IRBNet™

Welcome to IRBNet
John Researcher

My Projects
Create New Project
My Reminders (3)

Other Tools
Forms and Templates

USER PROFILE LOGOUT

Message Reply

Date: 10/05/2009 11:32 AM
To: "John Researcher" <researcher_john@yahoo.com>
From: "Ann Halway" <no-reply@irbnet.org>
Reply To: "Ann Halway" <ahalway@mailinator.com>
Subject: IRBNet Board Action

Please note that Metropolitan IRB has taken the following action on IRBNet:

Submission: [137618-1] Motivations of Research Subjects: A Mixed Methods Study
Action: MODIFICATIONS REQUIRED
Effective Date: October 5, 2009

Should you have any questions you may contact Ann Halway at ahalway@mailinator.com.

IRBNet ID	Project Title	Action Type	Date
137618-1	Motivations of Research Subjects: A Mixed Methods Study	Board Action	10/05/2009 11:32 AM
137618-1	Motivations of Research Subjects: A Mixed Methods Study	Package Unlocked	10/02/2009 09:01 AM
137618-1	Motivations of Research Subjects: A Mixed Methods Study	Project	10/02/2009 01:29 PM

✓ Click the project title to go to the Project Overview page.

✓ Click action type to view message.

Silencing Reminders

Reminders are indicated with red flags. Silencing the Reminders will remove them from this page in the future.

Welcome to IRBNet
John Researcher

My Projects
Create New Project
My Reminders (3)

Other Tools
Forms and Templates

USER PROFILE LOGOUT

My Reminders

An IRBNet personal reminder is automatically activated for you each time you receive a new message or alert. You can also set additional reminders for yourself on the Messages & Alerts page. Other IRBNet users do not see your personal reminders. You can turn on or silence a personal reminder without affecting other IRBNet users. You can also choose to view recently silenced reminders (within the past 30 days) in addition to your active reminders.

1 - 4 of 4 10

Show Silenced Reminders Silence All Reminders

IRBNet ID	Project Title	Message Type	Date
137618-1	Motivations of Research Subjects: A Mixe...	Board Document Published	10/05/2009 11:32 AM
137618-1	Motivations of Research Subjects: A Mixe...	Board Action	10/05/2009 11:32 AM
137618-1	Motivations of Research Subjects: A Mixe...	Package Unlocked	10/02/2009 09:01 AM
107045-1	A Phase 3, Randomized, Placebo-	Project Access Granted	10/01/2009 01:29 PM

1 - 4 of 4 10

✓ Indicates an active Reminder. Clicking the red flag will "silence" the Reminder.

Project Messages & Alerts

All project-specific notifications remain filed in the Messages & Alerts page as a permanent part of the project file.

Project Messages & Alerts

[137618-1] Motivations of Research Subjects: A Mixed Methods Study

The following communications have been posted for this project. You can set an IRBNet personal reminder on any message or alert. Your personal reminders will automatically appear in your My Reminders list. Other IRBNet users do not see your personal reminders. You can turn on or silence a personal reminder without affecting other IRBNet users.

Silence All Reminders | 1 - 10 of 11 | 10

IRBNet ID	Project Title	Message Type	Date
137618-1	Motivations of Research Subjects: A Mixe...	Message (IRBNet message from John Researcher)	10/06/2009 08:45 AM
137618-1	Motivations of Research Subjects: A Mixe...	Message (IRBNet message from John Researcher)	10/06/2009 08:42 AM
137618-1	Motivations of Research Subjects: A Mixe...	Board Document Published	10/05/2009 11:32 AM
137618-1	Motivations of Research Subjects: A Mixe...	Board Action	10/05/2009 11:32 AM
137618-1	Motivations of Research Subjects: A Mixe...	Package Revisions Complete	10/02/2009 09:01 AM
137618-1	Motivations of Research Subjects: A Mixe...	Package Unlocked	10/02/2009 09:01 AM
137618-1	Motivations of Research Subjects: A Mixe...	Submission Notification	09/30/2009 12:16 PM
137618-1	Motivations of Research Subjects: A Mixe...		09/30/2009 12:10 PM
137618-1	Motivations of Research Subjects: A Mixe...		09/30/2009 12:06 PM
137618-1	Motivations of Research Subjects: A Mixe...		09/30/2009 12:05 PM

Write

Messages & Alerts (3)

Click here to access project-specific Messages & Alerts.

- ✓ Grey flags indicate messages and alerts that are silenced, either because:
 - ✓ It was sent to another member of the team, or;
 - ✓ You have previously silenced the message.

Revise Your Project

You can easily revise your project by creating a new package. All versions of your project become a permanent part of your electronic project record.

