MARSHALL UNIVERSITY

OFFICE OF
RESEARCH INTEGRITY

**IRBNet User Manual
IACUC**

User Manual

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

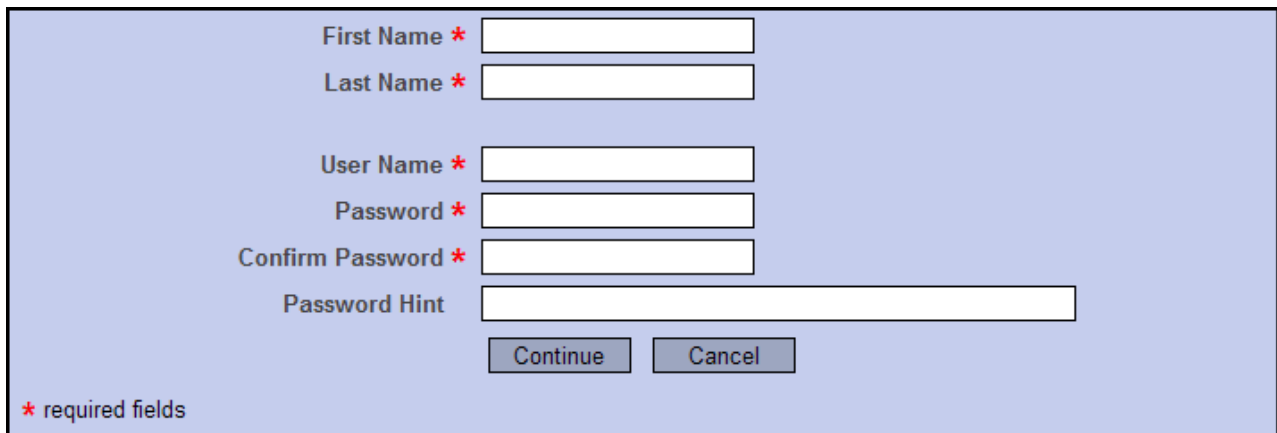# 1. Registration Instructions

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.

Login:	Username	Password	Login

   New User Registration | Forgot Your Password?

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

   First Name *
   Last Name *

   User Name *
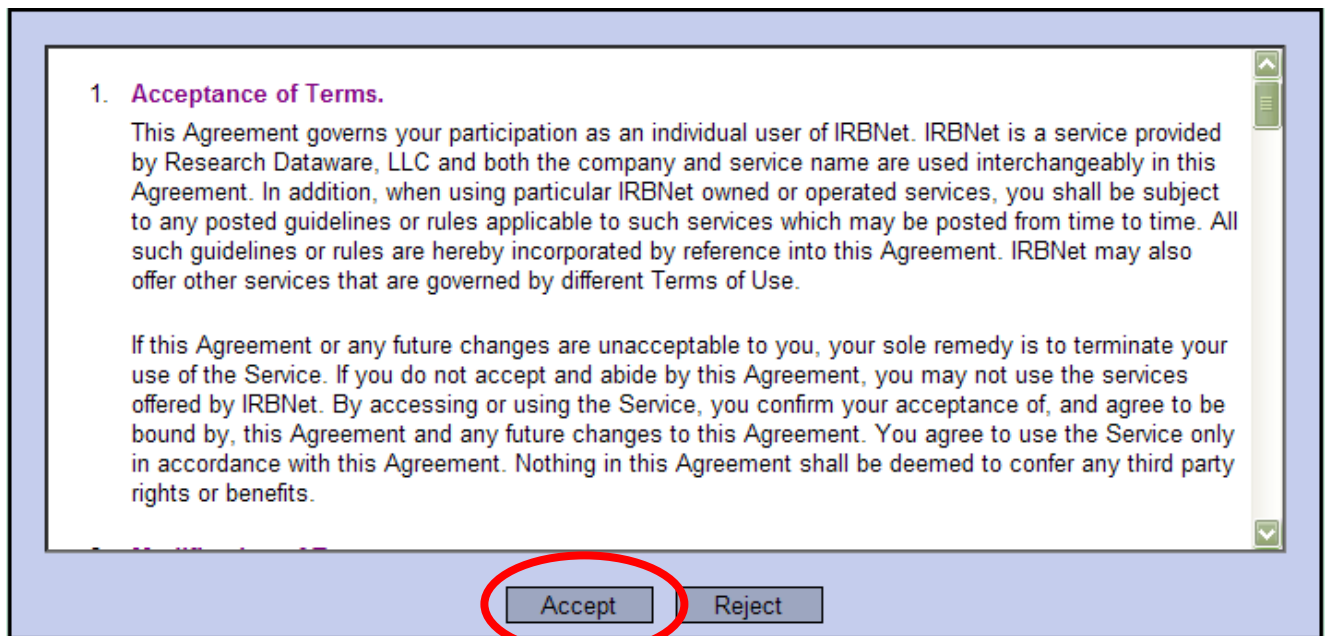   Password *
   Confirm Password *
   Password Hint

