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.

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

✓ 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.

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

- 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.

- 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.

- 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.

- 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.

- Click here to access project-specific Messages & Alerts.
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.

- Note that this is the first package in the sequence.
- To create a new package from an existing package, click on “Create a New Package.”

<table>
<thead>
<tr>
<th>Project Overview</th>
</tr>
</thead>
</table>

[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

<table>
<thead>
<tr>
<th>Reviewing Board</th>
<th>Board Ref #</th>
<th>Initial Approval Date</th>
<th>Project Status</th>
<th>Expiration Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Zanzibar IRB, Frederick, MD</td>
<td>2016-012</td>
<td>04/21/2016</td>
<td>Active - Open to Enrollment</td>
<td>04/20/2017</td>
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Package 431446-1 is: Locked

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<thead>
<tr>
<th>Submitted To</th>
<th>Submission Date</th>
<th>Submission Type</th>
<th>Board Ref #</th>
<th>Board Action</th>
<th>Effective Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Zanzibar IRB, Frederick, MD</td>
<td>04/21/2016</td>
<td>New Project</td>
<td>2016-012</td>
<td>Approved</td>
<td>04/21/2016</td>
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<table>
<thead>
<tr>
<th>User</th>
<th>Organization</th>
<th>Access Type</th>
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<tbody>
<tr>
<td>Bird, Lawrence</td>
<td>Zanzibar University, Frederick, MD</td>
<td>Write</td>
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<tr>
<td>Mays, Zachary</td>
<td>Zanzibar University, Frederick, MD</td>
<td>Read</td>
</tr>
<tr>
<td>Parsons, Alan</td>
<td>Zanzibar University, Frederick, MD</td>
<td>Full</td>
</tr>
</tbody>
</table>
Create a New Package: Alternative

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

- 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.

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 “Attach New Document”.

All documents from previously submitted packages are listed here.
Attach a Document

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

- 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.
Document Management Tools

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’.

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

- The Document Revision History lists the most recent document and every previous version submitted by package.
All Documents view

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

[Table]

<table>
<thead>
<tr>
<th>PKG</th>
<th>Document Type</th>
<th>Description</th>
<th>Last Modified</th>
<th>Submission Date</th>
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<tbody>
<tr>
<td>1</td>
<td>Protocol</td>
<td>ASM81 C2430 Protocol</td>
<td>05/23/2016 02:03 PM</td>
<td>05/23/2016</td>
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<tr>
<td>2</td>
<td>Consent Form</td>
<td>Consent Form 2016 v2</td>
<td>10/28/2016 11:17 AM</td>
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<td>Study Plan</td>
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<td>1</td>
<td>UMCP - IRB Initial Application - Part 1</td>
<td>IRB Application</td>
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</table>

There are 6 linked Training & Credentials records.

There is 1 linked COI Disclosure record.
Complete Submission Process

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

1. Attach any new T&C documents to this package as necessary.
2. Sign this Package
3. Submit this Package
Submit your package for review

Submit your package to your committee of record.

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.

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.

Note: The package will be locked upon submission.

✓ Send a kind word to your committee coordinators!
Access Current Project Overview

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

- IRBNet ID: 137618-2

✓ This takes you right to the Project Overview page.

✓ Note that a second package (-2) is created.

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

Project Status as of: 10/17/2016

<table>
<thead>
<tr>
<th>Reviewing Board</th>
<th>Board Ref #</th>
<th>Initial Approval Date</th>
<th>Project Status</th>
<th>Expiration Date</th>
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<td>Gotham IRB, Frederick, MD</td>
<td>Gotham2012-004</td>
<td>02/27/2016</td>
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Package 46442-2 is:Locked

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<th>Submitted To</th>
<th>Submission Date</th>
<th>Submission Type</th>
<th>Board Ref #</th>
<th>Board Action</th>
<th>Effective Date</th>
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</thead>
<tbody>
<tr>
<td>Gotham IRB, Frederick, MD</td>
<td>10/17/2016</td>
<td>Amendment/Modification</td>
<td>Gotham2004</td>
<td>Pending Review</td>
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</tbody>
</table>
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.