

**MARSHALL UNIVERSITY**



OFFICE OF  
RESEARCH INTEGRITY

**IRBNet User Manual**

## **User Manual**

This user manual is designed to assist in the use of IRBNet. You will find assistance in registration, submission, continuing review, amendments, adverse event reporting and closure. If you have any problems or questions please feel free to contact the Office of Research Integrity for assistance.

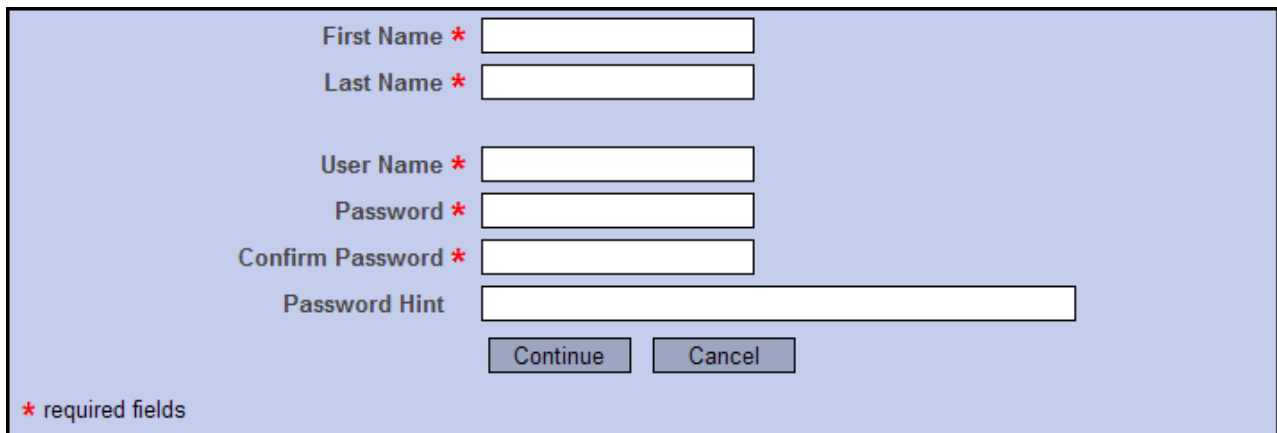
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## 1. Registration Instructions

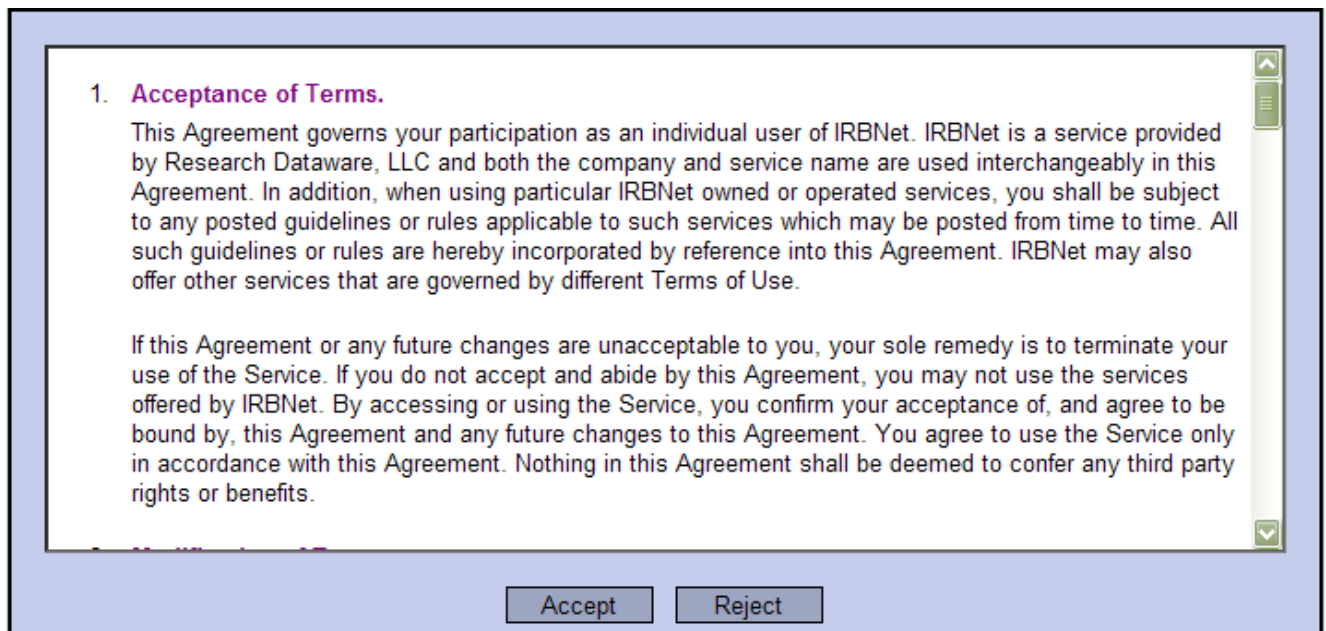
1. Go to <http://www.irbnet.org>
2. In the upper right hand corner, right below the login boxes, click the New User Registration button.



3. Fill in your name, choose a user name and choose a password.



4. Accept the Terms of Use



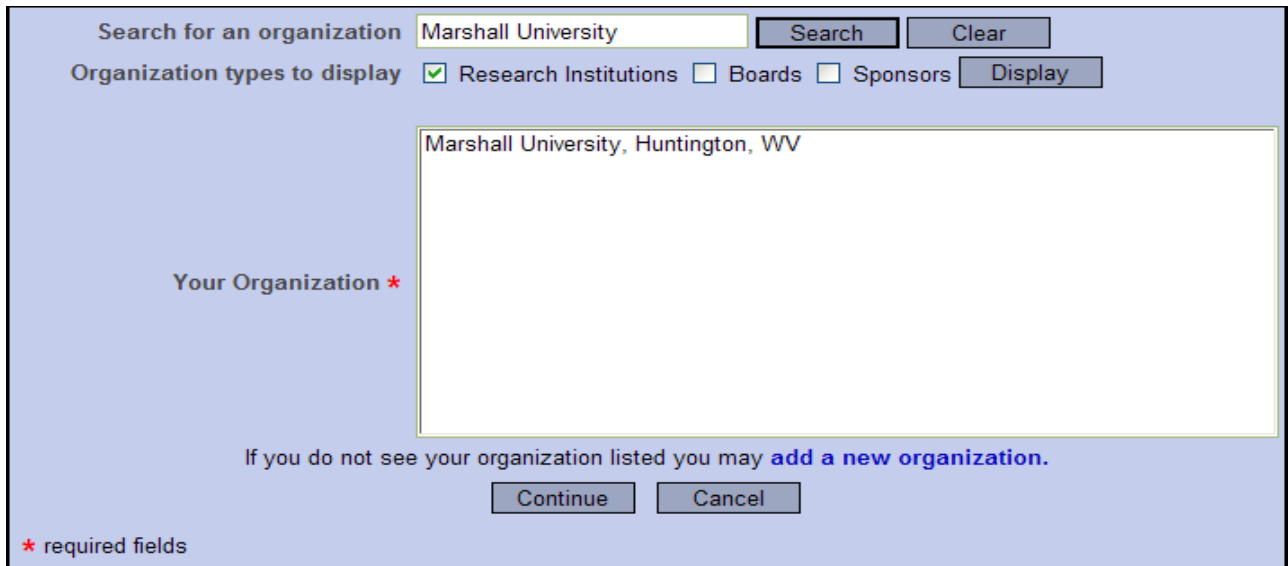
**1. Acceptance of Terms.**

This Agreement governs your participation as an individual user of IRBNet. IRBNet is a service provided by Research Dataware, LLC and both the company and service name are used interchangeably in this Agreement. In addition, when using particular IRBNet owned or operated services, you shall be subject to any posted guidelines or rules applicable to such services which may be posted from time to time. All such guidelines or rules are hereby incorporated by reference into this Agreement. IRBNet may also offer other services that are governed by different Terms of Use.