   Continue   Cancel
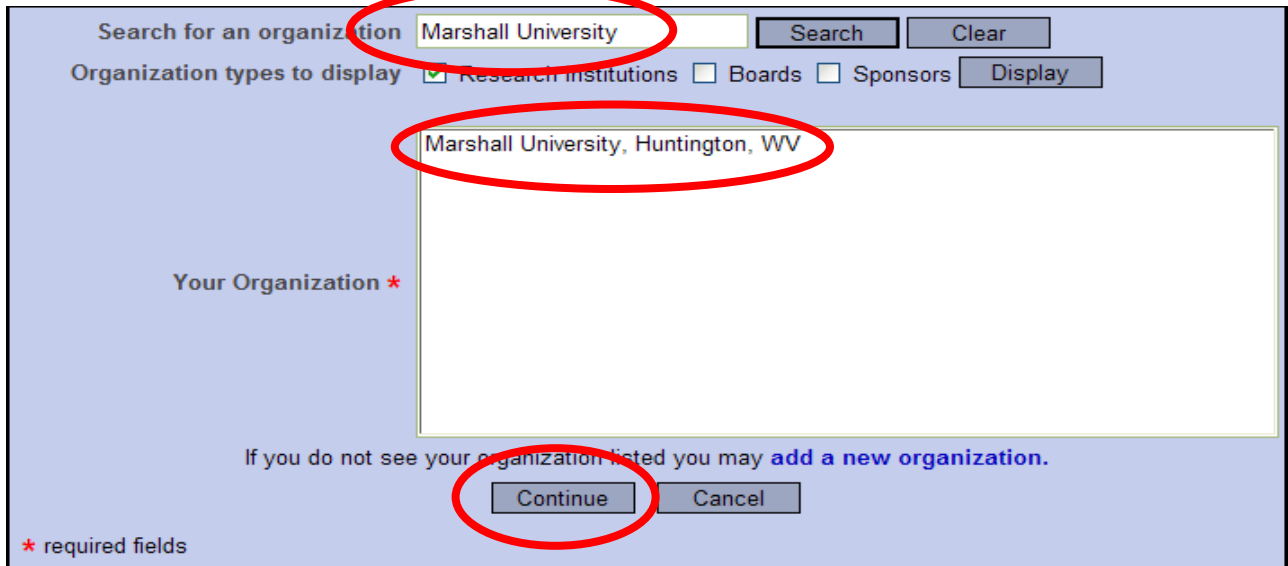
   * required fields

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

5. 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".
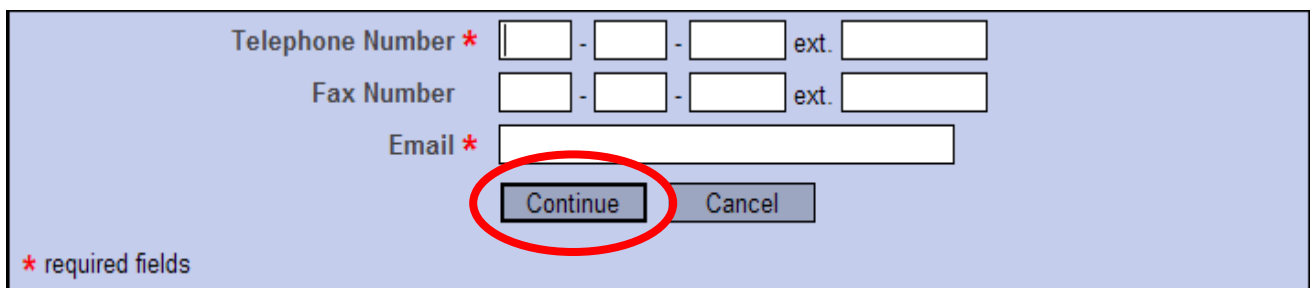

