

**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:

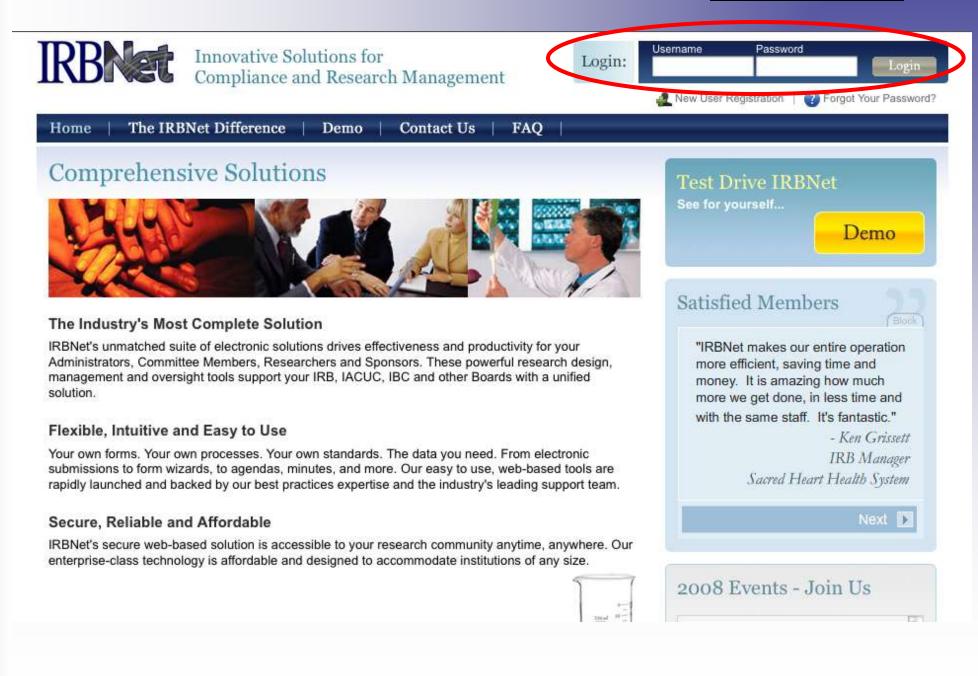
- Log In To IRBNet
- Access Your Study Manager
- Build Your Electronic Study Package
- Share with Your Research Team
- Communicate with Your Team
- Sign Your Study
- Submit Your Study for Review
- Access Your Review Decision and Board Documentation



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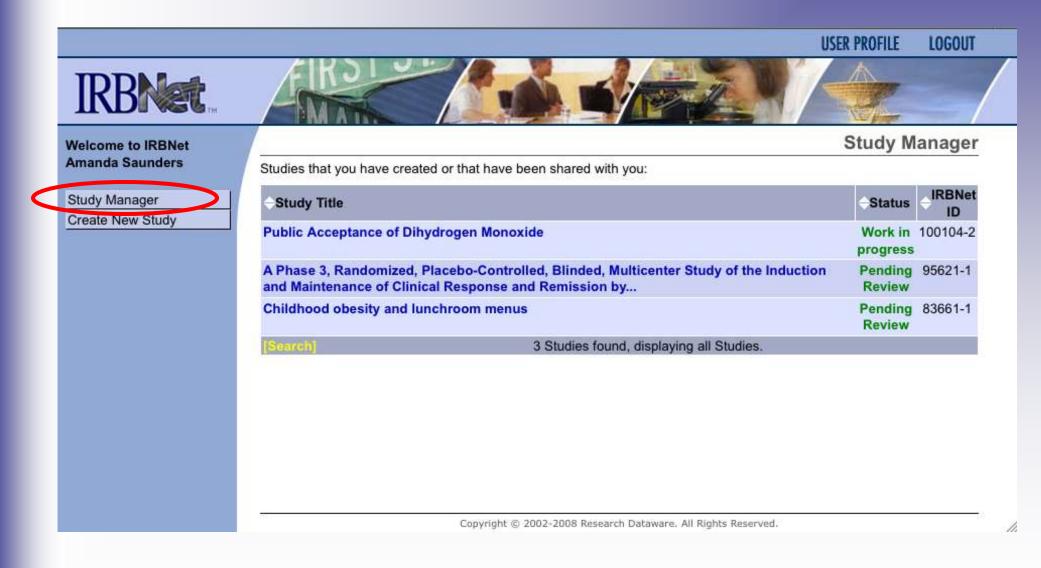
# **Researcher: Initial Study Submission** Training Energizer Log In To IRBNet

