# 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

# Log In To IRBNet

**with your User Name and Password at: <u>www.irbnet.org</u>**



**3**

## Access Your Study Manager

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



4

# Build Your Electronic Study Package
## Step 1: Provide basic information about your study.

USER PROFILE    LOGOUT

**IRBNet**™

**Welcome to IRBNet**
**John Smith**

Study Manager
Create New Study

**Study Manager**

**Create a New Study**

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

Research Institution: * Metropolitan University, Frederick, MD

Title: * 15464: RSV Concomitant Infection

Local Principal Investigator:
First Name:* Simon
Last Name:* Archuletta        Degree(s): MD

Keywords: Taminofex, Pediatric

Sponsor: National Science Foundation

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

Internal Reference Number: DEPT-890A

Continue    Cancel

* required fields

**5**

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



- ✓ Drop down menu for libraries and their forms

- ✓ Add study documents here

**6**

## 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 documents and attach.

✓ If your institution has an online IRBNet Document Wizard it will be located here.

**7**

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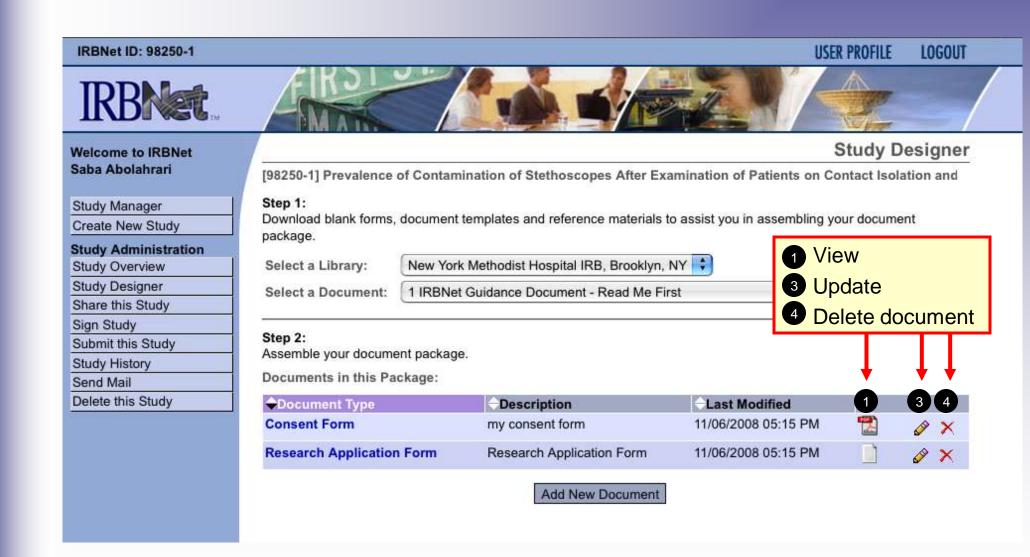## Step 2: Attach your electronic study documents.

8

## Share with Your Research Team

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

IRBNet ID: 83661-1                                    USER PROFILE    LOGOUT

**IRBNet**™

**Welcome to IRBNet**
**John Smith**

Study Manager
Create New Study

**Study Administration**
Study Overview
Study Designer
Share this Study
Sign Study
Submit this Study
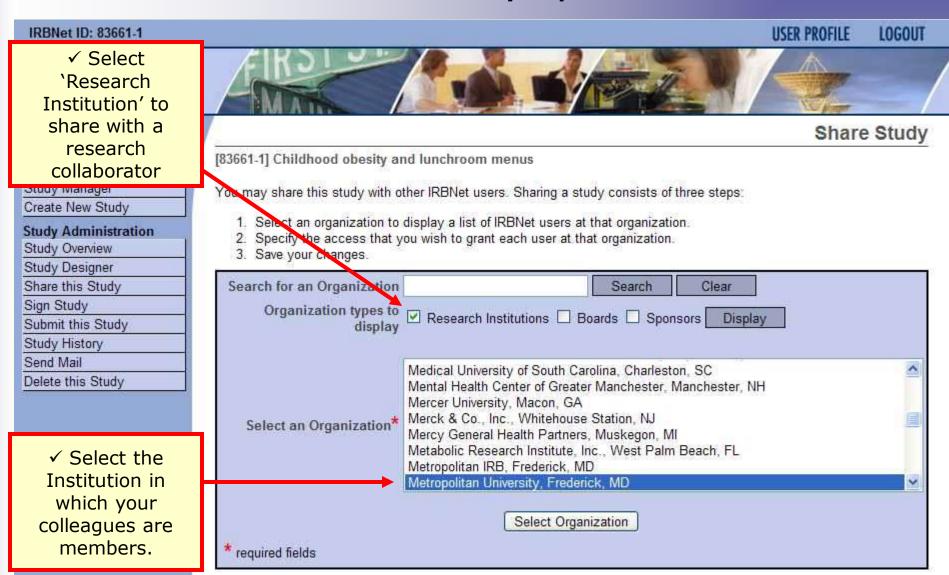Study History
Send Mail
Delete this Study

