



Researcher: Initial Study 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.*

As a Researcher, Research Manager, or Research Coordinator you should know how to:

- Log In To IRBNet
- Access Your Study Manager
- Build Your Electronic Study Package
- Share with Your Research Team
- Communicate with Your Team
- Sign Your Study
- Submit Your Study for Review
- Access Your Review Decision and Board Documentation



Researcher: Initial Study Submission

Training Energizer

Log In To IRBNet

with your User Name and Password at: www.irbnet.org



Innovative Solutions for
Compliance and Research Management

Login:

Username:

Password:

Login



New User Registration



Forgot Your Password?

Home

The IRBNet Difference

Demo

Contact Us

FAQ

Comprehensive Solutions



The Industry's Most Complete Solution

IRBNet's unmatched suite of electronic solutions drives effectiveness and productivity for your Administrators, Committee Members, Researchers and Sponsors. These powerful research design, management and oversight tools support your IRB, IACUC, IBC and other Boards with a unified solution.

Flexible, Intuitive and Easy to Use

Your own forms. Your own processes. Your own standards. The data you need. From electronic submissions to form wizards, to agendas, minutes, and more. Our easy to use, web-based tools are rapidly launched and backed by our best practices expertise and the industry's leading support team.

Secure, Reliable and Affordable

IRBNet's secure web-based solution is accessible to your research community anytime, anywhere. Our enterprise-class technology is affordable and designed to accommodate institutions of any size.

Test Drive IRBNet

See for yourself...

Demo

Satisfied Members

Block

"IRBNet makes our entire operation more efficient, saving time and money. It is amazing how much more we get done, in less time and with the same staff. It's fantastic."

- Ken Grissett

IRB Manager

Sacred Heart Health System

Next

2008 Events - Join Us



Researcher: Initial Study Submission

Training Energizer

Access Your Study Manager

The STUDY MANAGER provides you with quick access to all of your studies.

USER PROFILE LOGOUT

IRBNet™

Welcome to IRBNet
Amanda Saunders

Study Manager
Create New Study

Study Manager

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

Study Title	Status	IRBNet ID
Public Acceptance of Dihydrogen Monoxide	Work in progress	100104-2
A Phase 3, Randomized, Placebo-Controlled, Blinded, Multicenter Study of the Induction and Maintenance of Clinical Response and Remission by...	Pending Review	95621-1
Childhood obesity and lunchroom menus	Pending Review	83661-1

[Search] 3 Studies found, displaying all Studies.


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Build Your Electronic Study Package

Step 1: Provide basic information about your study.

USER PROFILE

LOGOUT



Welcome to IRBNet
Amanda Saunders

Study Manager

Create New Project

Project Information

Create a New Project

To create a new project, first provide the basic project information below. Once your project is created you may attach project documentation and share the project with other users.

Research Institution:

Metropolitan University, Frederick, MD

15464: Concomitant Infection

Title: *

Local Principal Investigator:

First Name: * Lawrence

Last Name: * Bird

Degree(s): MD

Keywords: Taminoxef, Pediatric

Sponsor: National Science Foundation

You may specify an internal account number, billing identifier or reference number for this project.

Internal Reference Number: Dept - 890A

Continue

Cancel

* required fields

Researcher: Initial Study Submission

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Build Your Electronic Study Package

Step 2: Attach your electronic study documents.

IRBNet ID: 107645-1

IRBNet™

Welcome to IRBNet
Amanda Saunders

Project Administration

- Study Manager
- Create New Project
- Project Overview**
- Designer**
- Share this Project
- Sign this Package
- Submit this Package
- Project History
- Send Mail
- Delete this Package

Designer

[107645-1] A Phase 3, Randomized, Placebo-Controlled, Blinded, Multicenter Study of the Induction and Maintenance of Remission in Patients with Acute Myeloid Leukemia

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: Application for Continued Approval

Download

Step 2:
Assemble your document package.

Documents in this Package:

There are currently no documents in this package.

Add New Document

✓ Drop down menu for institution-specific libraries.

✓ Select appropriate document and download.

✓ Add study documents here.

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Attach Document

IRBNet provides two mechanisms for entering documents into the system.

IRBNet ID: 107645-1 USER PROFILE LOGOUT

IRBNet

Welcome to IRBNet
Amanda Saunders

Study Manager
Create New Project

Project Administration
Project Overview
Designer
Share this Project
Sign this Package
Submit this Package
Project History
Send Mail
Delete this Package

Attach Document

[107645-1] A Phase 3, Randomized, Placebo-Controlled, Blinded, Multicenter Study of the Induction and Maintenance

You may attach documents to this package by clicking the "Browse..." button to locate a document and then by clicking "Attach". The "Document Type" and optional "Description" are informational fields to assist you in managing your attached documents.