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



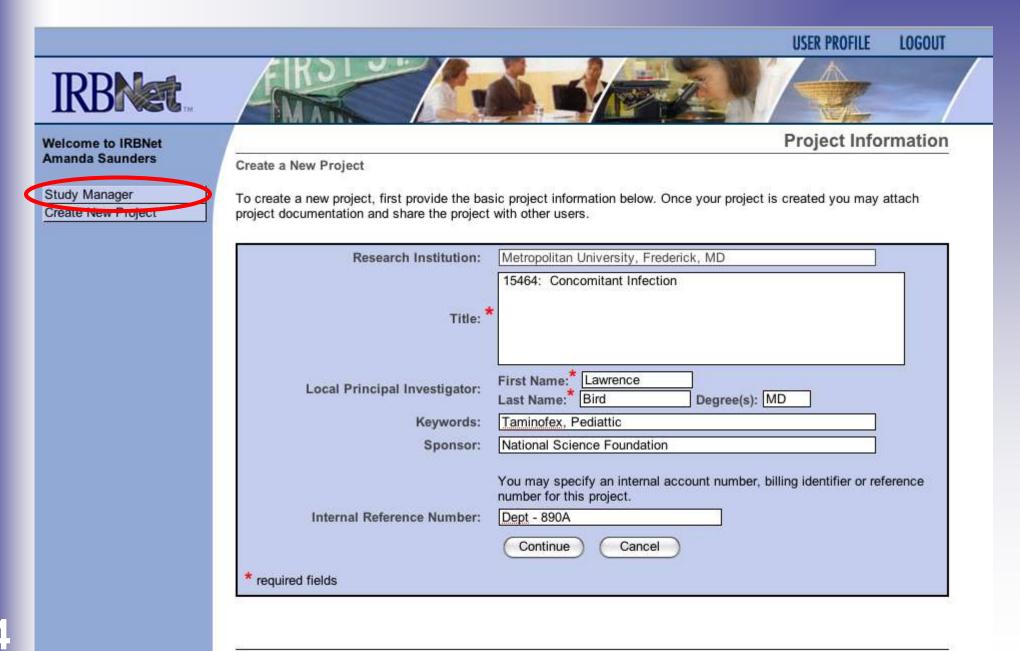
### **Access Your Study Manager**

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



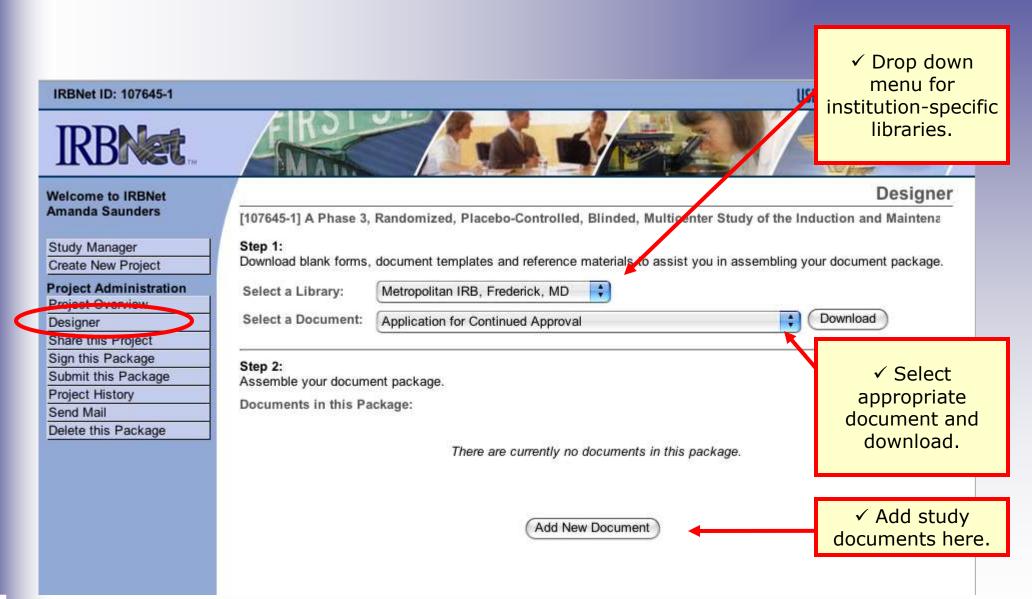
# **Build Your Electronic Study Package**

Step 1: Provide basic information about your study.



