

Important IRBnet Updates and Instructions
Effective January 27, 2009

As of March 1, 2008, all NEW protocols submitted to the CHW Human Research Review Board must be submitted electronically through IRBnet.

Previously approved protocols needing amendments or continuing review should be still be submitted on paper until you are notified via e-mail when your archives have been scanned in by the HRRB Office Staff.

Step # 1: Register for an IRBnet account at www.irbnet.org

Using the 'New User Registration' link in the upper right corner of the page:

1. Create a username and password, and a password hint, Select 'Continue'.
2. Read and 'Accept' the terms and conditions.
- 3. Select "Children's Hospital of Wisconsin, Milwaukee, WI" from the list of institutions.****
4. Supply your contact information.
5. Confirm your registration information and click 'Register'. If you have an error, you can fix it by clicking on the yellow (Edit) in parentheses.
6. Wait for an activation e-mail from IRBnet.
7. Confirm account through the activation link in the e-mail.



WARNING

****If you do not register as a CHW Researcher, you will not have access to the CHW HRRB specific forms and will not be able to properly submit your protocol.**

If you have already created an account and affiliated with MCW rather than CHW, you can correct this by selecting "User Profile" in the upper right of the screen. You can then "Add an Additional Affiliation" and select CHW.

You may keep your MCW affiliation if you like, but we suggest that you delete (or 'deactivate') that affiliation. If you do not delete it you will have to remember to select your CHW affiliation whenever you try to create a new study.

Step # 2: Creating a New Study (not previously submitted via paper)

1. **Select "Create New Study" from your menu tabs on the left.**



2. Next, provide basic study information and click 'Continue'.

Project Information

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:	<input type="text" value="Children's Hospital of Wisconsin, Milwaukee, WI"/>
Title: *	<input type="text" value="Enter The Study Title Here"/>
Local Principal Investigator:	First Name: * <input type="text" value="PI First Name"/>
	Last Name: * <input type="text" value="PI Last Name"/> Degree(s): <input type="text" value="MD"/>
Keywords:	<input type="text" value="Use this field to find your study more easily in the future"/>
Sponsor:	<input type="text" value="If you have a sponsor, please notify us here."/>
Internal Reference Number:	<input type="text" value="Leave BLANK"/>
	<input type="button" value="Continue"/> <input type="button" value="Cancel"/>

* required fields

3. In the Study Designer:

In IRBNet Step 1: 'Select a Document' use the dropdown list to choose and download the checklist for the type of study you are submitting and print it out. Download the forms specific to your submission, per the checklist and 'Save' them to your computer.

Study Designer

[106957-1] Enter The Study Title Here

Step 1:

Download blank forms, document templates and reference materials to assist you in assembling your document package.

Select a Library:

Select a Document:



Step 2:

Assemble your document package.

Documents in this Package:

There are currently no documents in this package.

IRBNet allows you to revise your existing project documents and maintain version history, or add entirely new documents to your package. [Learn more.](#)

[When should I do this?](#)

In IRBNet Step 2: Upload your completed forms and templates into IRBnet by clicking the 'Add New Document' button. This will bring you to the Attach Document page:

Attach Document

[106957-1] Enter The Study Title Here

You may attach documents to this study 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 * Browse...
Attach Cancel
* required fields

Click BROWSE to upload the completed forms/templates from your PC.

You may also use the IRBNet Document Wizards to create documents on-line. Documents that you create on-line are automatically attached to your study in PDF format.

On-Line Document Registration Page
Add Cancel

How to Locate/Complete the Protocol Registration Wizard

Our protocol Registration Page is found on the "Attach Documents" page in the On-line documents drop down menu (see below):

You may also use the IRBNet Document Wizards to create documents on-line. Documents that you create on-line are automatically attached to your study in PDF format.