Document Type * Adverse Event Report

Description

File *

* required fields

You may also use the IRBNet Document Wizards to create documents on-line. Documents created this way are automatically attached in PDF format.

On-Line Document Consent Form

✓ If your institution requires the completion of an online IRBNet Document Wizard, it will be located here.

✓ Browse your hard drive for completed documents and attach as required by your institution.



Researcher: Initial Study Submission Training Energizer

Build Your Electronic Study Package Step 2: Attach your electronic study documents.

IRBNet ID: 95621-1

USER PROFILE

LOGOUT



Welcome to IRBNet
Amanda Saunders

Study Manager

Create New Project

Project Administration

Project Overview

Designer

Sign this Package

Project History

Send Mail

This package is: **Locked**

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: Application for Continued Approval

Step 2:
Assemble your document package.
Documents in this Package:

Document Type	Description	Last Modified	1	3	4
Consent Form	Consent Form	09/06/2008 11:34 AM			
Protocol	protocol	09/06/2008 11:31 AM			
Research Application Form	Research Application Form	09/06/2008 11:33 AM			
Study Plan	study plan	09/06/2008 11:33 AM			

Add New Document

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

1 View

3 Update

4 Delete document

1

3

4

Researcher: Initial Study Submission

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Share with Your Research Team

Step 3: You may collaborate both within your Institution and across Institutions in the course of your study.

The screenshot shows the IRBNet web interface. At the top, the IRBNet ID is 107645-1. The user is logged in as Amanda Saunders. The left sidebar contains a 'Project Administration' menu with options: Study Manager, Create New Project, Project Overview, Designer, Share this Project (highlighted with a red circle), Sign this Package, Submit this Package, Project History, Send Mail, and Delete this Package. The main content area is titled 'Share Project' and shows details for '[107645-1] A Phase 3, Randomized, Placebo-Controlled, Blinded, Multicenter Study of the Induction and Maintenance of Remission in Acute Myeloid Leukemia'. It explains that users can share projects with other researchers, committee members, administrators, and sponsors. A red arrow points from the 'Share this Project' menu item to the first bullet point in the list, which is also circled in red. The list includes 'Share', 'Multi-site', and 'Transfer' options, each with a description of its use. A yellow box at the bottom left contains a note: '✓ Almost every study requires the "Share" designation.'

IRBNet ID: 107645-1

USER PROFILE LOGOUT

IRBNet

Welcome to IRBNet
Amanda Saunders

Study Manager
Create New Project

Project Administration
Project Overview
Designer
Share this Project
Sign this Package
Submit this Package
Project History
Send Mail
Delete this Package

Share Project

[107645-1] A Phase 3, Randomized, Placebo-Controlled, Blinded, Multicenter Study of the Induction and Maintenance of Remission in Acute Myeloid Leukemia

You may share this project with other Researchers, Committee Members, Administrators and Sponsors. You may also send a complete copy of this project to a Principal Investigator at another site if this is a multi-site project. You may also transfer ownership of this project to another individual.

- **Share:** Use this option if you wish to share your project with other Researchers, Committee Members, Administrators or Sponsors at your own institution or any other institution. For example, you may wish to share this project with other members of your research team so that you may collaborate in the design and development of the project, or with a selected Committee Member or Administrator to solicit feedback prior to submitting your project for review. You may provide any individual with **Full**, **Write** or **Read** access.
- **Multi-site:** Use this option only if your project is a multi-site project and you wish to send a complete and independent copy of this project to a Principal Investigator at another site. The local Principal Investigator will be able to obtain project documents from the lead site and may modify their copy of these documents (such as consent forms) to meet the requirements of their local Board. You will be able to monitor the progress of this project at every local site. The other local Principal Investigators will also be able to monitor the progress of this project at every local site (including your own).
- **Transfer:** Transfer your ownership of this project to another user. In doing so you will relinquish all access to this project and the designated user will be granted **Full** access.

✓ Almost every study requires the "Share" designation.

Researcher: Initial Study Submission

Training Energizer

Share with Your Research Team

You can grant each member of your team the level of access that they require.