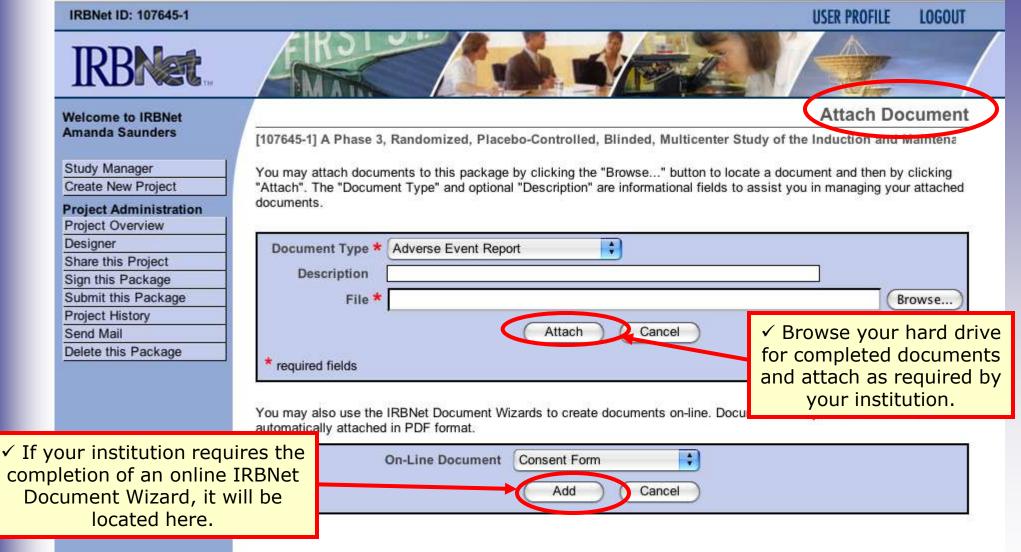
# **Build Your Electronic Study Package**

**Step 2: Attach your electronic study documents.** 



# **Attach Document**

**IRBNet** provides two mechanisms for entering documents into the system.



# **Build Your Electronic Study Package**

Step 2: Attach your electronic study documents.

IRBNet ID: 95621-1				US	ER PROFILE	LOGOUT
<b>IRBNet</b>	<b>FRO</b>					
Velcome to IRBNet					D	esigner
manda Saunders	[95621-1] A Phase 3,	Randomized	, Placebo-Controlled, Blinded, M	ulticenter Study of the Ind	uction and N	laintenar
Study Manager	This package is:	Locked				
reate New Project						
roject Administration roject Overview	Step 1: Download blank forms	, document te	emplates and reference materials to	assist you in asse	ïew	
esigner	Select a Library:	Metropolita	n IRB, Frederick, MD 📑			
ign this Package	Select a Document:				pdate	
roject History	Select a Document.	Application	for Continued Approval	4 r	elete do	ncumen
end Mail						Joannon
	Step 2: Assemble your docum				Ļ	
	Documents in this Pa	ackage:				66
	Document Type		Description	Last Modified	1	34
	Consent Form		Consent Form	09/06/2008 11:34 AM		0 ×
	Protocol		protocol	09/06/2008 11:31 AM	1	ØX
	Research Applicatio	n Form	Research Application Form	09/06/2008 11:33 AM		Ø X
	Study Plan		study plan	09/06/2008 11:33 AM		X
			Add New Documen	Ð		050