**Share Study**

**[83661-1] Childhood obesity and lunchroom menus**

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

♦ **Share:** Use this option if you wish to share your study with other Researchers, Committee Members, Administrators or Sponsors at your own institution or any other institution. For example, you may wish to share this study with other members of your research team so that you may collaborate in the design and development of the study, or with a selected Committee Member or Administrator to solicit feedback prior to submitting your study. You may provide any individual with **Full, Write** or **Read** access.

♦ **Multi-site:** Use this option only if your study is a multi-site study and you wish to send a complete and independent copy of this study to a Principal Investigator at another site. The local Principal Investigator will receive their own independent copy of all study documents 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 study at every local site. The other local Principal Investigators will also be able to monitor the progress of this study at every local site (including your own).

♦ **Transfer:** Transfer your ownership of this study to another user. In doing so you will relinquish all access to this study and the designated user will be granted **Full** access.

✓ Almost every study requires the "Share" designation.

**9**

# Share with Your Research Team

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



IRBNet ID: 83661-1

USER PROFILE    LOGOUT

✓ Select 'Research Institution' to share with a research collaborator

Share Study

[83661-1] Childhood obesity and lunchroom menus

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

You may share this study with other IRBNet users. Sharing a study 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 [                    ]  [Search]  [Clear]

Organization types to display  ☑ Research Institutions ☐ Boards ☐ Sponsors  [Display]

Select an Organization*
- Medical University of South Carolina, Charleston, SC
- Mental Health Center of Greater Manchester, Manchester, NH
- Mercer University, Macon, GA
- Merck & Co., Inc., Whitehouse Station, NJ
- Mercy General Health Partners, Muskegon, MI
- Metabolic Research Institute, Inc., West Palm Beach, FL
- Metropolitan IRB, Frederick, MD
- **Metropolitan University, Frederick, MD**

✓ Select the Institution in which your colleagues are members.

[Select Organization]

* required fields

**10**

# Share with Your Research Team
**You can grant each member of your team the level of access that they require.**

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

Welcome to IRBNet
John Smith

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

**Share Study**

[83661-1] Childhood obesity and lunchroom menus

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

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

Users that are granted "Write" access may edit study 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 study documents or perform any other administrative functions.

| IRBNet User | Permission Access | | | |
|---|---|---|---|---|
| Chandry, Francis | ○ Full | ○ Write | ◉ Read | ○ No Access |
| Garg, Kapil | ○ Full | ○ Write | ◉ Read | ○ No Access |
| Johnson, Randy | ○ Full | ◉ Write | ○ Read | ○ No Access |
| Katen, John | ○ Full | ○ Write | ○ Read | ◉ No Access |
| Olmsted, Andy | ○ Full | ◉ Write | ○ Read | ○ No Access |
| Palazzo, Enrico | ○ Full | ○ Write | ◉ Read | ○ No Access |
| Randall, Alice | ◉ Full | ○ Write | ○ Read | ○ No Access |
| Saunders, Amanda | ○ Full | ○ Write | ◉ Read | ○ No Access |
| Wilson, Barnaby | ○ Full | ○ Write | ○ Read | ◉ No Access |