If this Agreement or any future changes are unacceptable to you, your sole remedy is to terminate your use of the Service. If you do not accept and abide by this Agreement, you may not use the services offered by IRBNet. By accessing or using the Service, you confirm your acceptance of, and agree to be bound by, this Agreement and any future changes to this Agreement. You agree to use the Service only in accordance with this Agreement. Nothing in this Agreement shall be deemed to confer any third party rights or benefits.

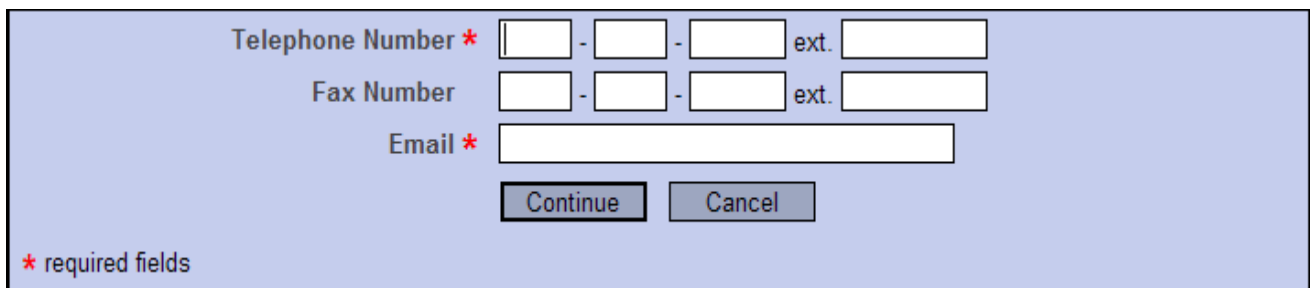
Accept Reject

- Next, add an affiliation. In the *Search for and organization* box, type Marshall University and click “Search”. Highlight Marshall University (in the lower box) and click “Continue”.



The screenshot shows a web form with a light blue background. At the top, there is a text input field containing "Marshall University" and two buttons: "Search" and "Clear". Below this is a section titled "Organization types to display" with three checkboxes: "Research Institutions" (checked), "Boards" (unchecked), and "Sponsors" (unchecked), followed by a "Display" button. A large white text area below contains the text "Marshall University, Huntington, WV". To the left of this area is the label "Your Organization \*". At the bottom of the form, there is a message: "If you do not see your organization listed you may [add a new organization.](#)" and two buttons: "Continue" and "Cancel". In the bottom left corner, there is a red asterisk followed by the text "\* required fields".

- Enter your telephone number and a working email address. The email you use here will be the one used by the IRB board to communicate with you for approval and questions. Your email address will not be used for marketing purposes.



The screenshot shows a web form with a light blue background. It contains three rows of input fields. The first row is labeled "Telephone Number \*" and has four input boxes: three for the area code, number, and exchange, and one for the extension, with "ext." text between the last two. The second row is labeled "Fax Number" and has the same four input boxes. The third row is labeled "Email \*" and has a single wide text input box. Below the input fields are two buttons: "Continue" and "Cancel". In the bottom left corner, there is a red asterisk followed by the text "\* required fields".

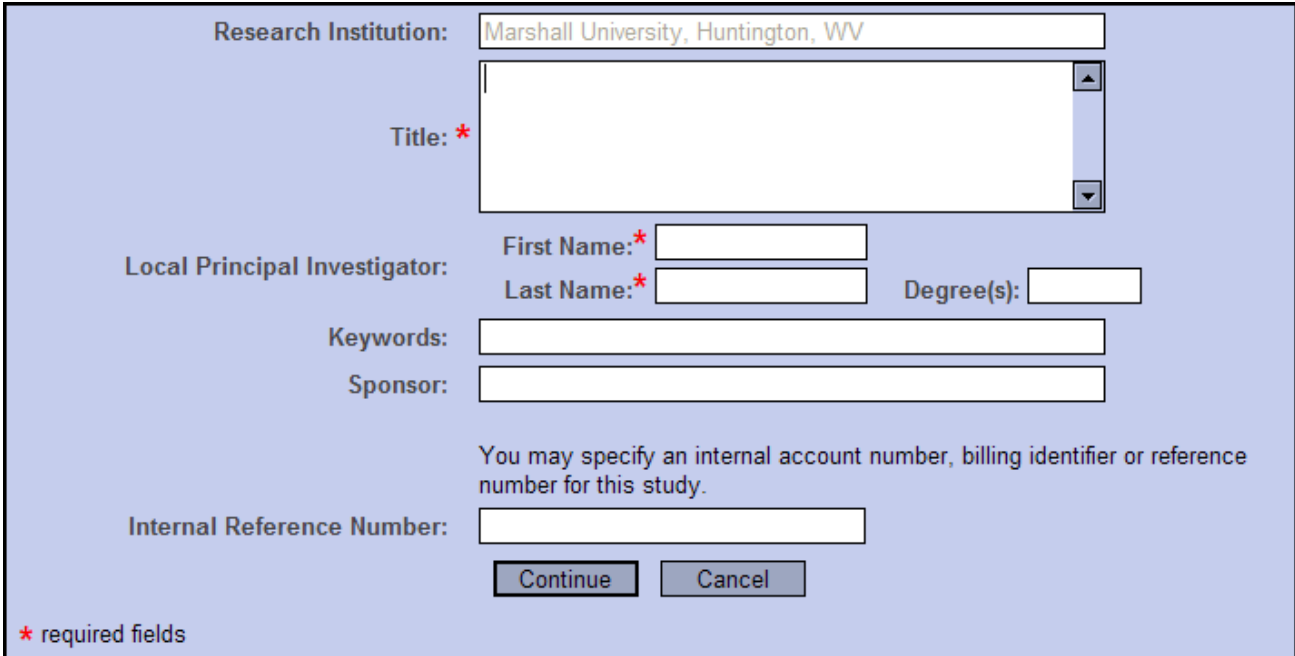
- The last screen will confirm the information you have entered. Make sure that in the second box, it lists *Researcher* at Marshall University. Click the Register button.
- Once you have clicked the Register button, an email will be sent to you. If you do not receive that confirmation email in a short period then check your spam folder to see if it is there. If the notification is in your spam folder then mark it as “Not Spam” and click “Deliver”. That email contains a link which will confirm your registration. Once you click that link, you will be taken back to the home page of IRBNet. At this point you should be able to login and begin creating a new study.

## 2. Submission Instructions

To submit a study for review, you must first Create a New Project (Study) to hold your documents. Any type of document can be uploaded, but two things are required before any action can be taken on behalf of the board. Your study MUST include all the required forms for a complete package. A list of the required forms for a package can be found in the library (Submission Checklist) under the “Designer” tab on IRBNet. All forms can be accessed through our website or the IRBNet library.

### To create your first package:

1. Go to [www.irbnet.org](http://www.irbnet.org) and login using the user name and password you created previously.
2. On the navigation bar to your left, click the button titled “Create New Project”.
3. Pick a title for your study. Enter the first and last name of the Principal Investigator. If you are a student then you would enter your professor’s name here. (*see picture below*)
4. The keywords box is for your reference only and will assist you later if you need to search through your studies to find one pertaining to a specific topic (or student). (*see picture below*)
5. If this IRB study is sponsored then enter the name of the funding agency in the “Sponsor” box.