# **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: 107645-1



#### 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

 ✓ Almost every study requires the "Share" designation. USER PROFILE LOGOUT

#### Share Project

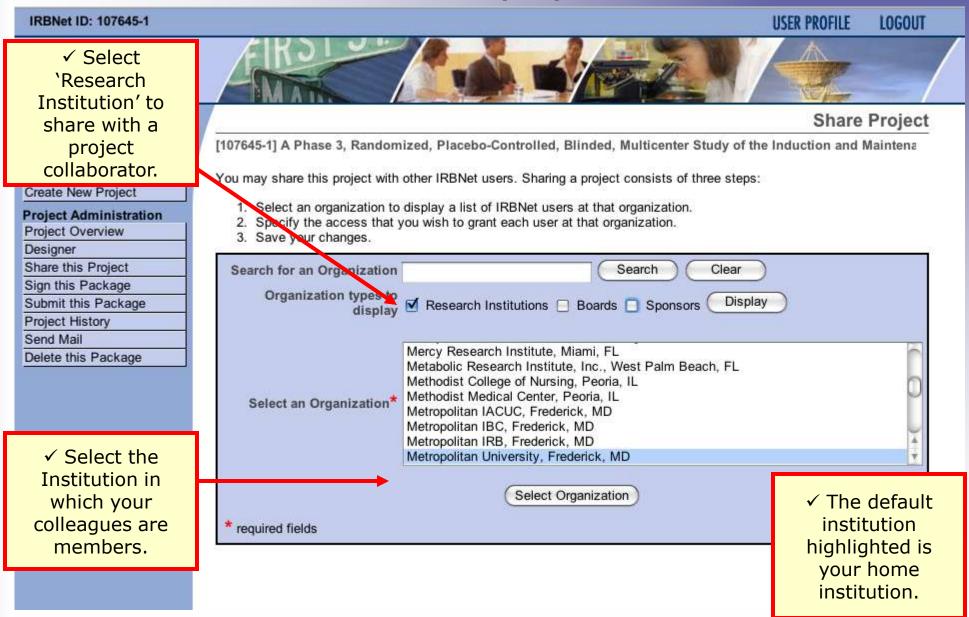
[107645-1] A Phase 3, Randomized, Placebo-Controlled, Blinded, Multicenter Study of the Induction and Maintena

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.

# **Share with Your Research Team**

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



### Share with Your Research Team You can grant each member of your team the level

#### of access that they require.

#### Share Project

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

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.

IPDivet User	Permissio	on Access			
Bird, Lawrence	💽 Full	🔘 Write	O Read	🕒 No Access	
Chandry, Francis	🔘 Full	O Write	O Read	No Access	
Chennamsetty, Maruti	🔘 Full	O Write	O Read	No Access	
Garg, Kapil	O Full	O Write	O Read	No Access	
Johnson, Randy	🔘 Full	🔘 Write	O Read	No Access	
Katen, John	🔘 Full	O Write	O Read	No Access	
Morris, Melanie	🔘 Full	O Write	🔘 Read	No Access	
Olmsted, Andrew	O Full	O Write	O Read	No Access	
Palazzo, Enrico	🔘 Full	🔘 Write	💮 Read	No Access	
Randall, Alice	🔘 Full	O Write	<ul> <li>Read</li> </ul>	O No Access	
Rawlings, John	🔘 Full	O Write	🔘 Read	No Access	
Researcher, John	O Full	O Write	Read	O No Access	
Rosenbleet, Ben	🔘 Full	🔘 Write	🔘 Read	No Access	
Smith, John	🔘 Full	• Write	O Read	O No Access	
Wilson, Barnaby	🔘 Full	O Write	Read	O No Access	
	15 Us	ers found.	displaying a	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:

Thank you for your help!

Your Comments

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

Welcome to IRBNet Amanda Saunders

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

10

Save ) ( Cancel

## **Communicate with Your Team**

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

**USER PROFILE** 

LOGOUT

Send Mail

#### IRBNet ID: 107645-1



Welcome to IRBNet Amanda Saunders

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

Please select the users that will receive your message.

