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:	Children's Hospital of Wisconsin, Milwaukee, WI
Title: *	Enter The Study Title Here
Local Principal Investigator:	First Name:* PI First Name Last Name:* PI Last Name Degree(s): MD
Keywords:	Use this field to find your study more easily in the future
Sponsor:	If you have a sponsor, please notify us here.
	You may specify an internal account number, billing identifier or reference number for this study.
Internal Reference Number:	Leave BLANK

Continue Cancel

* required fields

3. In the Study Designer:

<u>In IRBNet Step 1</u>: '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 '<u>Save' them to your computer</u>.

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: Children's Hospital of Wisconsin Human Research Review Board, Milwauk

Select a Document: Abstract Template

Download

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.

Add New Document When should I do this?

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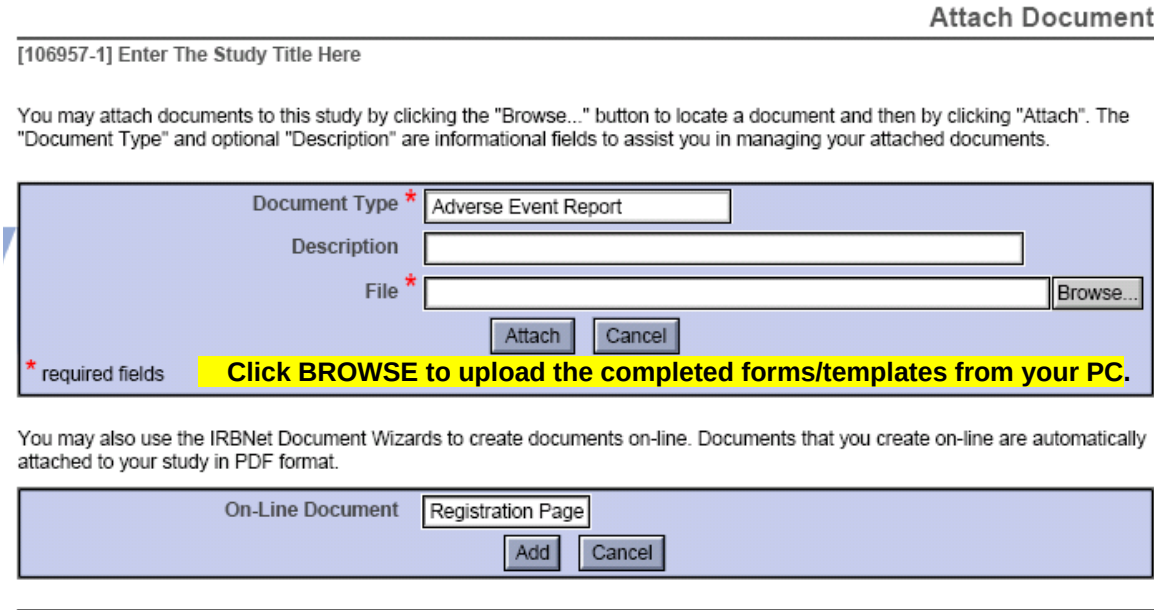
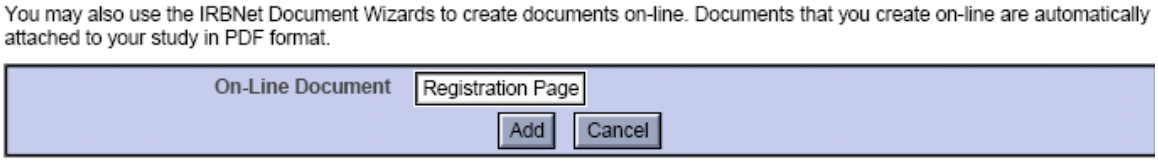
<u>In IRBNet Step 2:</u> Upload your completed forms and templates into IRBnet by clicking the 'Add New Document' button. This will bring you to the Attach Document page:



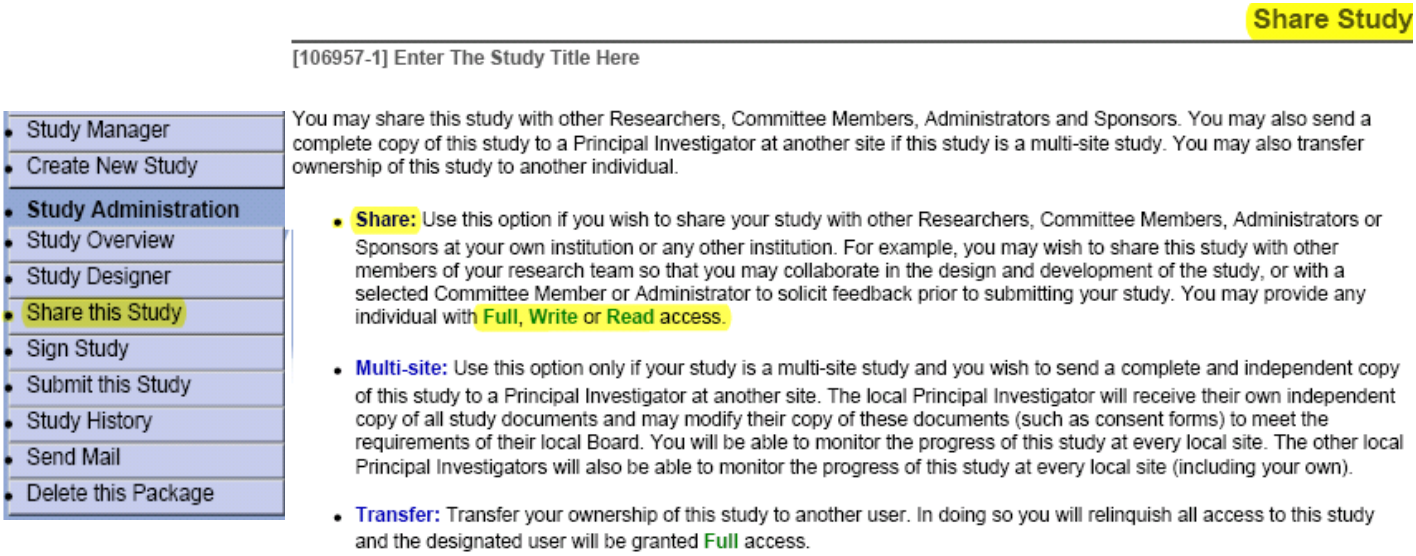
How to Locate/Complete the Protocol Registration Wizard

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



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



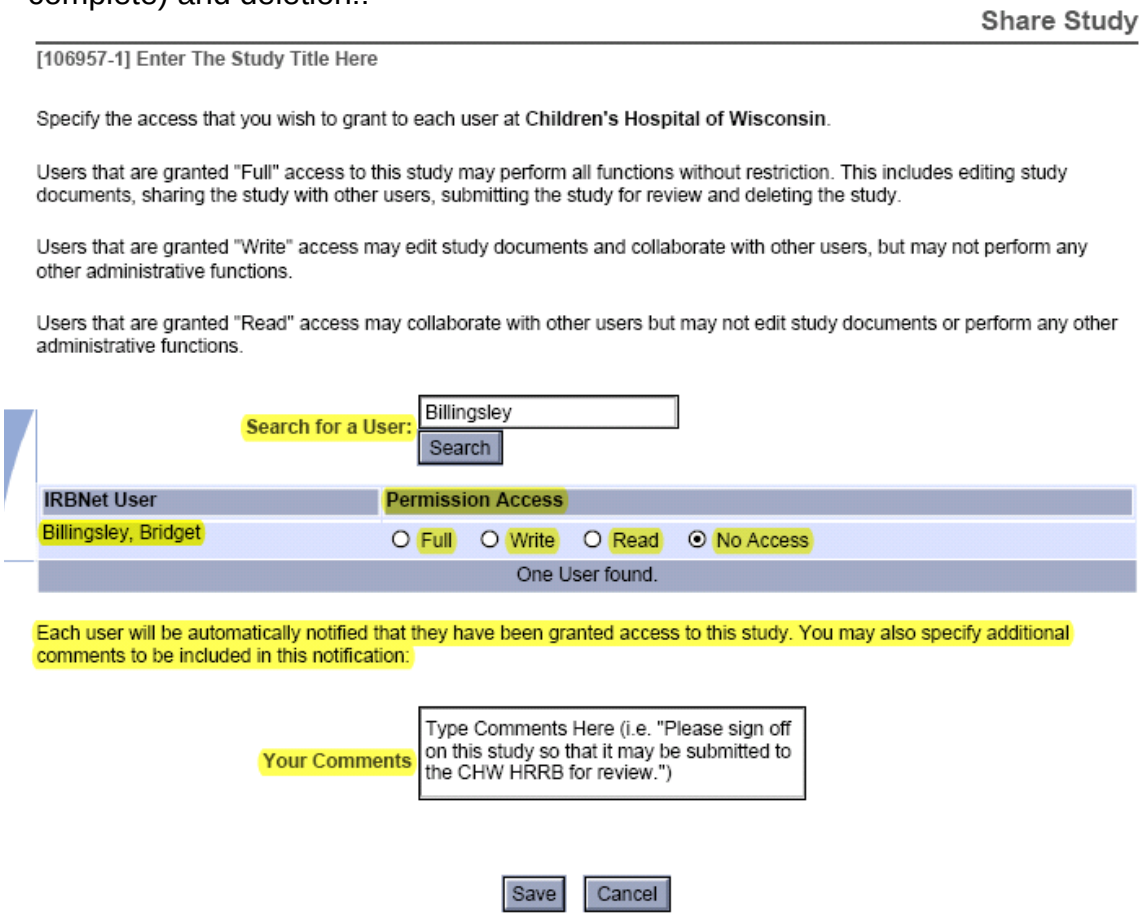
1. Click on the 'Share this Study' tab on the left (as shown). This will bring you to the "Share Study" page. On the "Share Study" page, click the word 'Share' at the beginning of the first paragraph.

