



National
Research
Network®

Researcher 2: Post-Submission Advanced Topics

Training Energizer

IRBNet

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, and Research Coordinators. This Energizer illustrates how to:

- Perform My Projects Management
- Manage My Reminders
- Review Project Messages & Alerts
- Create a New Package for Your Project
- 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.

Use the Search field combined with the Search By Tag menu to enable focused searching.

The screenshot shows the IRBNet interface for a user named John Researcher. The page title is 'My Projects'. A search bar and a 'Search By Tag' dropdown menu are visible. A table lists projects with columns for IRBNet ID, Project Title, Principal Investigator, Submission Type, Board Action, and Effective Date. A red box highlights the search bar and the 'Search By Tag' dropdown. A red arrow points from the search bar to the 'Oncology Dept...' tag in the table. Another red box highlights the 'Oncology Dept...' tag. A red arrow points from the 'Oncology Dept...' tag to the search bar.

✓ Search example: Find all oncology department projects with Dr. Smith as the PI (Search "Smith" + "Oncology Dept" tag)¹

Search: Search By Tag:

Search Clear

1 - 3 of 3 10

| IRBNet ID | Project Title | Principal Investigator | Submission Type | Board Action | 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 | 02/16/2010 |
| 107645-2 | Multicenter, Prospective, Randomized, Co... Need Signatur... | Price | Work in progress (Not submitted) | | |

✓ Click any Project Tag to search for all projects with that Tag.



Receive Notifications

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

USER PROFILE LOGOUT

IRBNet™

Welcome to IRBNet
Jennifer Researcher

Help

My Projects

Create New Project

My Reminders (4)

Other Tools
Forms and Templates

My Projects

Shows projects that you have created and projects that have been shared with you by other network. Use Reminders, Tags and Archiving to help organize your workspace and keep it running smoothly. (Learn More)

Search: Search By Tag:

Search Clear

1 - 3 of 3

Create and Manage Tags Show Archived Projects (4) Project Status View

| IRBNet ID | Project Title | Principal Investigator | Submission Type | Board Action | Effective Date |
|-----------|-----------------------------------------------------------------|------------------------|----------------------------------|------------------------|----------------|
| 37618-1 | Motivations of Research Subjects: A Mxe... | Researcher | New Project | Modifications Required | 10/05/2009 |
| 108459-3 | Double-Blind, Multicenter Phase 3 Study ... Oncology Dept... | Researcher | Adverse Event | Acknowledged | 02/16/2010 |
| 107645-2 | Multicenter, Prospective, Randomized, Co... Need Signatur... | Price | Work in progress (Not submitted) | | |

1 - 3 of 3

✓ Click My Reminders to view all of your active notifications concerning any of your IRBNet projects.

My Projects

My Reminders (4)

✓ The flag indicates an active Reminder for this project.



Review 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.

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.

Thank You

| IRBNet ID | Project Title | Message 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 | 9 01:29 PM |

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✓ Click the Project Title to go to the Project Overview page.

✓ Click Message Type to view email notification.



Silence Reminders

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

Welcome to IRBNet
Jennifer Researcher

Help
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.

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 |

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



Review Project Messages & Alerts

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

Welcome to IRBNet
Jennifer Researcher

[Help](#)

[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](#)

[Create a New Package](#)

Messages & Alerts (3)

Other Tools

[Forms and Templates](#)

Project Overview

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.

1 - 10 of 11

[Silence All Reminders](#)

| | 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... | | 10/02/2009 09:01 AM |
| ▼ | 137618-1 | Motivations of Research Subjects: A Mixe... | | 10/02/2009 09:01 AM |
| ▼ | 137618-1 | Motivations of Research Subjects: A Mixe... | | 10/02/2009 09:01 AM |
| ▼ | 137618-1 | Motivations of Research Subjects: A Mixe... | | 10/02/2009 09:01 AM |

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✓ 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 communication.



Revise Your Project: Create a New Package

With Full Access you can easily revise their project by creating a new package. All versions of your project become a permanent part of your electronic project record.