6. Enter your telephone number and a working email address. The email you use here will be the one used by the IRB board to communicate with you for approval and questions. Your email address will not be used for marketing purposes.
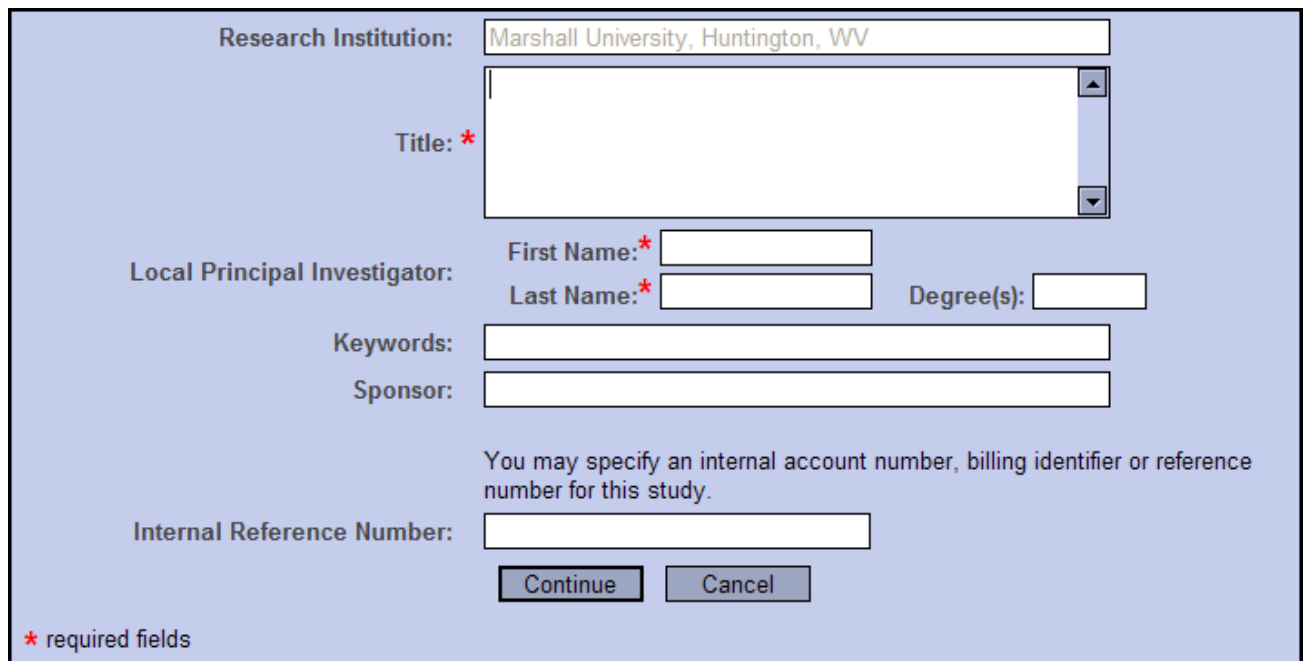

7. The last screen will confirm the information you have entered. Make sure that in the second box, it lists *Researcher* at Marshall University. Click the Register button.

8. 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. <u>Submission Instructions</u>

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. All forms can be accessed through the IACUC website or the IRBNet library.

To create your first package:

1. Go to 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. Enter a title for your study. Enter the first and last name of the Principal Investigator. *(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 IACUC study is sponsored then enter the name of the funding agency in the "Sponsor" box.

Research Institution:	Marshall University, Huntington, WV
Title: *	
Local Principal Investigator:	First Name:* ____ Last Name:* ____ Degree(s): ____
Keywords:	
Sponsor:	
	You may specify an internal account number, billing identifier or reference number for this study.
Internal Reference Number:	
	Continue Cancel

* required fields

6. Click the "Continue" button when finished.

7. You will be brought to a screen called the *Study Designer*. Step 1 is where you can access the library of forms. Just click on the first dropdown list and select IACUC. 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. Step 2 is for assembling your documents. At this point, there will be a message stating there are currently 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 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.

9. Once you have attached a document to your study package, the Study Designer page will now list your documents.
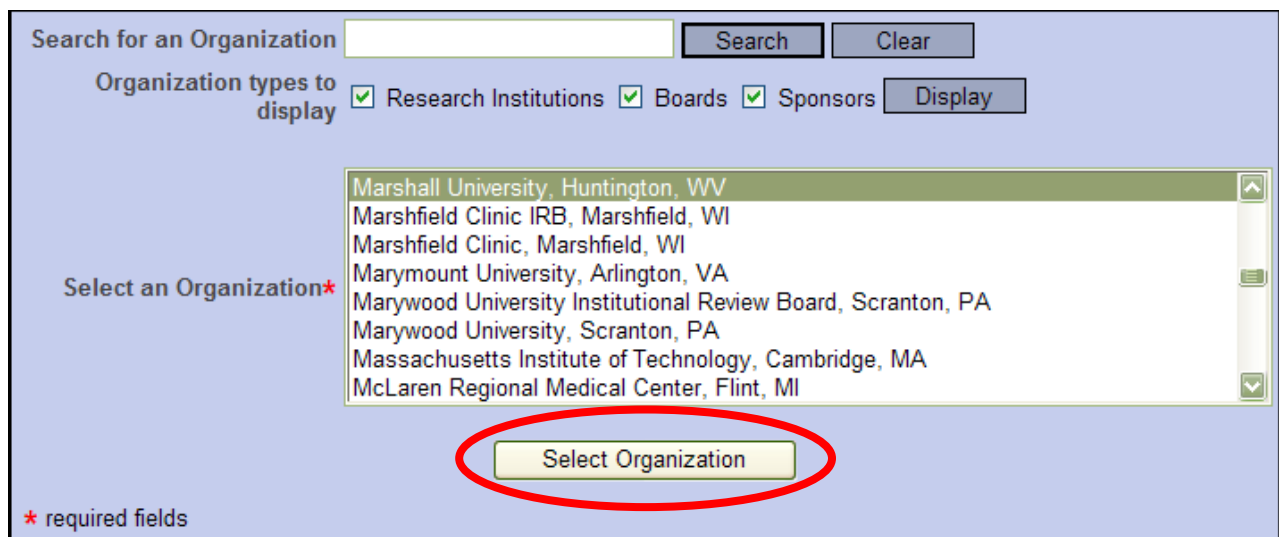
10. Repeat the steps to upload until all documents have been uploaded to your package.