9 Users found, displaying all Users.

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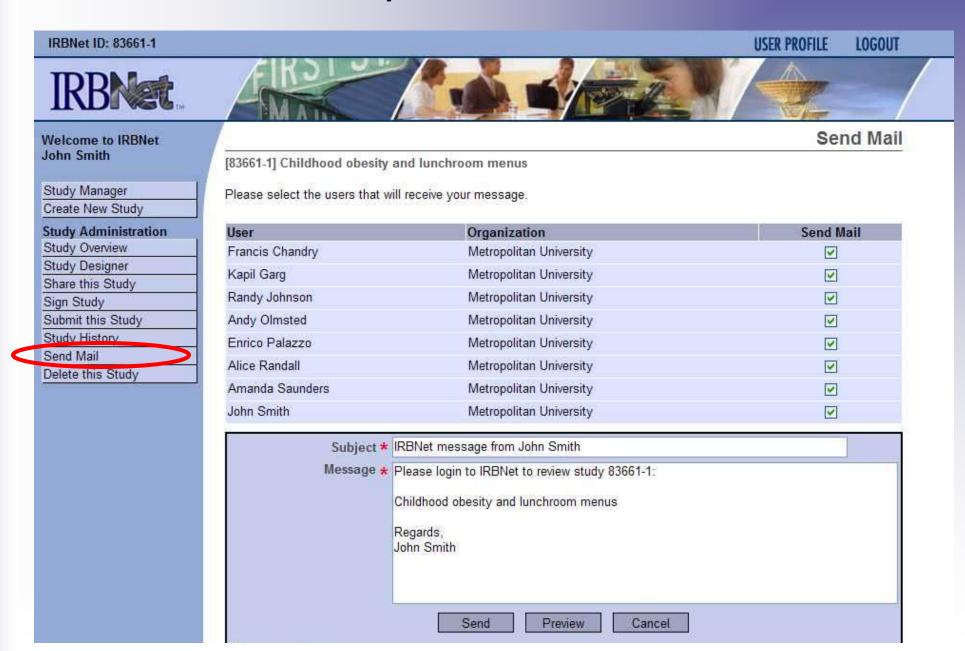
**Your Comments**

Thank you for your assistance in collaboration. I look forward to an excellent project!
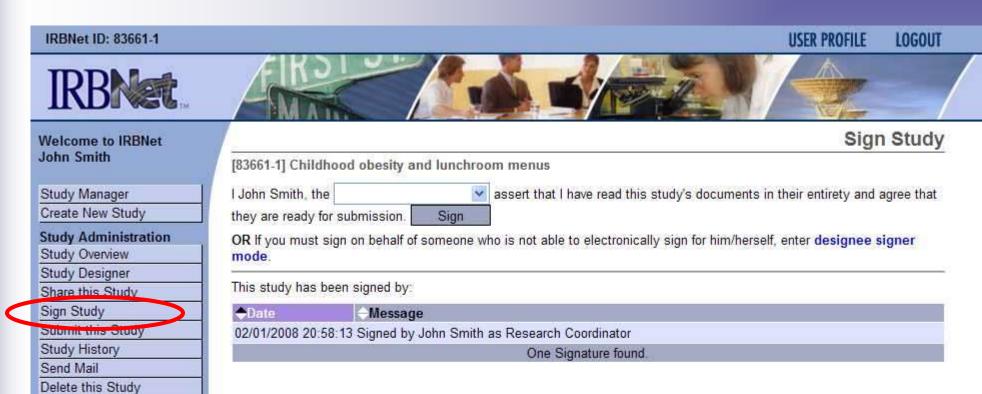
Save    Cancel