Research Institution:

Title: \*

Local Principal Investigator: First Name: \*  Last Name: \*  Degree(s):

Keywords:

Sponsor:

Internal Reference Number:

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

\* required fields

6. Click the “Continue” button.

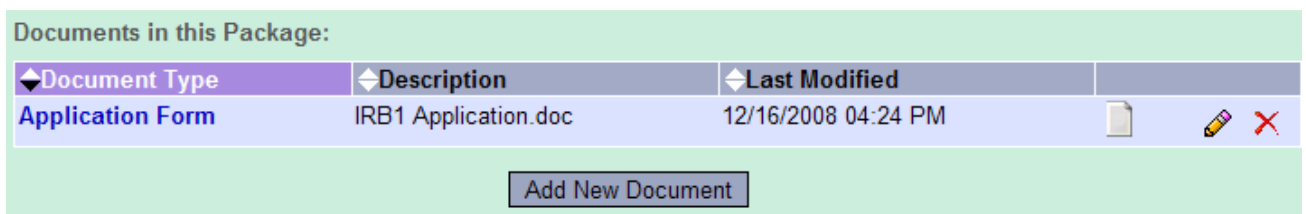
7. You will be brought to a screen called the *Study Designer*. This is where you can access the library of forms. Just click on the first dropdown list and select your IRB (#1 or #2). Then click on the document dropdown list. You can download any document to your hard drive so that you can edit it and then attach it to the study. At this point, there will also be a message stating there are no documents attached to this study. Click the button “Add New Document” to attach all the documents that you downloaded and edited.
8. In the “Document Type” box, pick the best match for the document you are uploading. If it is the application, choose the “Application” choice. If the type of document you are submitting is not in the list then choose “Other” and enter the type of document in the Description field. Click the “Browse” button and find the document on your hard drive. Once you find the document, click the “Attach” button to upload the document.






The screenshot shows a form with the following fields and buttons:

- Document Type \***: A dropdown menu with "Other" selected.
- Description**: A text input field.
- File \***: A text input field with a "Browse..." button to its right.
- Buttons**: "Attach" and "Cancel" buttons.
- Legend**: A red asterisk followed by the text "\* required fields".

9. Once you have attached a document to your study package, the Study Designer page will now list your documents.



Documents in this Package:			
Document Type	Description	Last Modified	
Application Form	IRB1 Application.doc	12/16/2008 04:24 PM	  

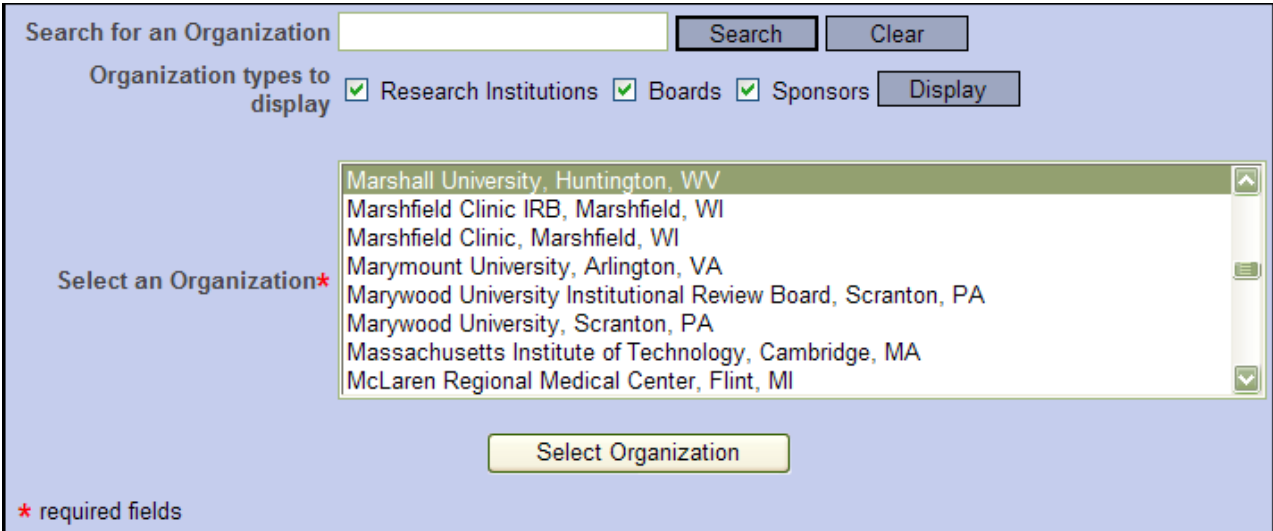
**Add New Document**

10. Repeat the steps to upload until all documents have been uploaded to your package.

11. Now it is time to share the study. On the left side navigation bar, click the “Share this Project” button. On the Share Study screen, choose “Share”.

- **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.

12. The next page will default to Marshall University, so if it is highlighted just click on “Select Organization”. If Marshall University does not appear in the selection box then search for Marshall University and then select it.



Search for an Organization

Organization types to display  Research Institutions  Boards  Sponsors

Select an Organization\*

- Marshall University, Huntington, WV
- Marshfield Clinic IRB, Marshfield, WI
- Marshfield Clinic, Marshfield, WI
- Marymount University, Arlington, VA
- Marywood University Institutional Review Board, Scranton, PA
- Marywood University, Scranton, PA
- Massachusetts Institute of Technology, Cambridge, MA
- McLaren Regional Medical Center, Flint, MI

\* required fields

13. You will be brought to a screen showing all MU faculty, staff and students who are registered with IRBNet. Use the search tool and type in the last name of the person you want to share your study with. Grant them the access you desire keeping in mind what access they will need.

### Permissions

#### **Full:**

The individual is a project owner and may manage and control all aspects of the project.

#### **Write:**

The individual may collaborate on project documentation, but may not share the project with others, submit packages for review, or take certain other actions reserved solely for the project owners.

#### **Read:**

The individual has read-only access to the project. This individual may electronically sign where necessary.

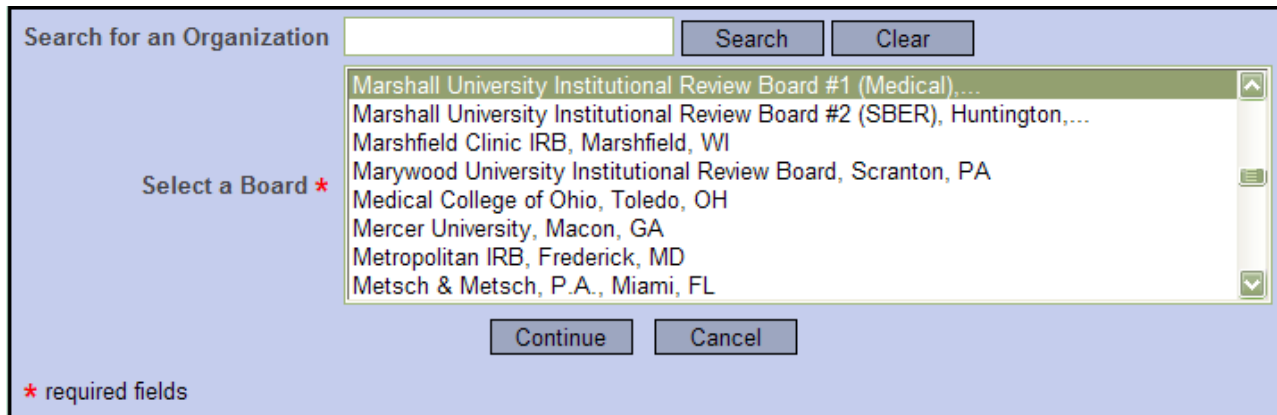
14. When all documents are uploaded and you have shared your study then you need to sign your study electronically. To do this, click the “Sign this Package” button on the left side navigation bar. In the drop down box, select your status on this study. **NOTE:** If you are a student doing research, your professor will need to sign as the Principal Investigator and you will sign as the Co-Investigator.

I Marshall Researcher, the  assert that I have read this study's 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, enter **designee signer mode**.