11. If desired, you can share the study. **Note:** If you do **not** desire to share the study then skip to step 14. If you choose to share the study then the person you desire to share with must be registered on IRBNet in order for you to find them in the search function. 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 MU is highlighted just click on the button labeled "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 [   ] Search   Clear
Organization types to display ☑ Research Institutions ☑ Boards ☑ Sponsors Display

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

Select Organization

* required fields

13. You will be brought to a screen with a search tool (box) to search all who are registered on 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 (if applicable) then you need to sign your study electronically. To do this, click the "Sign this Package" button on the left side navigation bar. Then, in the drop down box, select your status on this study (i.e. Principal Investigator).

I Marshall Researcher, the [Principal Investigator ▼] assert that I have read this study's documents in their 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, enter **designee signer mode**.

15. Once you have signed, click the "Submit this Package" button on the left navigation bar. All MU boards will appear on the list so highlight the IACUC board and click "Continue".

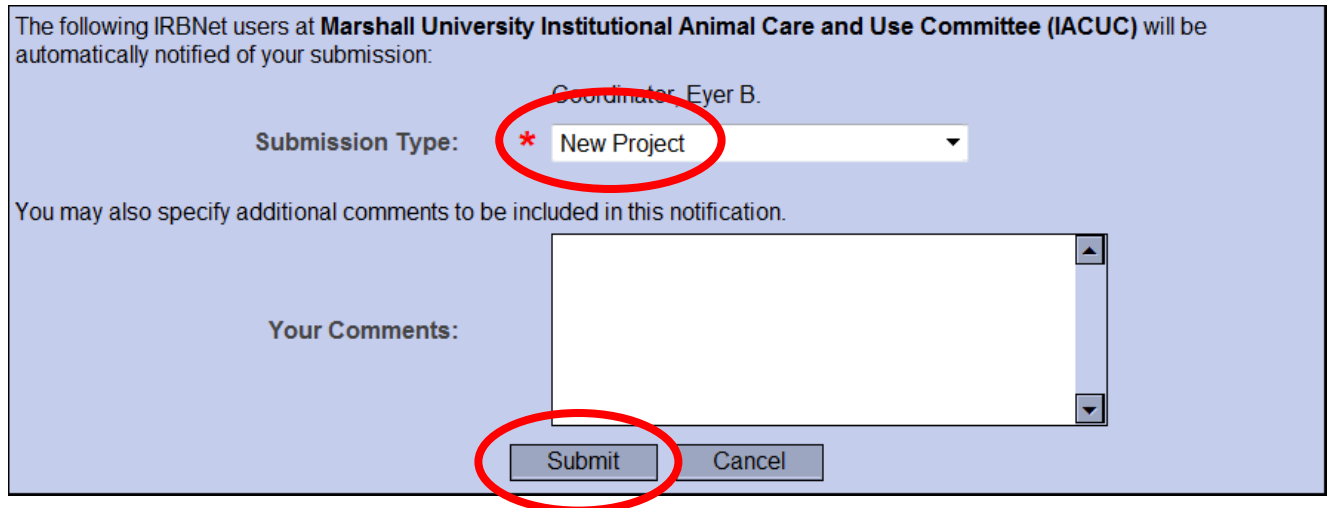Search for an Organization [   ] [Search] [Clear]

Select a Board
- Marshall University Institutional Review Board #1 (Medical),...
- Marshall University Institutional Review Board #2 (SBER), Huntington,...
- Marshall University (MUSOM) Conflict of Interest Committee,...
- Marshall University Institutional Animal Care and Use Committee...
- Marshfield Clinic IRB, Marshfield, WI
- Marywood University Institutional Review Board, Scranton, PA
- Marywood University Exempt Review Committee, Scranton, PA
- Marywood University Institutional Animal Care and Use Committee...

[Continue] [Cancel]

* required fields

16. On the final screen, in the Submission Type drop-down menu, choose the appropriate type (initially it will be New Project). 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 Animal Care and Use Committee (IACUC)** will be automatically notified of your submission:

Coordinator, Eyer B.

Submission Type: ✱ New Project ▾

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

Your Comments:

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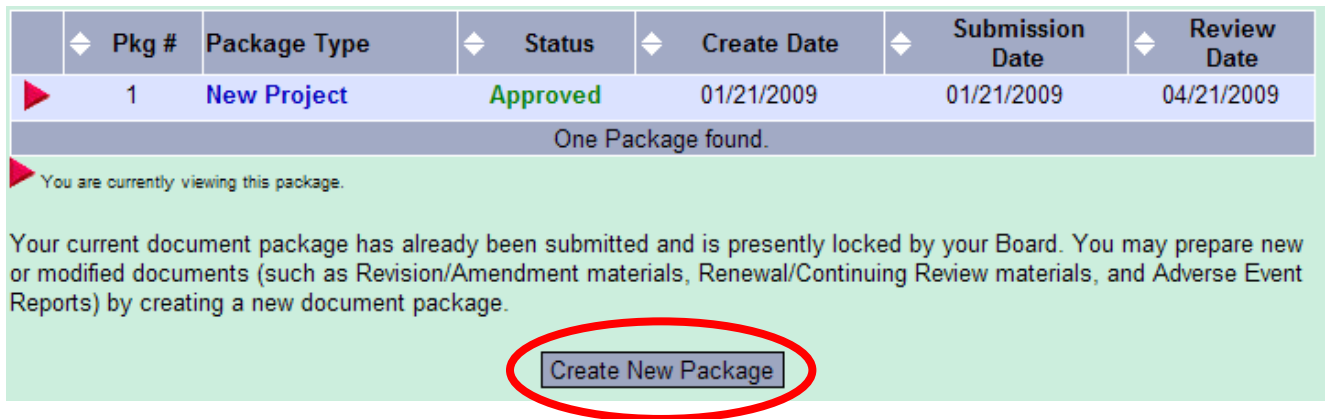
17. Once you hit the Submit button, you will be given a confirmation showing the time it was submitted. Keep in mind that this study is now locked. You will be contacted if corrections are needed. If nothing additional is required then everyone with full access will be notified via email once the study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

3. <u>Revision Instructions</u> (When IACUC Chair/Board deems "Modifications Required")

If you have submitted a package and the IACUC Chair/Board has deemed that "Modifications are Required" then you need to submit a revision. Once you have the study open (by clicking on the title) 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.

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.

3. A list of Documents from Previous Packages can be seen at the bottom of the page, download the document to be revised by clicking on the Document Type or on the paper icon.

4. Make any necessary changes to the downloaded document, and save the revised document to **your** computer.

5. Once the edited document is saved on your computer, click on "Add New Document" on IRBNet.

7. 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 filed. Click the "Browse" button and find the document on your computer. Once you find the document, click the "Attach" button to upload the document.

8. Be sure to sign the package by clicking on the left navigation button labeled "Sign This Package" and choose your role (i.e. Principal Investigator).

9. Once you have signed, click the "Submit this Package" button on the left navigation bar. All MU boards will appear on the list so highlight the IACUC board and click "Continue".

10. On the final screen, in the Submission Type drop-down menu, choose the appropriate submission type. You can leave comments in the Comment box, but they are not required. Finally, click the Submit button.
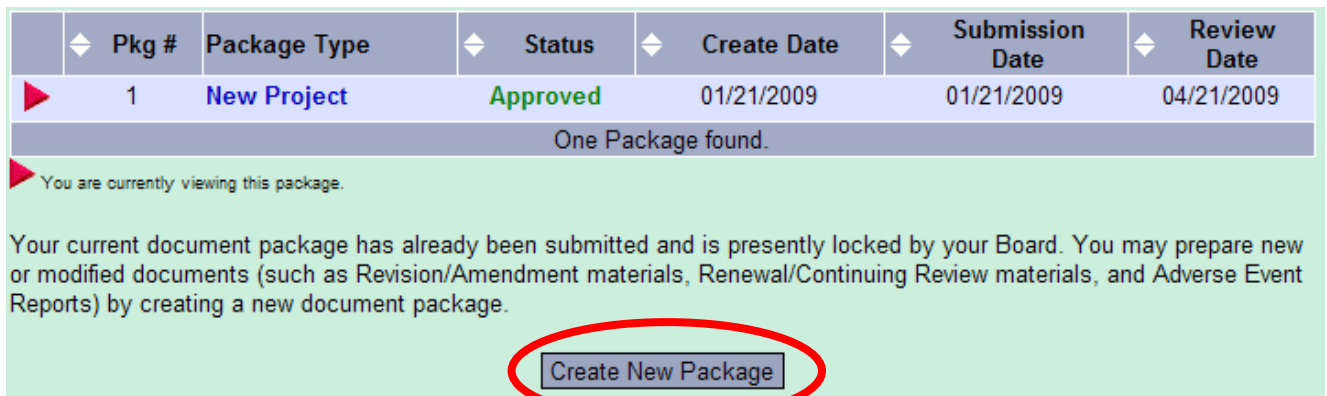
4. Annual Review Instructions

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 (by clicking on the title) 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.

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. This is also where you can access the library of forms (if needed). 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.**

[Add New Document] When should I do this?