Project Overview

Welcome to IRBNet
Jennifer Researcher

Help

My Projects

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

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

[431446-1] Prevalence and Outcomes of Pulmonary Contusions Following Blunt Trauma

You have Full access to this project. [\(Edit\)](#)

Research Institution Zanzibar University, Frederick, MD

Title Prevalence and Outcomes of Pulmonary Contusions Following Blunt Trauma

Principal Investigator Jeter, Judith, MD

Sponsor Veterans Affairs

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

Project Status as of: 04/21/2016

| Reviewing Board | Board Ref # | Initial Approval Date | Project Status | Expiration Date |
|-----------------------------|-------------|-----------------------|-----------------------------|-----------------|
| Zanzibar IRB, Frederick, MD | 2016-012 | 04/21/2016 | Active - Open to Enrollment | 04/20/2017 |

Package 431446-1 is: Locked

Package 1 of 1 | Jump

| Submitted To | Submission Date | Submission Type | Board Ref # | Board Action | Effective Date | |
|-----------------------------|-----------------|-----------------|-------------|--------------|----------------|---------------------------------|
| Zanzibar IRB, Frederick, MD | 04/21/2016 | New Project | 2016-012 | Approved | 04/21/2016 | Review Details View Workspace |

✓ To create a new package from an existing package, click on "Create a New Package."

Shared with the following users:

| User | Organization | Access Type |
|----------------|------------------------------------|-------------|
| Bird, Lawrence | Zanzibar University, Frederick, MD | Write |
| Mays, Zachary | Zanzibar University, Frederick, MD | Read |
| Parsons, Alan | Zanzibar University, Frederick, MD | Full |



Create a New Package: Alternative

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

IRBNet ID: 137618-1 USER PROFILE LOGOUT

Project History

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

1 - 1 of 1 | 10

| Pkg # | Submission Type | Submission Date | Review Type | Board Action | Effective Date |
|-------|-----------------|-----------------|------------------|------------------------|----------------|
| 1 | New Project | 09/30/2009 | Expedited Review | Modifications Required | 10/05/2009 |

1 - 1 of 1 | 10

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](#)

Project History

✓ Click "Create New Package."

The Project History lists all packages in the project lifecycle.



Add or Revise Project Documents

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

- ✓ You are taken to the Designer page.
- ✓ Note that a second Package (-2) is created.
- ✓ This Package is a Work in Progress.

Package: **48774-2 Work in progress (Not submitted)**

[Click to add a package description or notes.](#)

[Need Forms? Show Form Libraries](#)

Assemble your document package here. You can add new project documents, revise existing project documents while maintaining version history, and link your project team's Training & Credentials to your package. [Learn more](#)

Documents in this Package:

There are no documents in this package.

There are no Training & Credentials records linked to this package. | [View](#)

- ✓ 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).

[Start a Wizard](#) OR [Attach New Document](#) (When should I do this?)

- ✓ All documents from previously submitted packages are listed here.

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

| Pkg # | Document Type | Description | Last Modified | Submission Date | 1 | 2 |
|-------|--------------------------------|-------------------|---------------------|-----------------|---|---|
| 1 | Consent Form | Consent Form 2016 | 05/23/2016 02:03 PM | 05/23/2016 | | |
| 1 | Protocol | | 05/23/2016 02:03 PM | 05/23/2016 | | |
| 1 | Study Plan | | 05/23/2016 02:33 PM | 05/23/2016 | | |
| 1 | UMCP - IRB Initial Application | | 05/23/2016 02:03 PM | 05/23/2016 | | |

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



Attach a Document

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

Welcome to IRBNet

Attach Document

- ✓ Browse your hard drive for documents, choose the file, and then click 'Update' to attach.
- ✓ This view is for updating a document from package 1. The view for attaching a new document is similar.

774-2] UT Dallas Research Project

You are updating an attachment. To help you identify the file that was attached:

- This attachment was loaded from the file **Consent Form - Spinal Motion.doc**.
- It was attached on **05/23/2016**.
- It has a size of **93184** bytes.

Document Type * Consent Form

Description Consent Form 2016 v2

File * Choose File Consent Form... Motion.doc

Update Cancel

required fields

- Reviews
- Project History
- Messages & Alerts (2)
- Other Tools
- Forms and Templates

IRBNet provides powerful Submission Package navigation tools to update and review project documents, and to navigate your Project Documents.