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

IRBNet ID: 137618-1 USER PROFILE LOGOUT

IRBNet™

Welcome to IRBNet
John Researcher

Project Administration

- My Projects
- Create New Project
- My Reminders (3)
- Project Overview
- Designer
- Share this Project
- Sign this Package
- Submit this Package
- Delete this Package
- Send Project Mail
- Reviews
- Project History**
- Messages & Alerts (3)

Project Overview

[137618-1] Motivations of Research Subjects: A Mixed Methods Study

You have Full access to this project. (Edit)

Research Institution	Metropolitan University, Frederick, MD
Title	Motivations of Research Subjects: A Mixed Methods Study
Principal Investigator	Researcher, John, PhD
Status	Modifications Required
Lock Status	Locked
Keywords	Incentive, Extra Credit
Sponsor	National Research Foundation

The documents for this project can be accessed from the Designer.

Submitted to:
Metropolitan IRB 09/30/2009 **Modifications Required** 10/05/2009. [Review details.](#)

Shared with the following IRBNet users

	Organization	Access Type
er	Metropolitan University, Frederick, MD	Full
y	Metropolitan University, Frederick, MD	Read
	Metropolitan University, Frederick, MD	Write

✓ To create a new package from an existing package, click on "Project History."

Create a New Package

The Project History page displays all packages in this project. From here you can create a second package.

IRBNet ID: 137618-1 USER PROFILE LOGOUT

IRBNet

Welcome to IRBNet
John Researcher

My Projects
Create New Project
My Reminders (3)

Project Administration
Project Overview
Designer
Share this Project
Sign this Package
Submit this Package
Delete this Package
Send Project Mail
Reviews
Project History
Messages & Alerts (3)

Other Tools
Forms and Templates

Project History

[137618-1] Motivations of Research Subjects: A Mixed Methods Study

The following document packages are available in Project History:

Pkg #	Package Type	Status	Create Date	Submission Date	Review Date
1	New Project	Modifications Required	09/30/2009	09/30/2009	10/05/2009

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."

Access New Package

The new package has a status of **Work in Progress** and is editable.

The screenshot shows the IRBNet web interface. At the top, the user ID is 137618-2, and there are links for 'USER PROFILE' and 'LOGOUT'. The main header features the IRBNet logo and a navigation menu with 'Project History' circled in red. Below the header, the project title is '[137618-2] Motivations of Research Subjects: A Mixed Methods Study'. A message states 'The following document packages are available in Project History:'. A table lists two packages:

Pkg #	Package Type	Status	Create Date	Submission Date	Review Date
2	New Document Package	Work in progress	10/06/2009		
1	New Project	Modifications Required	09/30/2009	09/30/2009	10/05/2009

Below the table, it says '2 Packages found, displaying all Packages.' and 'You are currently viewing this package.' A red arrow points from the 'New Document Package' row to a yellow callout box. Another yellow callout box points to the 'New Document Package' text in the table.

Project History

[137618-2] Motivations of Research Subjects: A Mixed Methods Study

The following document packages are available in Project History:

Pkg #	Package Type	Status	Create Date	Submission Date	Review Date
2	New Document Package	Work in progress	10/06/2009		
1	New Project	Modifications Required	09/30/2009	09/30/2009	10/05/2009

2 Packages found, displaying all Packages.

You are currently viewing this package.

- ✓ Note that a second package is created.
- ✓ The Project History lists all packages in the project lifecycle.
- ✓ Now click on the New Document Package to begin building the package.

Add or Revise Documents

Bring forward and revise documents previously submitted, or add a new document as required.

The screenshot shows the IRBNet Designer interface. On the left is a navigation menu with options like 'My Projects', 'Project Administration', and 'Other Tools'. The main content area is titled '[137618-2] Motivations of Research Subjects: A Mixed Methods Study' and is in the 'Designer' role. It includes instructions for Step 1 (downloading forms) and Step 2 (assembling the package). A table lists documents from previous packages that can be revised, with icons for adding new documents and revising existing ones. Annotations highlight the 'Designer' role, the 'Add New Document' button, and the revision icons in the table.

Welcome to IRBNet
John Researcher

My Projects
Create New Project
My Reminders (3)

Project Administration
Project Overview
Designer
Share this Project
Sign this Package
Submit this Package
Delete this Package
Send Project Mail
Reviews
Project History
Messages & Alerts (3)

Other Tools
Forms and Templates

[137618-2] Motivations of Research Subjects: A Mixed Methods Study

Designer

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: IRB Submission Checklist [Download]

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 your package. [Learn more.](#)

Add New Document (with icon)

OR

Documents from Previous Packages that you can Revise: (When should I...)

Pkg #	Document Type	Description	Last Modified	Pkg Submission Date	Pkg Status	1	2
1	Application Form	IRB Application	09/30/2009 12:04 PM	09/30/2009	Modifications Required		
1	Consent Form	Consent Form	09/30/2009 12:04 PM	09/30/2009	Modifications Required		
1	Protocol	ASM981 C2439 Protocol.pdf	09/30/2009 12:04 PM	09/30/2009	Modifications Required		

✓ To revise an older document:

- 1 Download the previous version to your computer, modify as required and save.
- 2 Click on the pencil icon (see next page for more information).

✓ To add a new document, click "Add New Document".

✓ All documents from previously submitted packages are listed here.