Metropolitan University Metropolitan University	Ø
Metropolitan University	-
Metropolitan University	
Metropolitan University	
Metropolitan University	•
Metropolitan University	M
Maintenance of Clinical Response and Remission by MLN0002 in Patients Crohn's Disease Regards, Amanda <u>Saunders</u>	s with Moderate to Sever
	Metropolitan University Metropolitan University Metropolitan University RBNet message from Amanda Saunders Please login to IRBNet to review project 107645-1: Phase 3, Randomized, Placebo-Controlled, Blinded, <u>Multicenter</u> Study of Maintenance of Clinical Response and Remission by MLN0002 in Patients Crohn's Disease

Create New Project

Study Manager

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

Delete this Package

# **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	[107645-1] A Phase 3, Randomized, Placebo-Controlled, Blinded, Multicenter Study of the	Sign Pa	
Study Manager Create New Project Project Administration Project Overview Designer	I Lawrence Bird, the second the documents in the entirety and agree that they are ready for submission. Sign OR If you must sign on behalf of someone who is not able to electronically sign for him/herself, mode.	project r the dro	ose your role from opdown enu
Share this Project Sign this Package Submit this Package Project History Send Mail Delete this Package	Message         02/02/2009 08:27:29 Signed by Amanda Saunders as Research Coordinator         One Signature found.	to y institu	occording our ution's ements.
✓ 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.

#### IRBNet ID: 107645-1



#### Submit Package

LOGOUT

**USER PROFILE** 

#### Welcome to IRBNet Amanda Saunders

Study Manager	
Create New Project	
Project Administratio	n
Project Overview	inc)

Project Overview Designer Share this Project Sign this Package Submit this Package Project History Send Mail Delete this 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	
* required fields	Continue Cancel	<ul> <li>✓ The default IR highlighted is your home IRB.</li> </ul>

# 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
<b>IRBNet</b>		
Welcome to IRBNet		Submit Package
Amanda Saunders	[107645-1] A Phase 3, Randomized, Placebo-Controlled, Blinded, Multicenter	Study of the Induction and Maintena
Study Manager         Create New Project         Project Administration         Project Overview         Designer         Share this Project	The following IRBNet users at Metropolitan IRB will be automatically notified of y Halway, Ann Submission Type: * New Project You may also specify additional comments to be included in this notification.	vour submission:
Sign this Package Submit this Package Project History Send Mail Delete this Package	Your Comments:	✓ Send a kind word to your committee coordinators!
	Submit Cancel	

# **Receive Your Review Decision**

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

Welcome to IRBNet			Project Overvie	
Amanda Saunders	[107645-1] A Phase 3, Ran	domized, Placebo-Controlled, Blinded, Multicenter Stud	dy of the Induction and Mainten	
Study Manager	You have Full access to t	his project. (Edit)		
Create New Project	Resear	rch Institution Metropolitan University, Frederick, MD		
Project Administration Project Overview Designer		Title A Phase 3, Randomized, Placebo-Controlled Induction and Maintenance of Clinical Response Patients with Moderate to Severe Crohn's D	onse and Remission by MLN0002	
Share this Project	Principa	al Investigator Bird, Lawrence, MD		
Sign this Package		Status Pending Review		
Submit this Package		Lock Status Locked by your Board and not editable		
Project History		Keywords Crohn, Multicenter,		
Send Mail	Sponsor National Science Foundation			
Delete this Package	Internal Refer	rence Number Dept-890B		
ck "Review				
Details"	The documents for this proj	ect can be accessed from the Designer.		
Jeldiis				
Petalls	Submitted to:			
		9 Pending Review Review details.		
	Metropolitan IRB 02/02/200		Access Type	
	Metropolitan IRB 02/02/200 Shared with the following IF	RBNet users	Access Type Read	
	Metropolitan IRB 02/02/200 Shared with the following IF IRBNet User	RBNet users Organization		
	Metropolitan IRB 02/02/200 Shared with the following IF IRBNet User John Researcher	RBNet users Organization Metropolitan University, Frederick, MD	Read	
	Metropolitan IRB 02/02/200 Shared with the following IF IRBNet User John Researcher Lawrence Bird	RBNet users Organization Metropolitan University, Frederick, MD Metropolitan University, Frederick, MD	Read Full	
	Metropolitan IRB 02/02/200 Shared with the following IF IRBNet User John Researcher Lawrence Bird Amanda Saunders	RBNet users Organization Metropolitan University, Frederick, MD Metropolitan University, Frederick, MD Metropolitan University, Frederick, MD	Read Full Full	

# **Receive Your Review Decision**

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



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.