4. 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 * [Other ▾]
Description [ ]
File * [ ] [Browse...]
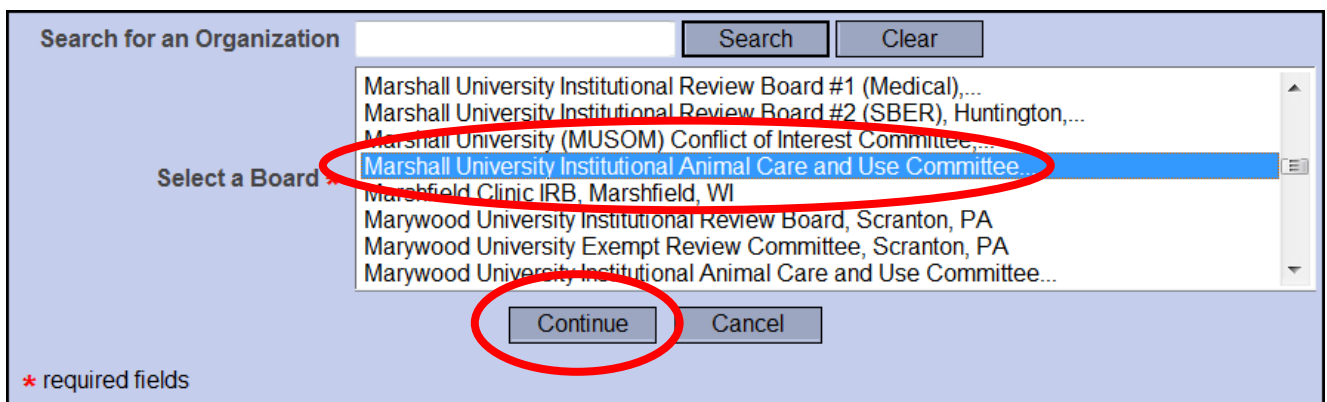[Attach] [Cancel]
* required fields

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

6. 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 (i.e. Principal Investigator).

I Marshall Researcher, the [Principal Investigator ▼] assert that I have read this study's documents in their 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, enter **designee signer mode**.

7. Once you have signed, click the "Submit this Package" button on the left navigation bar. All MU boards will appear on the list so just highlight the IACUC board and click "Continue".
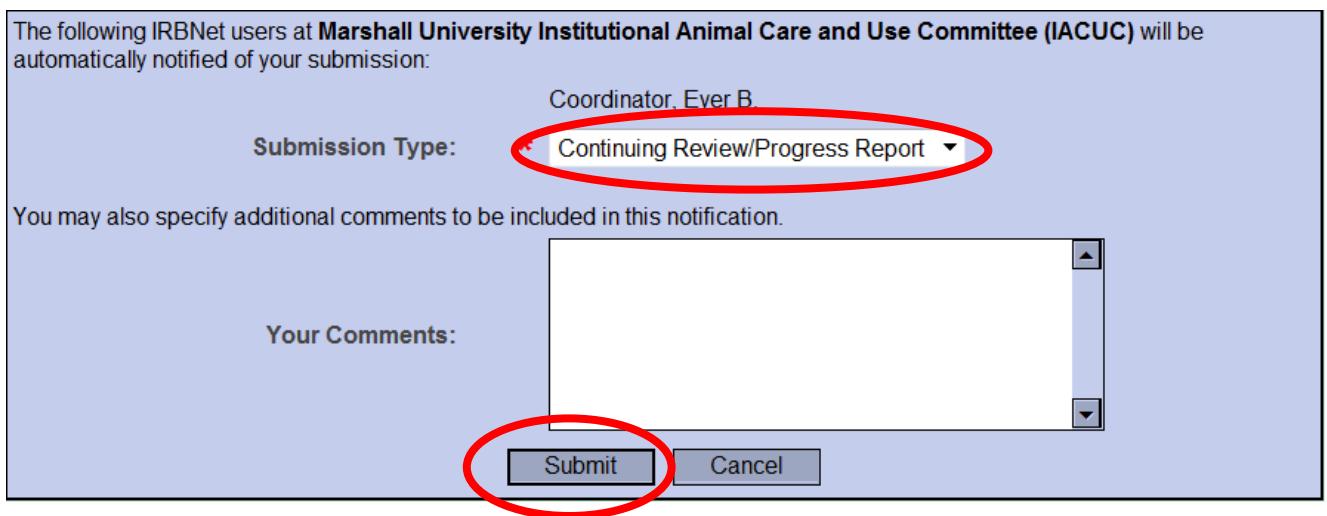
Search for an Organization [   ] [Search] [Clear]

Select a Board *
- Marshall University Institutional Review Board #1 (Medical),...
- Marshall University Institutional Review Board #2 (SBER), Huntington,...
- Marshall University (MUSOM) Conflict of Interest Committee,...
- Marshall University Institutional Animal Care and Use Committee...
- Marshfield Clinic IRB, Marshfield, WI
- Marywood University Institutional Review Board, Scranton, PA
- Marywood University Exempt Review Committee, Scranton, PA
- Marywood University Institutional Animal Care and Use Committee...

[Continue] [Cancel]

* required fields

8. 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 Animal Care and Use Committee (IACUC)** will be automatically notified of your submission:

Coordinator, Ever B.