The screenshot shows the IRBNet 'Share Project' interface. At the top, the header includes 'IRBNet ID: 107645-1' and links for 'USER PROFILE' and 'LOGOUT'. A banner image at the top right shows a collage of research-related scenes. The main heading is 'Share Project'. Below it, the project title is '[107645-1] A Phase 3, Randomized, Placebo-Controlled, Blinded, Multicenter Study of the Induction and Maintenance of Remission in Patients with Acute Myeloid Leukemia'. A message states: 'You may share this project with other IRBNet users. Sharing a project consists of three steps: 1. Select an organization to display a list of IRBNet users at that organization. 2. Specify the access that you wish to grant each user at that organization. 3. Save your changes.' The main form area is titled 'Search for an Organization' and includes a search input field, 'Search' and 'Clear' buttons, and a section for 'Organization types to display' with checkboxes for 'Research Institutions' (checked), 'Boards', and 'Sponsors', along with a 'Display' button. Below this is a list of organizations, with 'Metropolitan University, Frederick, MD' highlighted. A 'Select Organization' button is at the bottom of the list. A sidebar on the left contains a 'Project Administration' menu with options like 'Project Overview', 'Designer', 'Share this Project', 'Sign this Package', 'Submit this Package', 'Project History', 'Send Mail', and 'Delete this Package'. Three red callout boxes provide instructions: one points to the 'Research Institutions' checkbox, another points to the highlighted organization in the list, and a third points to the highlighted organization.

IRBNet ID: 107645-1

USER PROFILE LOGOUT

Share Project

[107645-1] A Phase 3, Randomized, Placebo-Controlled, Blinded, Multicenter Study of the Induction and Maintenance of Remission in Patients with Acute Myeloid Leukemia

You may share this project with other IRBNet users. Sharing a project consists of three steps:

1. Select an organization to display a list of IRBNet users at that organization.
2. Specify the access that you wish to grant each user at that organization.
3. Save your changes.

Search for an Organization

Organization types to display: ☒ Research Institutions ☐ Boards ☐ Sponsors **Display**

Select an Organization*

- Mercy Research Institute, Miami, FL
- Metabolic Research Institute, Inc., West Palm Beach, FL
- Methodist College of Nursing, Peoria, IL
- Methodist Medical Center, Peoria, IL
- Metropolitan IACUC, Frederick, MD
- Metropolitan IBC, Frederick, MD
- Metropolitan IRB, Frederick, MD
- Metropolitan University, Frederick, MD**

Select Organization

* required fields

✓ Select 'Research Institution' to share with a project collaborator.

✓ Select the Institution in which your colleagues are members.

✓ The default institution highlighted is your home institution.

Researcher: Initial Study Submission

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Share with Your Research Team

You can grant each member of your team the level of access that they require.

Welcome to IRBNet
Amanda Saunders

Study Manager

Create New Project

Project Administration

Project Overview

Designer

Share this Project

Sign this Package

Submit this Package

Project History

Send Mail

Delete this Package

Share Project

[107645-1] A Phase 3, Randomized, Placebo-Controlled, Blinded, Multicenter Study of the Induction and Maintenance of Remission in Patients with Ulcerative Colitis

Specify the access that you wish to grant to each user at **Metropolitan University**.

Users that are granted "Full" access to this project may perform all functions without restriction. This includes editing project documents, sharing the project with other users, submitting document packages for review and deleting document packages.

Users that are granted "Write" access may edit project documents and collaborate with other users, but may not perform any other administrative functions.

Users that are granted "Read" access may collaborate with other users but may not edit project documents or perform any other administrative functions.

IRBNet User	Permission Access			
Bird, Lawrence	<input checked="" type="radio"/> Full	<input type="radio"/> Write	<input type="radio"/> Read	<input type="radio"/> No Access
Chandry, Francis	<input type="radio"/> Full	<input type="radio"/> Write	<input type="radio"/> Read	<input checked="" type="radio"/> No Access
Chennamsetty, Maruti	<input type="radio"/> Full	<input type="radio"/> Write	<input type="radio"/> Read	<input checked="" type="radio"/> No Access
Garg, Kapil	<input type="radio"/> Full	<input type="radio"/> Write	<input type="radio"/> Read	<input checked="" type="radio"/> No Access
Johnson, Randy	<input type="radio"/> Full	<input type="radio"/> Write	<input type="radio"/> Read	<input checked="" type="radio"/> No Access
Katen, John	<input type="radio"/> Full	<input type="radio"/> Write	<input type="radio"/> Read	<input checked="" type="radio"/> No Access
Morris, Melanie	<input type="radio"/> Full	<input type="radio"/> Write	<input type="radio"/> Read	<input checked="" type="radio"/> No Access
Olmsted, Andrew	<input type="radio"/> Full	<input type="radio"/> Write	<input type="radio"/> Read	<input checked="" type="radio"/> No Access
Palazzo, Enrico	<input type="radio"/> Full	<input type="radio"/> Write	<input type="radio"/> Read	<input checked="" type="radio"/> No Access
Randall, Alice	<input type="radio"/> Full	<input type="radio"/> Write	<input checked="" type="radio"/> Read	<input type="radio"/> No Access
Rawlings, John	<input type="radio"/> Full	<input type="radio"/> Write	<input type="radio"/> Read	<input checked="" type="radio"/> No Access
Researcher, John	<input type="radio"/> Full	<input type="radio"/> Write	<input checked="" type="radio"/> Read	<input type="radio"/> No Access
Rosenbleet, Ben	<input type="radio"/> Full	<input type="radio"/> Write	<input type="radio"/> Read	<input checked="" type="radio"/> No Access
Smith, John	<input type="radio"/> Full	<input checked="" type="radio"/> Write	<input type="radio"/> Read	<input type="radio"/> No Access
Wilson, Barnaby	<input type="radio"/> Full	<input type="radio"/> Write	<input checked="" type="radio"/> Read	<input type="radio"/> No Access