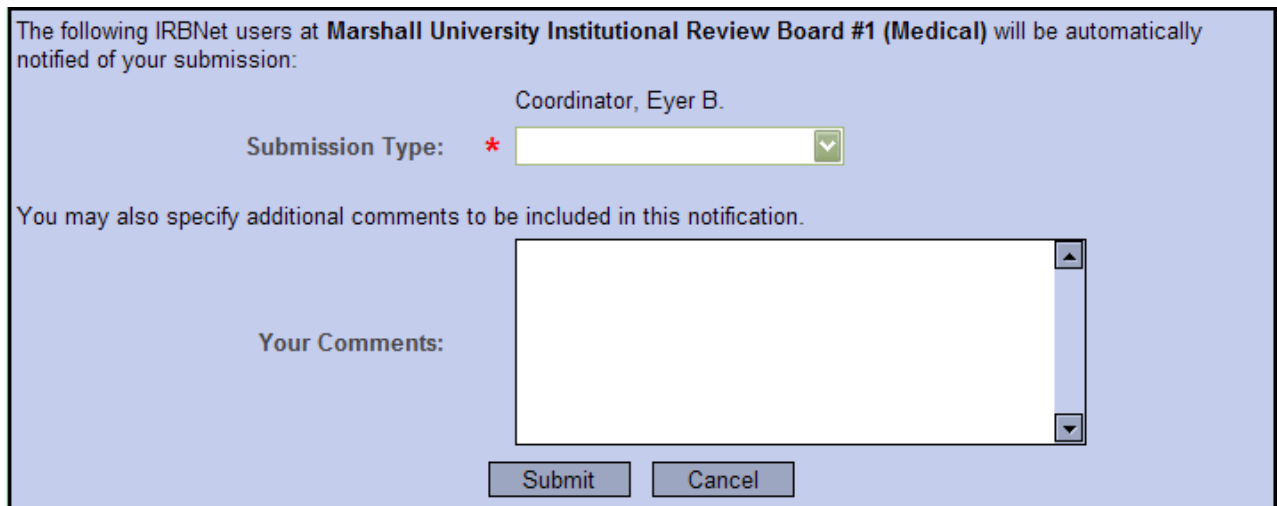
15. (**Note:** If you are a student then you would stop at this point, because your professor will submit the study when he/she is sure it is complete.)

16. Once you (and your professor, if applicable) have signed, click the “Submit this Package” button on the navigation bar. Both MU IRBs will appear on the list so highlight the IRB to which you will be submitting. Click “Continue”.



The screenshot shows a web form with a search bar at the top labeled "Search for an Organization" containing a text input field, a "Search" button, and a "Clear" button. Below the search bar is a dropdown menu titled "Select a Board \*". The dropdown is open, showing a list of IRB options: "Marshall University Institutional Review Board #1 (Medical),...", "Marshall University Institutional Review Board #2 (SBER), Huntington,...", "Marshfield Clinic IRB, Marshfield, WI", "Marywood University Institutional Review Board, Scranton, PA", "Medical College of Ohio, Toledo, OH", "Mercer University, Macon, GA", "Metropolitan IRB, Frederick, MD", and "Metsch & Metsch, P.A., Miami, FL". The first option is highlighted. Below the dropdown are "Continue" and "Cancel" buttons. A red asterisk and the text "\* required fields" are located at the bottom left of the form area.

17. On the final screen, in the Submission Type drop-down menu, choose the appropriate type (initially it will be New Study). You can leave comments in the Comment box, but they are not required. Finally, click the Submit button.

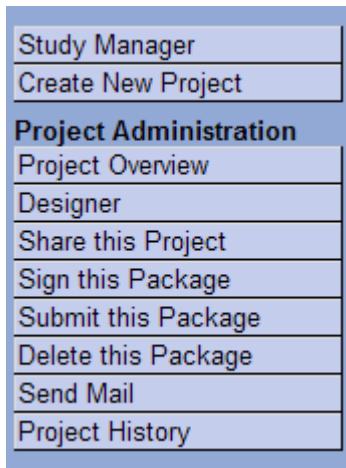


The screenshot shows a confirmation screen with the heading "The following IRBNet users at **Marshall University Institutional Review Board #1 (Medical)** will be automatically notified of your submission:". Below this heading, the text "Coordinator, Eyer B." is displayed. A "Submission Type:" label is followed by a red asterisk and a dropdown menu. Below this is a text area labeled "Your Comments:" with the instruction "You may also specify additional comments to be included in this notification." At the bottom of the form are "Submit" and "Cancel" buttons.

18. Once you hit the Submit button, you will be given a confirmation showing the time it was submitted. Keep in mind that this study is now locked. You will be contacted if corrections are needed. If nothing additional is required then everyone with full access will be notified via email once the study has been approved.

### 3. Revision Instructions (When IRB Chair/Board deems “Modifications Required”)

If you have submitted a package and the IRB Chair/Board has deemed that “Modifications are Required” then you need to submit a revision. Once you have the study open just click on the “Project History” button on the left side navigation bar.



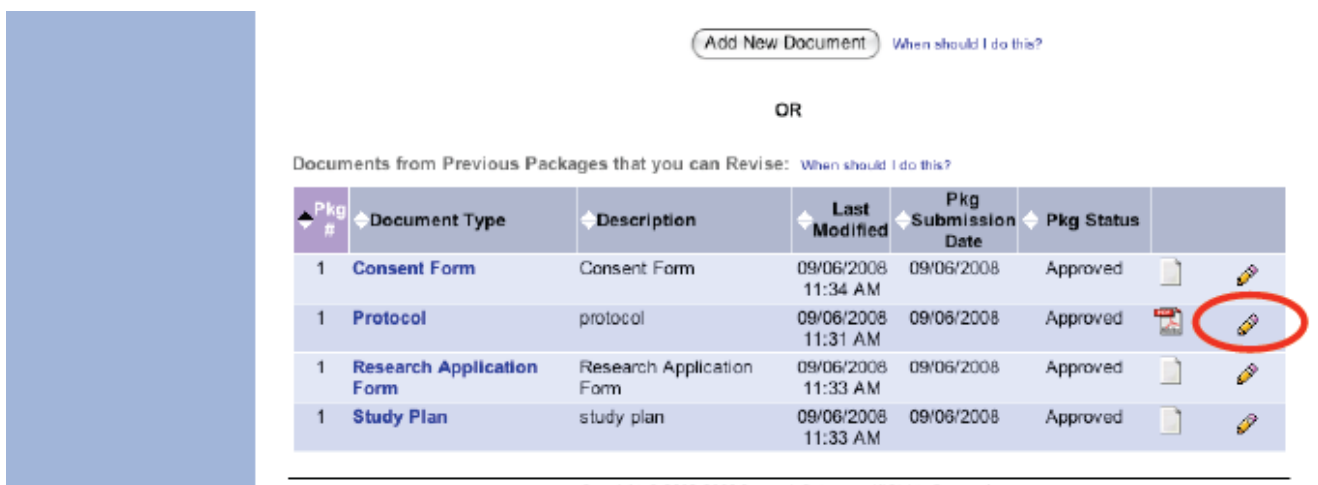
1. You will be brought to a screen called the *Project History*. Click on the “Create New Package” button half way down the page.

◆	Pkg #	Package Type	◆	Status	◆	Create Date	◆	Submission Date	◆	Review Date
▶	1	New Project	◆	Approved	◆	01/21/2009	◆	01/21/2009	◆	04/21/2009
One Package found.										
▶ You are currently viewing this package.										
Your current document package has already been submitted and is presently locked by your Board. You may prepare new or modified documents (such as Revision/Amendment materials, Renewal/Continuing Review materials, and Adverse Event Reports) by creating a new document package.										
<a href="#">Create New Package</a>										

2. A “New Document Package” will appear as a “Work in Progress”. Click on this title and you will be brought to the *Designer* screen where you can add your documents for this package.

◆	Pkg #	Package Type	◆	Status	◆	Create Date	◆	Submission Date	◆	Review Date
▶	2	New Document Package	◆	Work in progress	◆	04/22/2009	◆		◆	
	1	New Project	◆	Approved	◆	01/21/2009	◆	01/21/2009	◆	04/21/2009
2 Packages found, displaying all Packages.										
▶ You are currently viewing this package.										

3. A “New Document Package” will appear as a “Work in Progress”. Click on this title and you will be brought to the *Designer* screen where you can add your documents for this package.
4. From the list of Documents from Previous Packages at the bottom of the page, download the document to be revised by clicking on the Document Type or on the paper icon.
5. Make any necessary changes to the downloaded document, and save the revised document to your computer.
6. Click on the pencil icon for that document in the Designer.