2. One 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

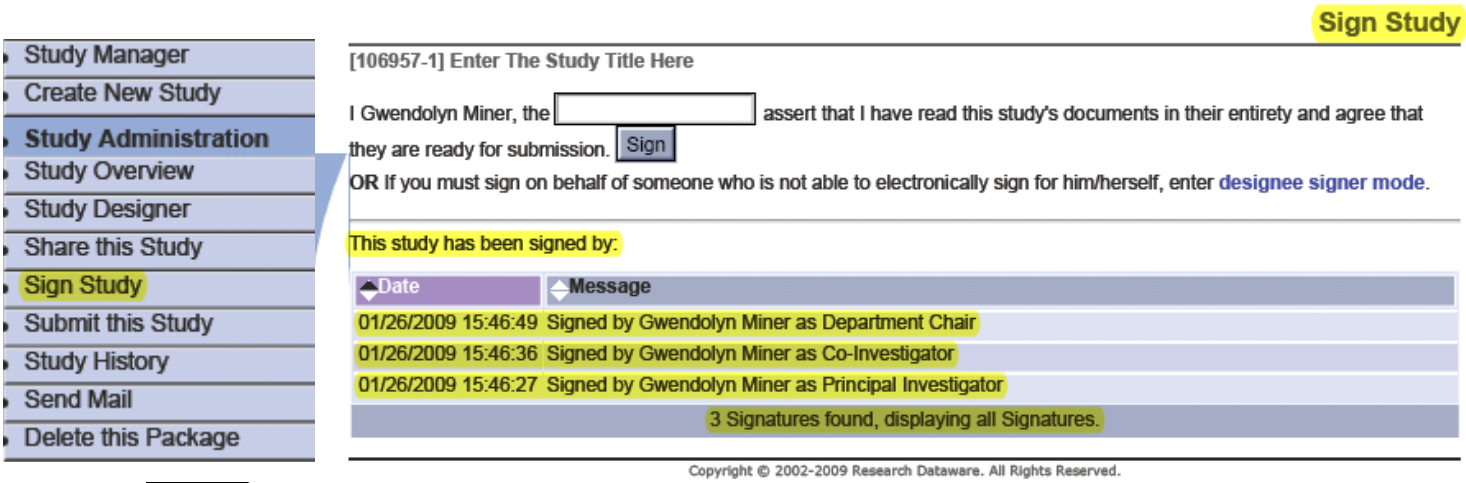
Assigning FULL access to a user on a study will allow them to perform ANY function on the study, including submission (even before it is complete) and deletion!!



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 <u>PRIOR to submission to the HRRB</u>. 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.

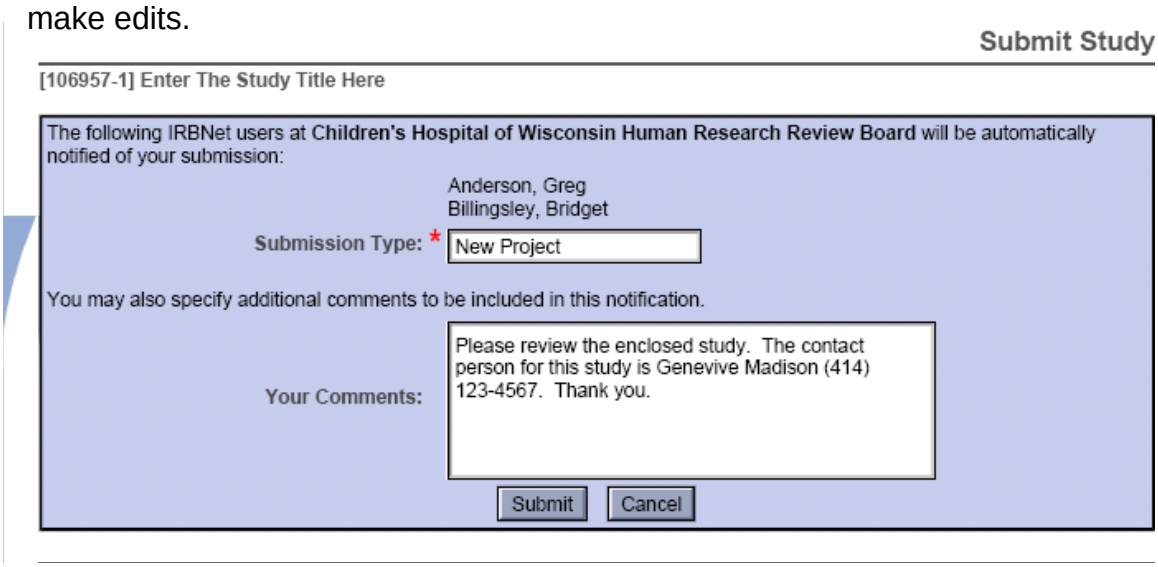


TIP

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.



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	APROVED Demo Study HIPAA Form	01/27/2009 11:50 AM	

ADDITIONAL ASSISTANCE

Local IRBnet Support

If you have local access problems 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.

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, please contact their support services:

IRBNet **Technical Support Desk**

877.261.6461
support@irbnet.org