- ✓ The Package Navigator enables rapid jumping between submission packages.
- ✓ Package Notes are readily visible.
- ✓ You may view all Project Documents at one time: click 'All Documents'.

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

Welcome to IRBNet
Designer

[48774] UT Dallas Research Project

Package: ▼ 48774-2 Work in progress (Not submitted)

Updated consent for review

(1) 48774-2
Work in progress (Not submitted)
Updated consent for review

(4) 48774-1
New Project
My first submission

(5) All Documents

+

Create a New Package

Assemble your submission package by maintaining version control of documents.

Document Type: Consent Form

Form 2016 v2







Last Modified: 10/28/2016 11:17 AM

1 2 3 4

There are no Training & Credentials records linked to this package. | [View All Links](#) | [Link / Un-Link Training Records](#) |


Start a Wizard OR Attach New Document (When should I do this?)

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

| Pkg # | Document Type | Description | Last Modified | Submission Date | |
|-------|---------------|-----------------------|---------------------|-----------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 1 | Protocol | ASM981 C2439 Protocol | 05/23/2016 02:03 PM | 05/23/2016 |    |
| 1 | Study Plan | Study Plan | 05/23/2016 | 05/23/2016 |    |

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

1 2 3 4



Document Revision History

The Document Revision History tool reveals all document versions for each given Document Type within the project.

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 (2)
- Other Tools
- Forms and Templates

[Need Forms? Show Form Libraries](#)

Assemble your document package here. You can add new project documents, revise existing project documents while maintaining version history, and link your project team's Training & Credentials to your package. | [Learn more](#)

Documents in this Package:

| Document Type | Description | Last Modified | |
|---------------|----------------------|---------------------|--|
| Consent Form | Consent Form 2016 v2 | 10/28/2016 11:17 AM | |

Document Revision History

There are 2 records.

| Pkg # | Document Type | Description | Last Modified | Submission Date | |
|-------|---------------|----------------------|---------------------|-----------------|--|
| 2 | Consent Form | Consent Form 2016 v2 | 10/28/2016 11:17 AM | | |
| 1 | Consent Form | Consent Form 2016 | 05/23/2016 02:03 PM | 05/23/2016 | |

Document

| Pkg # | Docu | Description | Last Modified | Submission Date | |
|-------|-----------------------------------------|-----------------|---------------------|-----------------|--|
| 1 | Protoc | | | | |
| 1 | Study | | 02:33 PM | | |
| 1 | UMCP - IRB Initial Application - Part 1 | IRB Application | 05/23/2016 02:03 PM | 05/23/2016 | |

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



All Documents view

Selecting 'All Documents' from the Package Navigator reveals a comprehensive list of all documents assembled in the Designer.

- (1)

48774-2
Work in progress (Not submitted)
Updated consent for review
- (4)

48774-1
New Project
My first submission
- (5)

All Documents
- +

Create a New Package

Project Administration

- Project Overview
- Designer
- Share this Project
- Send Project Mail
- Reviews
- Project History
- Messages & Alerts (2)

Other Tools

- Forms and Templates

Designer

[48774] UT Dallas Research Project

▼ All Documents

| Show All Versions | As Of Package 48774-2 ▼

| Pkg # | Document Type | Description | Last Modified | Submission Date | |
|-------|-----------------------------------------|-----------------------|---------------------|-----------------|--|
| 2 | Consent Form | Consent Form 2016 v2 | 10/28/2016 11:17 AM | | |
| 1 | Protocol | ASM981 C2439 Protocol | 05/23/2016 02:03 PM | 05/23/2016 | |
| 1 | Study Plan | Study Plan | 05/23/2016 02:33 PM | 05/23/2016 | |
| 1 | UMCP - IRB Initial Application - Part 1 | IRB Application | 05/23/2016 02:03 PM | 05/23/2016 | |

There are **6** linked **Training & Credentials** records. | [View All Links](#) |
 There is **1** linked **COI Disclosure** record. | [View All Links](#) |



Complete Submission Process

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

Welcome to IRBNet
Jennifer Researcher

Designer

Help

My Projects

Create New Project

My Reminders (3)

Project Administration

Project Overview

Designer

Share this Project

2 Sign this Package

3 Submit this Package

Delete this Package

Send Project Mail

Reviews

Project History

Messages & Alerts (3)