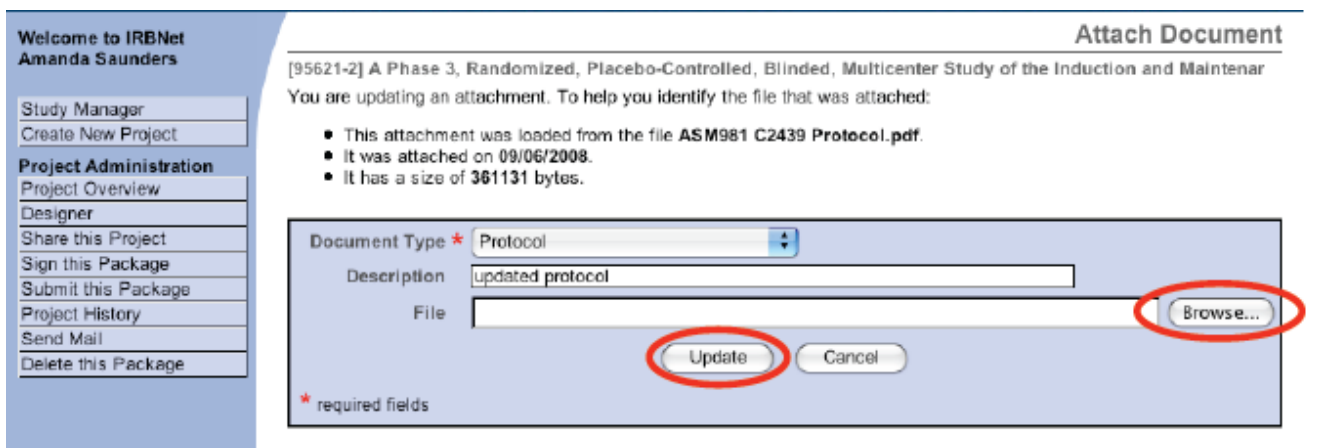
Add New Document When should I do this?

OR

Documents from Previous Packages that you can Revise: When should I do this?

▲ Pkg #	◆ Document Type	◆ Description	◆ Last Modified	◆ Pkg Submission Date	◆ Pkg Status		
1	Consent Form	Consent Form	09/06/2008 11:34 AM	09/06/2008	Approved		
1	Protocol	protocol	09/06/2008 11:31 AM	09/06/2008	Approved		
1	Research Application Form	Research Application Form	09/06/2008 11:33 AM	09/06/2008	Approved		
1	Study Plan	study plan	09/06/2008 11:33 AM	09/06/2008	Approved		

7. Browse your computer and select your revised version of the document to upload, make changes to Document Type and Description as appropriate, and click the Update button.



**Attach Document**

[95621-2] A Phase 3, Randomized, Placebo-Controlled, Blinded, Multicenter Study of the Induction and Maintenance of Remission in Patients with Crohn's Disease

You are updating an attachment. To help you identify the file that was attached:

- This attachment was loaded from the file **ASM981 C2439 Protocol.pdf**.
- It was attached on **09/06/2008**.
- It has a size of **361131** bytes.

Document Type \*

Description

File  Browse...

Update

\* required fields

8. An icon will now show that there are multiple documents to be viewed. This will allow a reviewer to see the original document and the revised document in one place.

9. If you need to add a new document then click on the “Add New Document” button.

**Step 2:**  
Assemble your document package.

New and Revised 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?](#)

10. In the Document Type box, pick the best match for the document you are uploading. If the type of document you are submitting is not in the list then choose “Other” and enter the type of document in the Description field. Click the “Browse” button and find the document on your computer. Once you find the document, click the “Attach” button to upload the document.

Document Type \*

Description

File \*

\* required fields

11. Be sure to sign the package and when you submit, choose “Revision” as the submission type.

The following IRBNet users at **Marshall University Institutional Review Board #2 (SBER)** will be automatically notified of your submission:

Coordinator, Eyer B.

Submission Type: \*

You may also specify additional comments to be

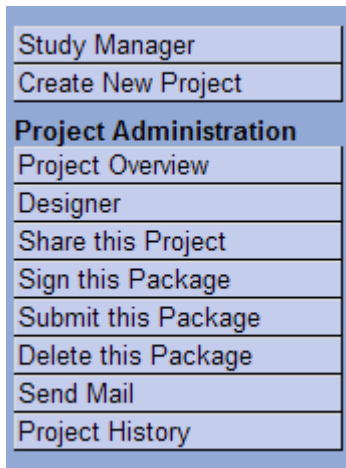
Your Comments:

- Adverse Event
- Close/Final Report
- Continuing Review/Renewal
- Modification/Amendment
- New Project
- Other
- Publication
- Reportable Event (Non-AE)
- Response Follow-Up
- Revision

#### 4. Continuing Review Instructions

##### To submit a continuing review package:

To submit a study for continuing review, you must first open the study. Keep in mind that you **do not** want to create a new project. You want to add a package to an already existing study. Once you have the study open just click on the “Project History” button on the left side navigation bar.



1. You will be brought to a screen called the *Project History*. Click on the “Create New Package” button half way down the page.

◆	Pkg #	Package Type	◆	Status	◆	Create Date	◆	Submission Date	◆	Review Date
▶	1	New Project		Approved		01/21/2009		01/21/2009		04/21/2009
One Package found.										
▶ You are currently viewing this package.										
Your current document package has already been submitted and is presently locked by your Board. You may prepare new or modified documents (such as Revision/Amendment materials, Renewal/Continuing Review materials, and Adverse Event Reports) by creating a new document package.										
<a href="#">Create New Package</a>										

- A “New Document Package” will appear as a “Work in Progress”. Click on this title and you will be brought to the *Designer* screen where you can add your documents for this package.

◆ Pkg #	Package Type	◆ Status	◆ Create Date	◆ Submission Date	◆ Review Date
▶ 2	New Document Package	Work in progress	04/22/2009		
1	New Project	Approved	01/21/2009	01/21/2009	04/21/2009
2 Packages found, displaying all Packages.					
▶ You are currently viewing this package.					

- This is also where you can access the library of forms. The first form in the library is the Submission Checklist and it lists the documents required for a continuing review. Click on the button “Add New Document” to attach all the documents required for the continuing review.

**Step 2:**

Assemble your document package.

New and Revised 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 the Document Type box, pick the best match for the document you are uploading. If it is the application, choose the “Application” choice. If the type of document you are submitting is not in the list then choose “Other” and enter the type of document in the Description filed. Click the “Browse” button and find the document on your hard drive. Once you find the document, click the “Attach” button to upload the document.

Document Type \*  ▼

Description

File \*

\* required fields

- Repeat the steps to upload until all documents have been uploaded to your package.
- When all required continuing review documents are uploaded you need to sign your package electronically. To do this, click the “Sign this Package” button on the left side navigation bar. In the drop down box, select your status on this study. **NOTE:** If you are a student doing research, your professor will need to sign as the Principal Investigator and you will sign as the Co-Investigator.

I Marshall Researcher, the  assert that I have read this study's 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, enter **designee signer mode**.

- Once you (and your professor, if applicable) have signed, click the “Submit this Package” button on the navigation bar. Both MU IRBs will appear on the list so just highlight the IRB to which you will be submitting. Click “Continue”.

Search for an Organization

Select a Board \*

Marshall University Institutional Review Board #1 (Medical),...  
 Marshall University Institutional Review Board #2 (SBER), Huntington,...  
 Marshfield Clinic IRB, Marshfield, WI  
 Marywood University Institutional Review Board, Scranton, PA  
 Medical College of Ohio, Toledo, OH  
 Mercer University, Macon, GA  
 Metropolitan IRB, Frederick, MD  
 Metsch & Metsch, P.A., Miami, FL

\* required fields

- On the final screen, in the “Submission Type” drop-down menu, choose “Continuing Review/Renewal”. You can leave comments in the Comment box, but they are not required. Finally, click the Submit button.

The following IRBNet users at **Marshall University Institutional Review Board #1 (Medical)** will be automatically notified of your submission:

Coordinator, Eyer B.