11

## Communicate with Your Team

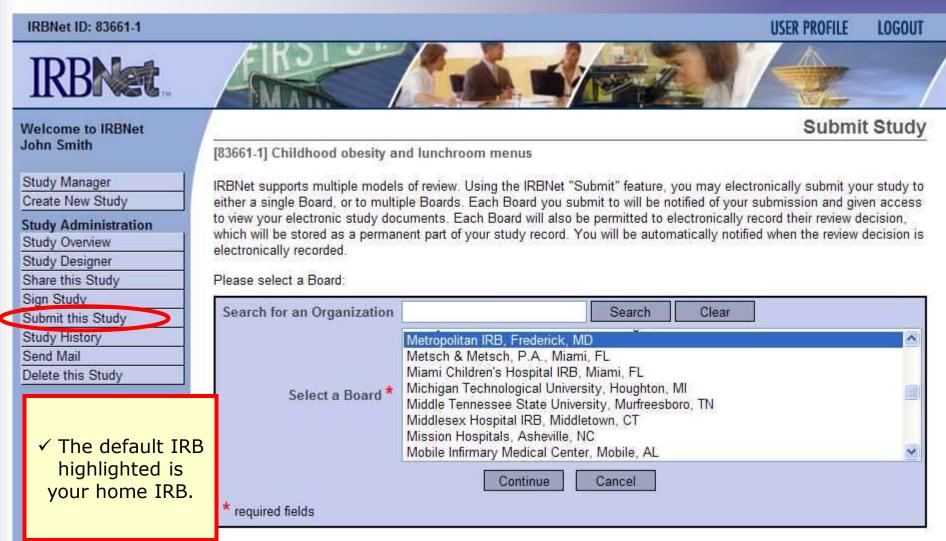**Use the Send Mail feature to quickly communicate with your team.**

## Sign Your Study

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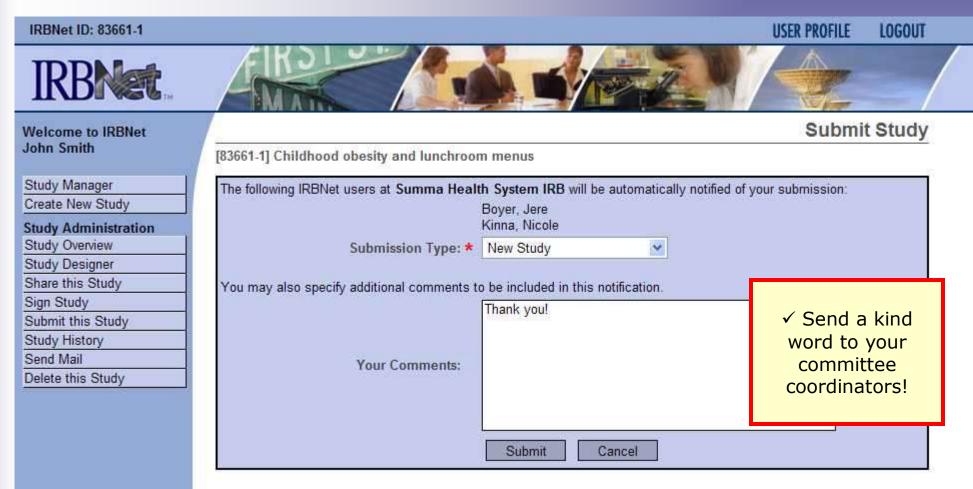


✓ Anyone with shared access to the study may sign a study.

## Submit Your Study for Review

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



✓ The default IRB highlighted is your home IRB.

14

**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.**



✓ Send a kind word to your committee coordinators!

# Receive Your Review Decision

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



✓ Click "Review Details"

# Receive Your Review Decision

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

**Welcome to IRBNet**
**Amanda Saunders**

Study Manager

Share this Study

Sign Study

Submit this Study

Study History

Send Mail

**Review Details**

[100104-1] A Phase 3, Randomized, Placebo-Controlled, Blinded, Multicenter Study

**Metropolitan IRB, Frederick, MD**

**Submission Details**

| | |
|---|---|
| Submitted To | Metropolitan IRB, Frederick, MD |
| Submitted by | Amanda Saunders |
| Submission Date | 11/06/2008 |
| Submission Type | New Study |
| Local Board Reference Number | 08-20012 |

✓ Submission Details are here.

**Review Details:**

| Agenda | Review Type | Status | Effective Date | Expiration Date |
|---|---|---|---|---|
| 11/06/2008 03:30 PM | Full Committee Review | Approved | 11/06/2008 | 11/06/2009 |

✓ Review Details are here.

**Board Documents:**

| Document Type | Description | Last Modified | View |
|---|---|---|---|
| Application Approved Letter | Application Approved Letter | 11/06/2008 05:34 PM | |

✓ Board documents are here.

17

## 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.

**RESEARCH DATAWARE**
*Innovation in Research Management*