Submission Type: [Continuing Review/Progress Report ▼]

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

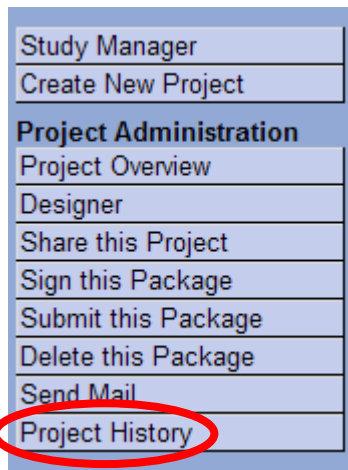Your Comments: [   ]

[Submit] [Cancel]

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.
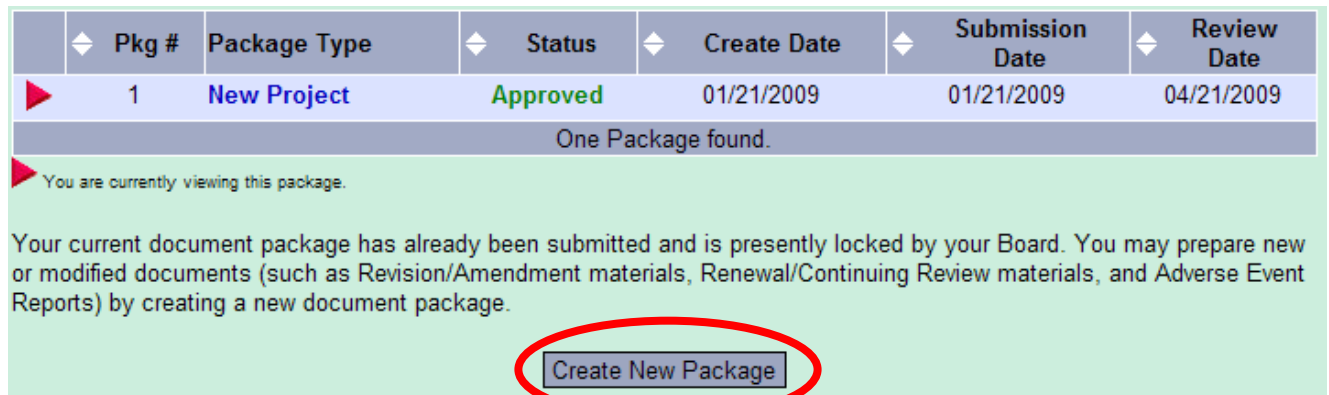
5. Modification/Amendment Instructions

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 (by clicking on the title) 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.

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.

Create New Package

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.

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

4. 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)
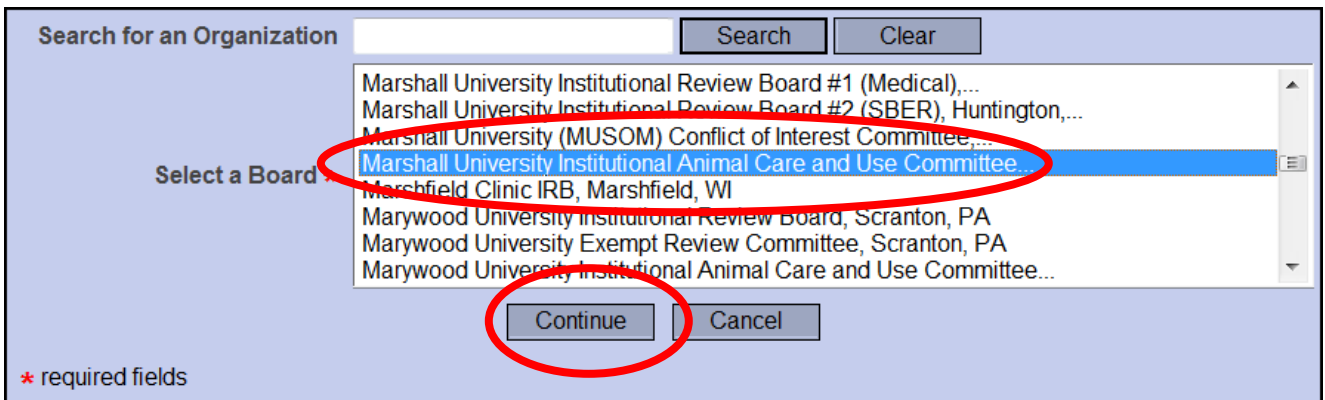

5. Repeat the steps to upload until all documents have been uploaded to your package.

6. 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 (i.e. Principal Investigator).

I Marshall Researcher, the Principal Investigator ▾ assert that I have read this study's documents in their 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, enter **designee signer mode**.