Submission Type: \*

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

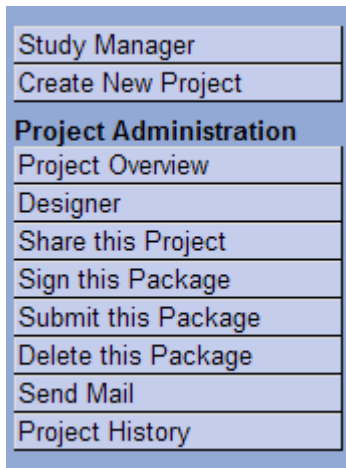
Your Comments:

9. Once you hit the Submit button, you will be given a confirmation showing the time it was submitted. Keep in mind that this study is now locked. You will be contacted if corrections are needed. If nothing additional is required then everyone with full access will be notified via email once the study has been approved.

## 5. Modification/Amendment Instructions

### To submit a Modification/Amendment package:

To submit a Modification/Amendment review, you must first open the study. Keep in mind that you **do not** want to create a new project. You want to add a package to an already existing study. Once you have the study open just click on the “Project History” button on the left side navigation bar.



1. You will be brought to the *Project History* screen. Click on the “Create New Package” button half way down the page.

	◆ Pkg #	Package Type	◆ Status	◆ Create Date	◆ Submission Date	◆ Review Date
▶	1	New Project	Approved	01/21/2009	01/21/2009	04/21/2009
One Package found.						
▶ You are currently viewing this package.						
<p>Your current document package has already been submitted and is presently locked by your Board. You may prepare new or modified documents (such as Revision/Amendment materials, Renewal/Continuing Review materials, and Adverse Event Reports) by creating a new document package.</p>						
<input type="button" value="Create New Package"/>						

- A “New Document Package” will appear as a “Work in Progress”. Click on this title and you will be brought to the *Designer* screen where you can add your documents for this package.

◆ Pkg #	Package Type	◆ Status	◆ Create Date	◆ Submission Date	◆ Review Date
▶ 2	New Document Package	Work in progress	04/22/2009		
1	New Project	Approved	01/21/2009	01/21/2009	04/21/2009
2 Packages found, displaying all Packages.					
▶ You are currently viewing this package.					

- You will be taken to the *Designer* screen where you can add your documents for the Modification/Amendment. Click “Add New Document”.

**Step 2:**  
Assemble your document package.

**New and Revised 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 the Document Type box, pick the best match for the document you are uploading. If it is the application, choose the “Application” choice. If the type of document you are submitting is not in the list then choose “Other” and enter the type of document in the Description filed. Click the “Browse” button and find the document on your hard drive. Once you find the document, click the “Attach” button to upload the document. (Include a memo stating the reason and description of the Amendment/Modification)

Document Type \*

Description

File \*

\* required fields

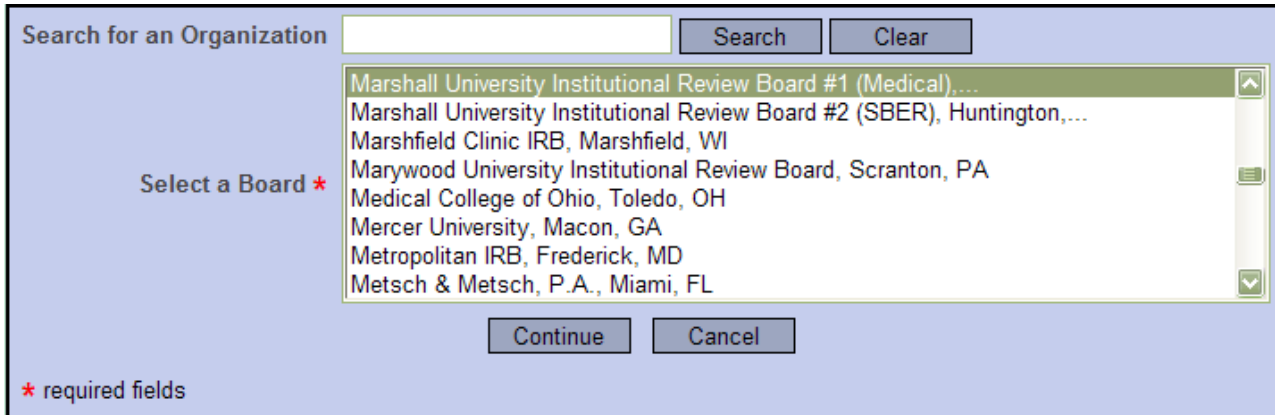
- Repeat the steps to upload until all documents have been uploaded to your package.

- When all required Modification/Amendment documents are uploaded you need to sign your package electronically. To do this, click the “Sign this Package” button on the left side navigation bar. In the drop down box, select your status on this study. **NOTE:** If you are a student doing research, your professor will need to sign as the Principal Investigator and you will sign as the Co-Investigator.

I Marshall Researcher, the  assert that I have read this study's 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, enter **designee signer mode**.

- Once you (and your professor, if applicable) have signed, click the “Submit this Package” button on the navigation bar. Both MU IRBs will appear on the list so just highlight the IRB to which you will be submitting. Click “Continue”.



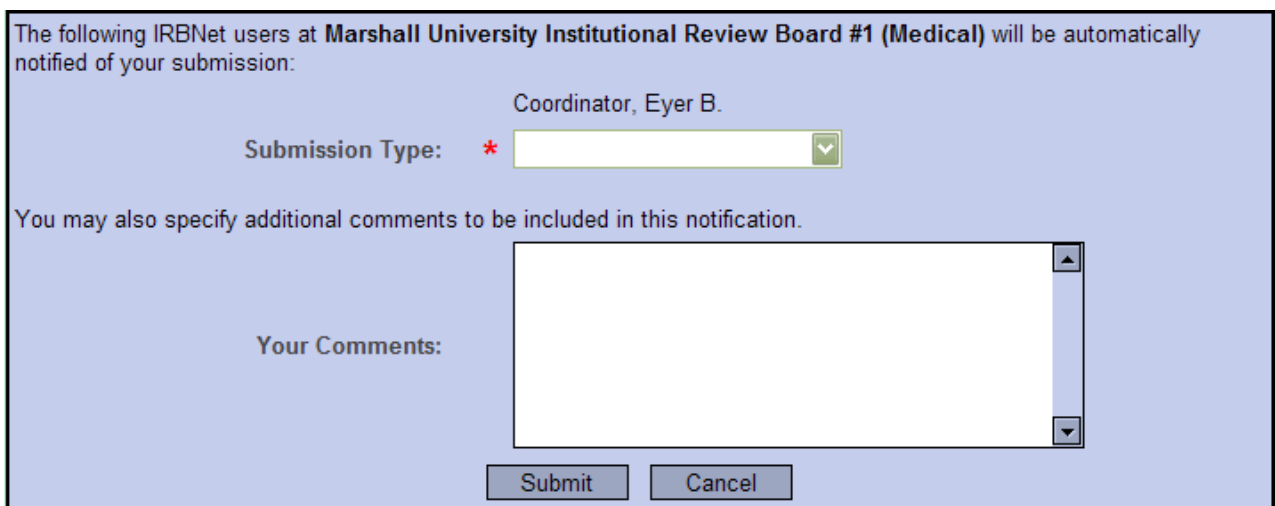
Search for an Organization

Select a Board \*

- Marshall University Institutional Review Board #1 (Medical),...
- Marshall University Institutional Review Board #2 (SBER), Huntington,...
- Marshfield Clinic IRB, Marshfield, WI
- Marywood University Institutional Review Board, Scranton, PA
- Medical College of Ohio, Toledo, OH
- Mercer University, Macon, GA
- Metropolitan IRB, Frederick, MD
- Metsch & Metsch, P.A., Miami, FL

\* required fields

- On the final screen, in the “Submission Type” drop-down menu, choose “Modification/Amendment”. You can leave comments in the Comment box, but they are not required. Finally, click the Submit button.



The following IRBNet users at **Marshall University Institutional Review Board #1 (Medical)** will be automatically notified of your submission:

Coordinator, Eyer B.