On-Line Document Registration Page
Add Cancel

After you have completed this form, click 'Save and Exit' and it will automatically combine into a PDF file and appear in your study designer automatically. This form and the responses you enter are what populates the IRBnet generated approval letters and other correspondence. **Do not use the outdated MS Word based registration document or your submission will be filed as incomplete!!!**

Step #3: Share Your Study with essential personnel

Share Study

[106957-1] Enter The Study Title Here

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.

• 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 Package

- **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**.

1. Click on the 'Share this Study' tab on the left (as shown). This will bring you to the "Share Study" page. On the "Share Study" page, click the word 'Share' at the beginning of the first paragraph.
2. On the next page you will be asked to identify the institution to which the person you wish to share your study with belongs. It will default to 'Children's Hospital of Wisconsin, Milwaukee, WI' the same affiliation required during registration. Click 'Select Organization'.
3. Search for the user you wish to share the study with by typing their name (Last Name recommended) in the 'Search' field. *(If the person you are looking for does not appear, they are not registered properly in IRBnet and you must ask for the affiliation they have registered under.)* Next, specify the access that you want this user to have. And click 'Save'. You may add additional comments (as shown below). Your comments will be included in the access notification e-mail generated by IRBNet.

WARNING



Assigning FULL access to a user on a study will allow them to perform ANY function on the study, including submission (even before it is complete) and deletion!!

Share Study

[106957-1] Enter The Study Title Here

Specify the access that you wish to grant to each user at Children's Hospital of Wisconsin.

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.

Search for a User:

IRBNet User	Permission Access
Billingsley, Bridget	<input type="radio"/> Full <input type="radio"/> Write <input type="radio"/> Read <input checked="" type="radio"/> No Access

One User found.

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

Step #4: Obtain/Verify Electronic Signatures

Just as with the paper submission process, the Investigator and research team are responsible for obtaining all needed reviews/signatures (Section Chief, Dept. Chair, Financial review, Pharmacy, Laboratory, ambulatory services, in-patient unit manager, etc.) **This is to be done PRIOR to submission to the HRRB.** Again, should you submit a study without all of the appropriate sign-offs it will be filed as **INCOMPLETE** and held until all signatures have been obtained.

While the mechanism for sign off has changed, the overall process is essentially the same as it existed prior to the IRBnet system.

Sign Study

Study Manager	[106957-1] Enter The Study Title Here								
Create New Study	I Gwendolyn Miner, the <input type="text"/> assert that I have read this study's documents in their entirety and agree that they are ready for submission. <input type="button" value="Sign"/>								
Study Administration	OR If you must sign on behalf of someone who is not able to electronically sign for him/herself, enter designee signer mode .								
Study Overview	This study has been signed by:								
Study Designer	<table border="1"><thead><tr><th>Date</th><th>Message</th></tr></thead><tbody><tr><td>01/26/2009 15:46:49</td><td>Signed by Gwendolyn Miner as Department Chair</td></tr><tr><td>01/26/2009 15:46:36</td><td>Signed by Gwendolyn Miner as Co-Investigator</td></tr><tr><td>01/26/2009 15:46:27</td><td>Signed by Gwendolyn Miner as Principal Investigator</td></tr></tbody></table>	Date	Message	01/26/2009 15:46:49	Signed by Gwendolyn Miner as Department Chair	01/26/2009 15:46:36	Signed by Gwendolyn Miner as Co-Investigator	01/26/2009 15:46:27	Signed by Gwendolyn Miner as Principal Investigator
Date	Message								
01/26/2009 15:46:49	Signed by Gwendolyn Miner as Department Chair								
01/26/2009 15:46:36	Signed by Gwendolyn Miner as Co-Investigator								
01/26/2009 15:46:27	Signed by Gwendolyn Miner as Principal Investigator								
Share this Study	3 Signatures found, displaying all Signatures.								
Sign Study									
Submit this Study									
Study History									
Send Mail									
Delete this Package									

Copyright © 2002-2009 Research Dataware. All Rights Reserved.



Notifications are NOT generated when someone signs off! However, you can monitor who has signed off on the study by viewing the 'Sign Study' page.