Other Tools

Forms and Templates

[431446] Prevalence and Outcomes of Pulmonary Contusions Following Blunt Trauma

Package: 431446-2 Work in progress (Not submitted)

Protocol Update 4/2016

Need Forms? Show Form Libraries

Assemble your document package here. You can add new project documents, revise existing project documents while maintaining version history, and link your project team's Training & Credentials to your package. [Learn more](#)

Documents in this Package:

| Document Type | Description | Last Modified | |
|---------------|---------------------------------|---------------------|--|
| Protocol | Cervical Clinical Protocol 2016 | 04/21/2016 11:42 AM | |

There are no Training & Credentials records linked to this package. [Link / Un-Link Training Records](#)

Start a Wizard

OR

Attach New Document

(When should I do this?)

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

| Pkg # | Document Type | Description | Last Mod |
|-------|------------------|------------------|---------------------|
| 1 | Application Form | Application Form | 04/21/2016 10:19 |
| 1 | Consent Form | Consent Form | 04/20/2016 05:11 PM |

1 ✓ Attach any new T&C documents to this package as necessary.





Submit your package for review



Submit your package to your committee of record.

IRBNet ID: 137618-1 USER PROFILE LOGOUT

Welcome to IRBNet
Jennifer Researcher

[Help](#)

[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](#)

Submit Package

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

IRBNet supports multiple models of review. Using the IRBNet "Submit" feature, you may electronically submit this document package to either a single Board, or to multiple Boards. Each Board you submit to will be notified of your submission and given access to view your electronic documents. Each Board will also be permitted to electronically record their review decision, which will be stored as a permanent part of your project record. You will be automatically notified when the review decision is electronically recorded.

Please select a Board:

Search for an Organization

Only show My Default Boards

Gotham IRB, Frederick, MD

Western Institutional Review Board (WIRB), Puyallup, WA

Select a Board *

* required fields

✓ The default board for your institution is highlighted.



Submit to your Board

The system enables you to send a message to your coordinator, and indicate submission type. IRBNet knows the coordinator of your committee.

IRBNet ID: 137618-1 USER PROFILE LOGOUT

IRBNet

Welcome to IRBNet
Jennifer Researcher

Help

- 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

Submit Package

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

The following users at **Gotham IRB** will be automatically notified of your submission:
Administrator, Tanya

Submission Type: * Amendment/Modification

You may also specify additional comments to be included in this notification.

Your Comments:
Please see my revisions to the protocol. Thank you very much!
~Alan

Submit Cancel

✓ Send a kind word to your committee coordinators!

Note: The package will be locked upon submission.



Access Current Project Overview

The newly-submitted package (xxxxxx-2) has a status of Pending Review.

IRBNet ID: 137618-2

USER PROFILE LOGOUT

IRBNet™

Welcome to IRBNet
Jennifer Researcher

Help

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

Create a New Package

Messages & Alerts (3)

Other Tools

Forms and Templates

137618-2 Motivations of Research Subjects

You have Full access to this project. (Edit)

Research Institution Gotham IRB, Frederick, MD

Title Phase II Study of the Effect of Quarterback Performance in Super Bowls: Tom vs Eli

Principal Investigator Researcher, Timothy, PhD/MD

Keywords pigskin, first down

The documents for this project can be accessed from the [Designer](#).

Project Status as of: 10/17/2016

| Reviewing Board | Board Ref # | Initial Approval Date | Project Status | Expiration Date |
|---------------------------|----------------|-----------------------|-----------------------------|-----------------|
| Gotham IRB, Frederick, MD | Gotham2012-004 | 02/27/2016 | Active - Open to Enrollment | 02/26/2017 |

Package 46442-2 is: Locked

| Submitted To | Submission Date | Submission Type | Board Ref # | Board Action | Effective Date |
|---------------------------|-----------------|------------------------|----------------|----------------|----------------|
| Gotham IRB, Frederick, MD | 10/17/2016 | Amendment/Modification | Gotham2012-004 | Pending Review | |

Shared with the following users:

| User | Organization | Access Type |
|------|--------------|-------------|
|------|--------------|-------------|



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.