Submission Type: \*

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

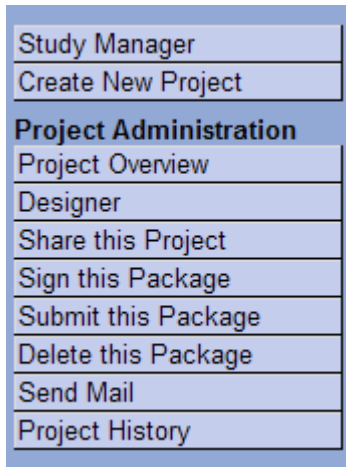
Your Comments:

9. Once you hit the Submit button, you will be given a confirmation showing the time it was submitted. Keep in mind that this study is now locked. You will be contacted if corrections are needed. If nothing additional is required then everyone with full access will be notified via email once the study has been approved.

## 6. Adverse Event Reporting Instructions

### To submit an AE/SAE package:

To submit an AE/SAE for review, you must first open the study. Keep in mind that you **do not** want to create a new project. You want to add a package to an already existing study. Once you have the study open just click on the “Project History” button on the left side navigation bar.



1. You will be brought to the *Project History* screen. Click on the “Create New Package” button half way down the page.

◆	Pkg #	Package Type	◆	Status	◆	Create Date	◆	Submission Date	◆	Review Date
▶	1	New Project		Approved		01/21/2009		01/21/2009		04/21/2009
One Package found.										
▶ You are currently viewing this package.										
<p>Your current document package has already been submitted and is presently locked by your Board. You may prepare new or modified documents (such as Revision/Amendment materials, Renewal/Continuing Review materials, and Adverse Event Reports) by creating a new document package.</p>										
<input type="button" value="Create New Package"/>										

- A “New Document Package” will appear as a “Work in Progress”. Click on this title and you will be brought to the *Designer* screen where you can add your documents for this package.

◆ Pkg #	Package Type	◆ Status	◆ Create Date	◆ Submission Date	◆ Review Date
▶ 2	New Document Package	Work in progress	04/22/2009		
1	New Project	Approved	01/21/2009	01/21/2009	04/21/2009
2 Packages found, displaying all Packages.					
▶ You are currently viewing this package.					

- You will then be taken to the *Designer* screen where you can add your documents for the AE/SAE. Click “Add New Document”.

**Step 2:**  
Assemble your document package.

New and Revised 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 the Document Type box, pick “Adverse Event Report”. Multiple AE/SAE reports can be submitted in a package. If the IRB Chair feels one of the AE/SAEs needs to be submitted separately you will be notified so it can be removed from the group and submitted individually. If there are other documents you also need to attach then choose the appropriate document type in the drop down box. If the type of document you are submitting is not in the list then choose “Other” and enter the type of document in the Description field. Click the “Browse” button and find the document on your hard drive. Once you find the document, click the “Attach” button to upload the document.

Document Type \*  ▼

Description

File \*

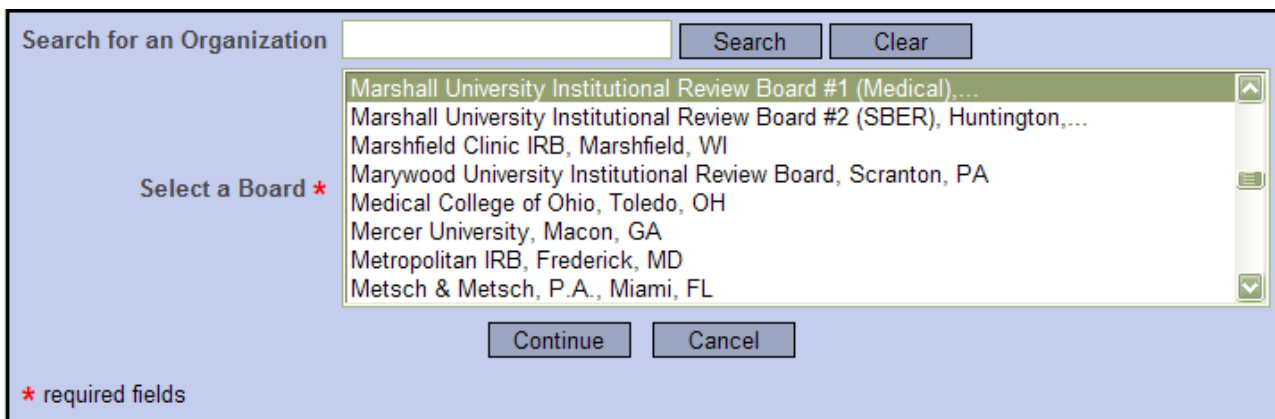
\* required fields

- Repeat the steps to upload until all documents have been uploaded to your package.
- When all required AE/SAE documents are uploaded you need to sign your package electronically. To do this, click the “Sign this Package” button on the left side navigation bar. In the drop down box, select your status on this study. **NOTE:** If you are a student doing research, your professor will need to sign as the Principal Investigator and you will sign as the Co-Investigator.

I Marshall Researcher, the  assert that I have read this study's 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, enter **designee signer mode**.

- Once you (and your professor, if applicable) have signed, click the “Submit this Package” button on the navigation bar. Both MU IRBs will appear on the list so just highlight the IRB to which you will be submitting. Click “Continue”.



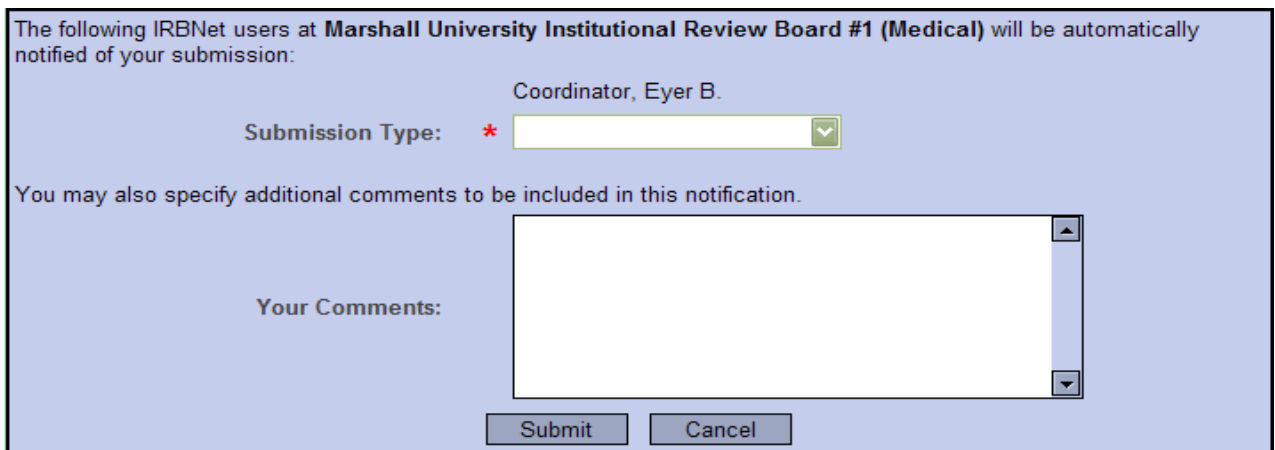
Search for an Organization

Select a Board \*

- Marshall University Institutional Review Board #1 (Medical),...
- Marshall University Institutional Review Board #2 (SBER), Huntington,...
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- Marywood University Institutional Review Board, Scranton, PA
- Medical College of Ohio, Toledo, OH
- Mercer University, Macon, GA
- Metropolitan IRB, Frederick, MD
- Metsch & Metsch, P.A., Miami, FL

\* required fields

- On the final screen, in the “Submission Type” drop-down menu, choose “Adverse Event”. You can leave comments in the Comment box, but they are not required. Finally, click the Submit button.



The following IRBNet users at **Marshall University Institutional Review Board #1 (Medical)** will be automatically notified of your submission:

Coordinator, Eyer B.