Step # 5: You are ready to SUBMIT your study!

Once all of the required signatures have been obtained, double-check the document list using the submission checklist for completeness. Click 'Submit' using the tab on the left and choose your submission type. The reviewing board will default to 'Children's Hospital of Wisconsin Human Review Board'. Once a study has been submitted, it is locked by the board and you will not be able to make edits.

Submit Study

[106957-1] Enter The Study Title Here
The following IRBNet users at Children's Hospital of Wisconsin Human Research Review Board will be automatically notified of your submission: Anderson, Greg Billingsley, Bridget
Submission Type: * <input type="text" value="New Project"/>
You may also specify additional comments to be included in this notification.
Your Comments: <input type="text" value="Please review the enclosed study. The contact person for this study is Genevive Madison (414) 123-4567. Thank you."/>
<input type="button" value="Submit"/> <input type="button" value="Cancel"/>

THE REVIEW PROCESS

Upon review of your complete submission, you may be required to submit modifications per the reviewer's request or field questions regarding your study. Your coordinator will instruct you on how to reply. Please respond promptly in order to facilitate a quick approval.

Once your study has been approved, you will find your approval packet in IRBnet by going to the 'Study Overview' page under "[Review Details](#)" (as shown below):

Study Overview

[104180-1] Demo Study: 12-29-2008

You have Full access for this study (Edit)	
Research Institution	Children's Hospital of Wisconsin, Milwaukee, WI
Study Title	Demo Study: 12-29-2008
Principal Investigator	Person, Researcher, PhD
Study Status	Approved
Lock Status	Locked by your Board and not editable
Keywords	demo, study
Sponsor	HRRB

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



Submitted to:

Children's Hospital of Wisconsin HRRB Committee 2 12/29/2008 **Approved** 01/29/2009. [Review details.](#)

Children's Hospital of Wisconsin Human Research Review Board 12/29/2008 **Forwarded** 12/29/2008. [Review details.](#)

Shared with the following IRBNet users

IRBNet User	Organization	Access Type
Gwendolyn Miner	Children's Hospital of Wisconsin, Milwaukee, WI	Full

'Review Details' Page:

Review Details

[104180-1] Demo Study: 12-29-2008

Children's Hospital of Wisconsin HRRB Committee 2, Milwaukee, WI

Submission Details	
Submitted To	Children's Hospital of Wisconsin HRRB Committee 2, Milwaukee, WI
Submitted by	Bridget Billingsley
Submission Date	12/29/2008
Submission Type	New Project
Local Board Reference Number	CHW 09/876, GC 543

Review Details:

Agenda	Review Type	Status	Effective Date	Expiration Date
Unassigned	Exempt Review	Approved	01/29/2009	

Board Documents:

Document Type	Description	Last Modified	View
Approval Letter	Approval Letter	01/27/2009 11:49 AM	
Stamped Document	APPROVED Demo Study Consent	01/27/2009 11:49 AM	
Stamped Document	APPROVED Demo Study HIPAA Form	01/27/2009 11:50 AM	

ADDITIONAL ASSISTANCE

Local IRBnet Support

If you have local access problems (i.e. registering, forms, etc.) or need CHW HRRB specific IRBnet training please contact:

Greg Anderson (Ganderson@chw.org – 414-337-7105) or Gwen Miner (Gminer@chw.org – 414-337-7133)

Trainings are held on Fridays in the CHW HRRB Office at the Children's Corporate Center, Suite C 745. Training lasts approximately 30 minutes.

Us:

Creating an account
Questions about forms
How to use the Wizard
training, etc

Them:

Login problems
website problems

IRBnet technical problems and afterhours support

IRBNet is web-based and has its own support desk available for any systematic problems. **CHW IS will not be able to provide IRBnet specific support.**

If you have specific technical issues with IRBnet (i.e. login or website error messages), please contact their support services:

IRBNet Technical Support Desk

877.261.6461
support@irbnet.org