15 Users found, displaying all Users.

Each user will be automatically notified that they have been granted access to this project. You may also specify additional comments to be included in this notification:

Your Comments

Thank you for your help!

Save

Cancel

✓ Grant the appropriate level of access required for each collaborator.

Researcher: Initial Study Submission

Training Energizer



Communicate with Your Team

Use the Send Mail feature to quickly communicate with your team.

IRBNet ID: 107645-1

USER PROFILE

LOGOUT



Welcome to IRBNet
Amanda Saunders

Study Manager

Create New Project

Project Administration

Project Overview

Designer

Share this Project

Sign this Package

Submit this Package

Project History

Send Mail

Delete this Package

Send Mail

[107645-1] A Phase 3, Randomized, Placebo-Controlled, Blinded, Multicenter Study of the Induction and Maintenance of Clinical Response and Remission by MLN0002 in Patients with Moderate to Severe Crohn's Disease

Please select the users that will receive your message.

User	Organization	Send Mail
Lawrence Bird	Metropolitan University	<input checked="" type="checkbox"/>
Alice Randall	Metropolitan University	<input type="checkbox"/>
John Researcher	Metropolitan University	<input type="checkbox"/>
Amanda Saunders	Metropolitan University	<input checked="" type="checkbox"/>
John Smith	Metropolitan University	<input type="checkbox"/>
Barnaby Wilson	Metropolitan University	<input checked="" type="checkbox"/>

Subject * IRBNet message from Amanda Saunders

Message * Please login to IRBNet to review project 107645-1:

A Phase 3, Randomized, Placebo-Controlled, Blinded, Multicenter Study of the Induction and Maintenance of Clinical Response and Remission by MLN0002 in Patients with Moderate to Severe Crohn's Disease

Regards,
Amanda Saunders

Send

Preview

Cancel

* required fields

Researcher: Initial Study Submission

Training Energizer

Sign Your Study

Step 4: Electronic signatures become a permanent part of your electronic study record.

IRBNet ID: 107645-1

USER PROFILE LOGOUT

IRBNet

Welcome to IRBNet
Lawrence Bird

Study Manager
Create New Project

Project Administration
Project Overview
Designer
Share this Project
Sign this Package
Submit this Package
Project History
Send Mail
Delete this Package

Sign Package

[107645-1] A Phase 3, Randomized, Placebo-Controlled, Blinded, Multicenter Study of the Induction and Maintenance of Remission in Acute Myeloid Leukemia

I, Lawrence Bird, the ~~certify that I have read the documents in their entirety and agree that they are ready for submission.~~

OR If you must sign on behalf of someone who is not able to electronically sign for him/herself, **mode**.

This package has been signed by:

Date	Message
02/02/2009 08:27:29	Signed by Amanda Saunders as Research Coordinator

One Signature found.

✓ Anyone with shared access to the study may sign a study.

✓ Choose your project role from the dropdown menu

✓ Sign according to your institution's requirements.

Researcher: Initial Study Submission

Training Energizer



Submit Your Study for Review

Step 5: You may submit your study to one or more boards for review.