Submission Type: \*

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

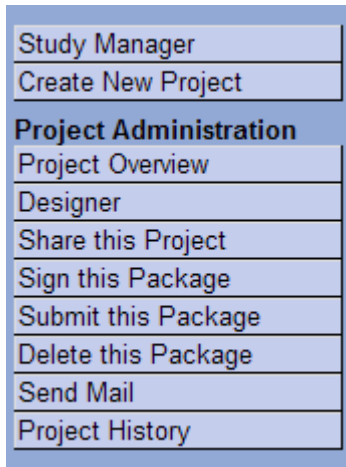
Your Comments:

9. Once you hit the Submit button, you will be given a confirmation showing the time it was submitted. Keep in mind that this study is now locked. You will be contacted if corrections are needed. If nothing additional is required then everyone with full access will be notified via email once the study has been approved.

## 7. Closure Instructions

### To submit a closure package:

To submit a closure, you must first open the study. Keep in mind that you **do not** want to create a new project. You want to add a package to an already existing study. Once you have the study open just click on the “Project History” button on the left side navigation bar.



1. You will be brought to the *Project History* screen. Click on the “Create New Package” button half way down the page.

◆	Pkg #	Package Type	◆	Status	◆	Create Date	◆	Submission Date	◆	Review Date
▶	1	New Project		Approved		01/21/2009		01/21/2009		04/21/2009
One Package found.										
▶ You are currently viewing this package.										
<p>Your current document package has already been submitted and is presently locked by your Board. You may prepare new or modified documents (such as Revision/Amendment materials, Renewal/Continuing Review materials, and Adverse Event Reports) by creating a new document package.</p>										
<input type="button" value="Create New Package"/>										

- A “New Document Package” will appear as a “Work in Progress”. Click on this title and you will be brought to the *Designer* screen where you can add your documents for this package.

◆ Pkg #	Package Type	◆ Status	◆ Create Date	◆ Submission Date	◆ Review Date
▶ 2	New Document Package	Work in progress	04/22/2009		
1	New Project	Approved	01/21/2009	01/21/2009	04/21/2009
2 Packages found, displaying all Packages.					
▶ You are currently viewing this package.					

- You will then be taken to the *Designer* screen where you can add the closure request form (available on the website) and a summary of the study. Click “Add New Document”.

**Step 2:**  
Assemble your document package.

New and Revised 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?](#)

- You should attach a memo stating your desire to close the study. In the “Document Type” box, pick “Other” and type “Closure Memo” in the description box. If there are other documents you also need to attach then choose the appropriate document type in the drop down box. If the type of document you are submitting is not in the list then choose “Other” and enter the type of document in the Description field. Click the “Browse” button and find the document on your hard drive. Once you find the document (or memo), click the “Attach” button to upload the document.

Document Type \*

Description

File \*

\* required fields

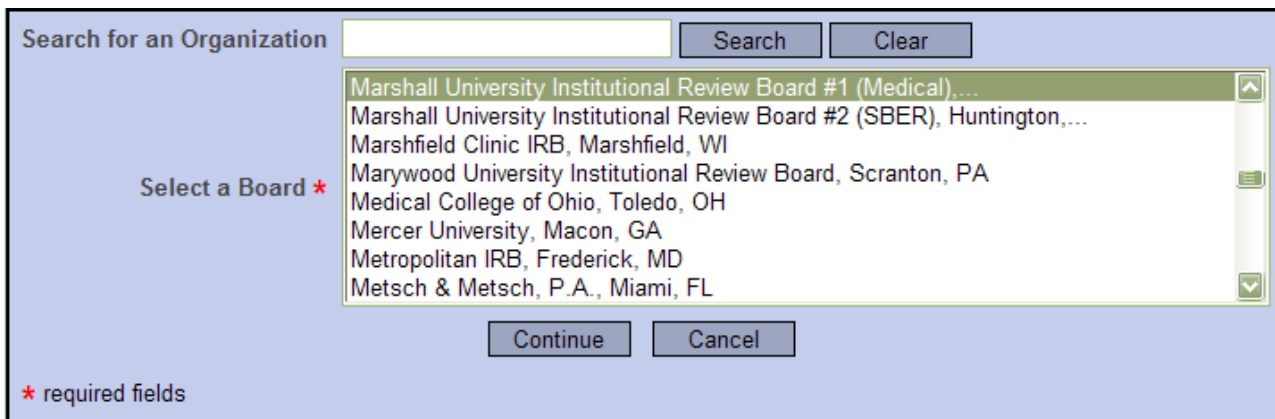
- Repeat the steps to upload until all documents have been uploaded to your package.

- When all required documents are uploaded you need to sign your package electronically. To do this, click the “Sign this Package” button on the left side navigation bar. In the drop down box, select your status on this study. **NOTE:** If you are a student doing research, your professor will need to sign as the Principal Investigator and you will sign as the Co-Investigator.

I Marshall Researcher, the  assert that I have read this study's 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, enter **designee signer mode**.

- Once you (and your professor, if applicable) have signed, click the “Submit this Package” button on the navigation bar. Both MU IRBs will appear on the list so just highlight the IRB to which you will be submitting. Click “Continue”.



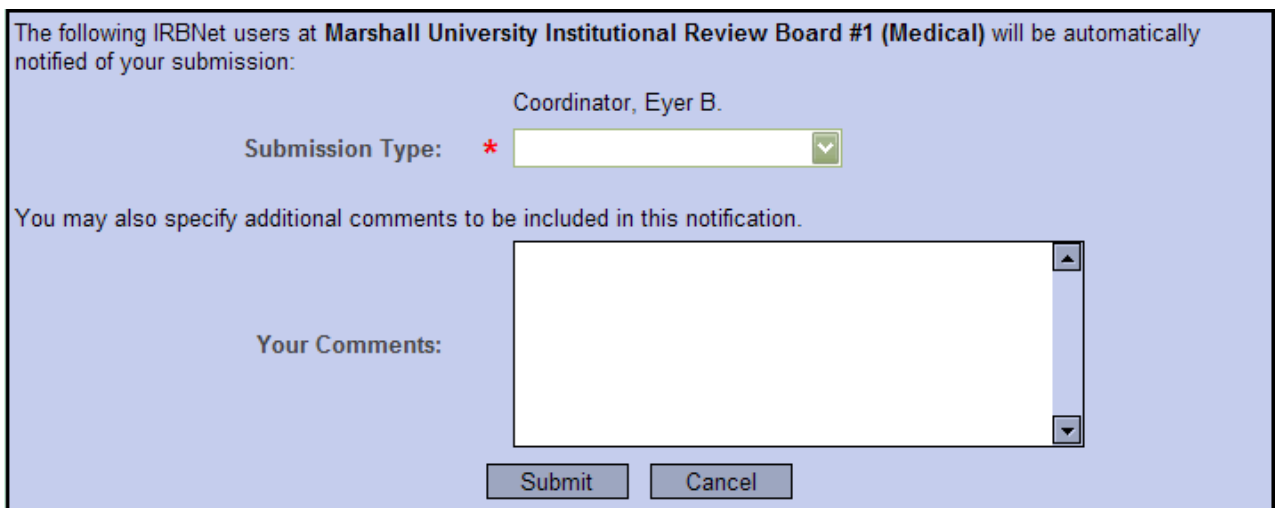
Search for an Organization

Select a Board \*

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- Mercer University, Macon, GA
- Metropolitan IRB, Frederick, MD
- Metsch & Metsch, P.A., Miami, FL

\* required fields

- On the final screen, in the “Submission Type” drop-down menu, choose “Close/Final Report”. You can leave comments in the Comment box, but they are not required. Finally, click the Submit button.



The following IRBNet users at **Marshall University Institutional Review Board #1 (Medical)** will be automatically notified of your submission:

Coordinator, Eyer B.

Submission Type: \*

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

Your Comments:

9. Once you hit the Submit button, you will be given a confirmation showing the time it was submitted. Keep in mind that this study is now locked. You will be contacted if corrections are needed. If nothing additional is required then everyone with full access will be notified via email once the study has been approved.