Attach Document

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

IRBNet ID: 137618-2 USER PROFILE LOGOUT

IRBNet™

Welcome to IRBNet
John Researcher

Attach Document

[137618-2] Motivations of Research Subjects: A Mixed Methods Study
You are updating an attachment. To help you identify the file that was attached:

- This attachment was loaded from the file **Consent Form.doc**.
- It was attached on **09/30/2009**.
- It has a size of **93184** bytes.

Document Type * Consent Form
Description Consent Form v2
File * Browse...

fields

- ✓ 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.

Document Management Tools

IRBNet provides powerful tools to update and review project documents.

The screenshot shows the IRBNet Designer interface for a project titled "[137618-2] Motivations of Research Subjects: A Mixed Methods Study". The interface includes a sidebar with navigation options like "My Projects", "Project Administration", and "Designer". The main content area shows "Step 1: Download blank forms, document templates and reference materials to assist you in assembling your package." and "Step 2: Assemble your document package." Below this, there is a table of "New and Revised Documents in this Package:" with columns for Document Type, Description, Last Modified, and icons for View, View revision history, Update, and Delete. A red box highlights these icons with numbered callouts: 1 View, 2 View revision history, 3 Update, and 4 Delete document. Below the table is an "Add New Document" button and a section for "Documents from Previous Packages that you can Revise:" with a table listing documents like "Application Form" and "Protocol".

Designer

[137618-2] Motivations of Research Subjects: A Mixed Methods Study

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

Select a Library: Metropolitan IRB, Frederick, MD

Select a Document: IRB Submission Checklist

Step 2:
Assemble your document package.

New and Revised Documents in this Package:

Document Type	Description	Last Modified	1	2	3	4
Consent Form	Consent Form v2	10/06/2009 09:28 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	2
1	Application Form	IRB Application	09/30/2009 12:04 PM	09/30/2009	Modifications Required		
1	Protocol	ASM981 C2439 Protocol.pdf	09/30/2009 12:04 PM	09/30/2009	Modifications Required		

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

Revision History

The document revision history tool reveals all versions of a document type in the project.

The screenshot shows the IRBNet Designer interface. On the left is a navigation sidebar with sections like 'My Projects', 'Project Administration', and 'Other Tools'. The main area displays project details for '[137618-2] Motivations of Research Subjects: A Mixed Methods Study'. It includes 'Step 1' instructions and selection dropdowns for 'Library' (Metropolitan IRB, Frederick, MD) and 'Document' (IRB Submission Checklist). 'Step 2' instructions are also present. A table titled 'New and Revised Documents in this Package:' shows a 'Consent Form' document type with a 'Last Modified' date of 10/06/2009 09:28 AM. A 'Document Revision History' dialog box is open, showing a table with two rows: row 2 (circled in red) for 'Consent Form v2' (10/06/2009 09:28 AM, Work in progress) and row 1 for 'Consent Form' (09/30/2009 12:04 PM, Modifications Required). A yellow callout box with a red border points to the dialog box, stating: '✓ The Document Revision History lists the most recent document and every previous version submitted by package.' A red circle highlights the 'Document Revision History' dialog title bar, and a red arrow points from the callout box to it.

Welcome to IRBNet
John Researcher

My Projects
Create New Project
My Reminders (3)

Project Administration
Project Overview
Designer
Share this Project
Sign this Package
Submit this Package
Delete this Package
Send Project Mail
Reviews
Project History
Messages & Alerts (3)

Other Tools
Forms and Templates

Designer

[137618-2] Motivations of Research Subjects: A Mixed Methods Study

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: IRB Submission Checklist

Step 2:
Assemble your document package.

New and Revised Documents in this Package:

Document Type	Description	Last Modified
Consent Form	Consent Form v2	10/06/2009 09:28 AM

Document Revision History

Pkg #	Document Type	Description	Last Modified	Pkg Submission Date	Pkg Status
2	Consent Form	Consent Form v2	10/06/2009 09:28 AM		Work in progress
1	Consent Form	Consent Form	09/30/2009 12:04 PM	09/30/2009	Modifications Required

12:04 PM Required

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

Complete Submission Process

When project documentation is completely assembled, sign and submit according to your institution's SOPs.

Welcome to IRBNet
John Researcher

- My Projects
- Create New Project
- My Reminders (3)
- Project Administration**
- Project Overview
- Designer
- Share this Project
- Sign this Package
- Submit this Package**
- Delete this Package
- Send Project Mail
- Reviews
- Project History
- Messages & Alerts (3)
- Other Tools**
- Forms and Templates

Designer

[137618-2] Motivations of Research Subjects: A Mixed Methods Study

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	Consent Form v2	10/06/2009 09:28 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	Application Form	IRB Application	09/30/2009 12:04 PM	09/30/2009	Modifications Required	
1	Protocol	ASM981 C2439 Protocol.pdf	09/30/2009 12:04 PM	09/30/2009	Modifications Required	

Where to Get Help...

Your Committee 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.