IRBNet ID: 107645-1

USER PROFILE

LOGOUT



Welcome to IRBNet
Amanda Saunders

Study Manager

Create New Project

Project Administration

Project Overview

Designer

Share this Project

Sign this Package

Submit this Package

Project History

Send Mail

Delete this Package

Submit Package

[107645-1] A Phase 3, Randomized, Placebo-Controlled, Blinded, Multicenter Study of the Induction and Maintena

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

Search

Clear

Select a Board *

Metropolitan IRB, Frederick, MD

Metsch & Metsch, P.A., Miami, FL

Miami Children's Hospital IRB, Miami, FL

Michigan Technological University, Houghton, MI

Middle Tennessee State University, Murfreesboro, TN

Middlesex Hospital IRB, Middletown, CT

Mission Health Cancer Institutional Review Board, Asheville, NC

Mission Health Institutional Review Board, Asheville, NC

Continue

Cancel

* required fields

✓ The default IRB highlighted is your home IRB.

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Researcher: Initial Study Submission Training Energizer

Submit to your Board: The system enables you to send a message to the coordinator, and elect what submission type it is. IRBNet knows the coordinator of your committee.

IRBNet ID: 107645-1 USER PROFILE LOGOUT

IRBNet

Welcome to IRBNet
Amanda Saunders

Study Manager
Create New Project

Project Administration
Project Overview
Designer
Share this Project
Sign this Package
Submit this Package
Project History
Send Mail
Delete this Package

Submit Package

[107645-1] A Phase 3, Randomized, Placebo-Controlled, Blinded, Multicenter Study of the Induction and Maintenance of Remission in Patients with Acute Myeloid Leukemia

The following IRBNet users at **Metropolitan IRB** will be automatically notified of your submission:
Halway, Ann

Submission Type: *

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

Your Comments:

Thank you for your help!

✓ Send a kind word to your committee coordinators!

Researcher: Initial Study Submission

Training Energizer

Receive Your Review Decision

Review decisions are available in real time from your Study Overview.

IRBNet

Welcome to IRBNet
Amanda Saunders

Project Administration

- Study Manager
- Create New Project
- Project Overview
- Designer
- Share this Project
- Sign this Package
- Submit this Package
- Project History
- Send Mail
- Delete this Package

Project Overview

[107645-1] A Phase 3, Randomized, Placebo-Controlled, Blinded, Multicenter Study of the Induction and Maintenance of Clinical Response and Remission by MLN0002 in Patients with Moderate to Severe Crohn's Disease

You have Full access to this project. (Edit)

Research Institution	Metropolitan University, Frederick, MD
Title	A Phase 3, Randomized, Placebo-Controlled, Blinded, Multicenter Study of the Induction and Maintenance of Clinical Response and Remission by MLN0002 in Patients with Moderate to Severe Crohn's Disease
Principal Investigator	Bird, Lawrence, MD
Status	Pending Review
Lock Status	Locked by your Board and not editable
Keywords	Crohn, Multicenter,
Sponsor	National Science Foundation
Internal Reference Number	Dept-890B

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

Submitted to:
Metropolitan IRB 02/02/2009 **Pending Review** [Review details.](#)

Shared with the following IRBNet users

IRBNet User	Organization	Access Type
John Researcher	Metropolitan University, Frederick, MD	Read
Lawrence Bird	Metropolitan University, Frederick, MD	Full
Amanda Saunders	Metropolitan University, Frederick, MD	Full
John Smith	Metropolitan University, Frederick, MD	Write
Barnaby Wilson	Metropolitan University, Frederick, MD	Read
Alice Randall	Metropolitan University, Frederick, MD	Read

✓ Click "Review Details"


Researcher: Initial Study Submission Training Energizer

Receive Your Review Decision

Details include Agenda Date, Review Type, Status, Effective and Expiration Dates, and Board Documents.

IRBNet ID: 87807-1

USER PROFILE LOGOUT



Welcome to IRBNet
Steven Colby

Study Manager

Designer

Share this Project

Sign this Package

Submit this Package

Review Details

[87807-1] Evaluation of Compliance with Performance of Annual Pelvic Exam/Pap Smear in NY Methodist Hospital
New York Methodist Hospital IRB, Brooklyn, NY



Submission Details

Submitted To	New York Methodist Hospital IRB, Brooklyn, NY
Submitted by	Anna Szafran-Swietlik
Submission Date	01/15/2009
Submission Type	New Project
Local Board Reference Number	87807

Review Details:

Agenda	Review Type	Status	Effective Date	Expiration Date
01/21/2009 03:00 PM	Expedited Review	Approved	01/21/2009	01/21/2010

Board Documents:

Document Type	Description	Last Modified	View
Approval Letter - IRB	Approval Letter - IRB	01/30/2009 10:20 AM	
Stamped Document	Study Questionnaire	01/23/2009 09:59 AM	

✓ Submission
Details are here.

✓ Review Details are
here.

✓ Board documents
are here.

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.