7. Once you 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".
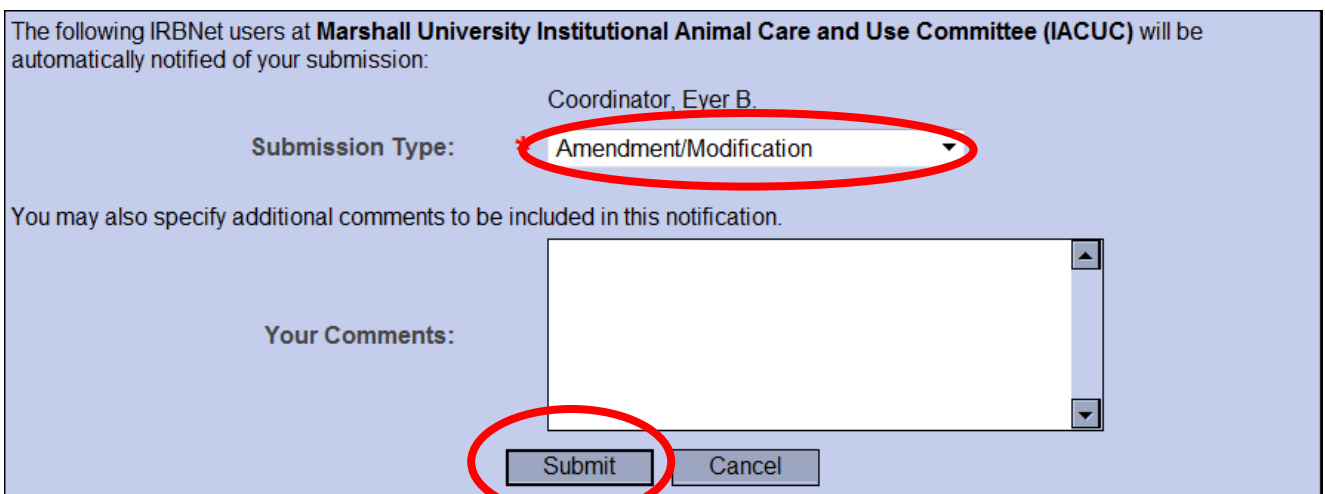
Search for an Organization [_____] Search Clear

Select a Board
- Marshall University Institutional Review Board #1 (Medical),...
- Marshall University Institutional Review Board #2 (SBER), Huntington,...
- Marshall University (MUSOM) Conflict of Interest Committee,...
- Marshall University Institutional Animal Care and Use Committee...
- Marshfield Clinic IRB, Marshfield, WI
- Marywood University Institutional Review Board, Scranton, PA
- Marywood University Exempt Review Committee, Scranton, PA
- Marywood University Institutional Animal Care and Use Committee...

Continue Cancel

* required fields

8. 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 Animal Care and Use Committee (IACUC)** will be automatically notified of your submission:

Coordinator, Eyer B.

Submission Type: * Amendment/Modification ▾

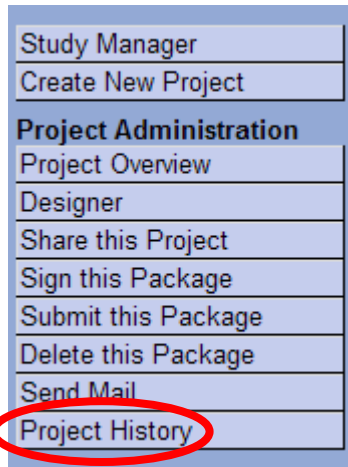You may also specify additional comments to be included in this notification.

Your Comments:

Submit Cancel

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.
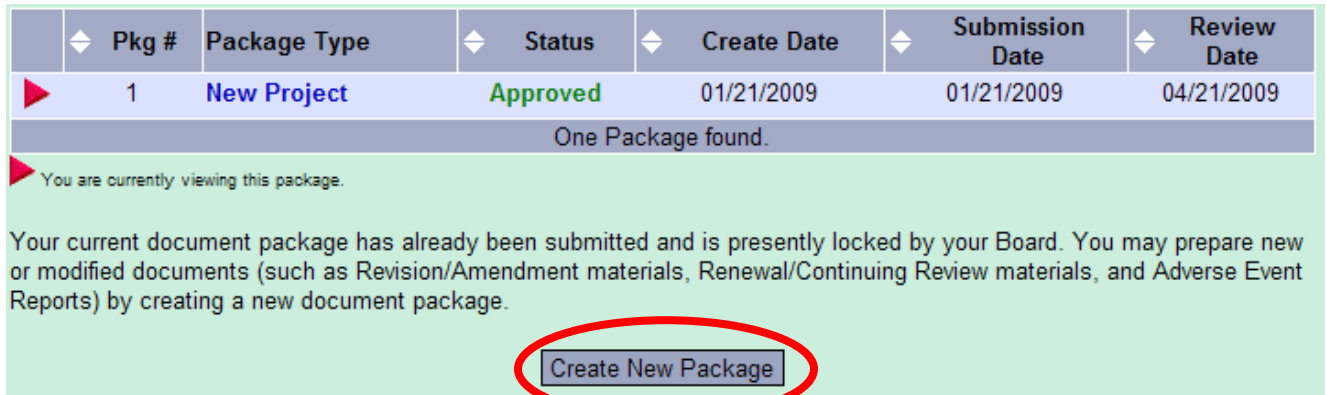
_____

6. 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 (by clicking on the title) 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.

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. You will then be taken to the *Designer* screen where you can add the Annual Review Form requesting closure. 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.**

[Add New Document] When should I do this?

4. You should attach the annual review form stating your desire to close the study. In the "Document Type" box, pick "Other" and type "Annual Review Form" 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 filed. 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 * [Other ▾]
Description [ ]
File * [ ] [Browse...]
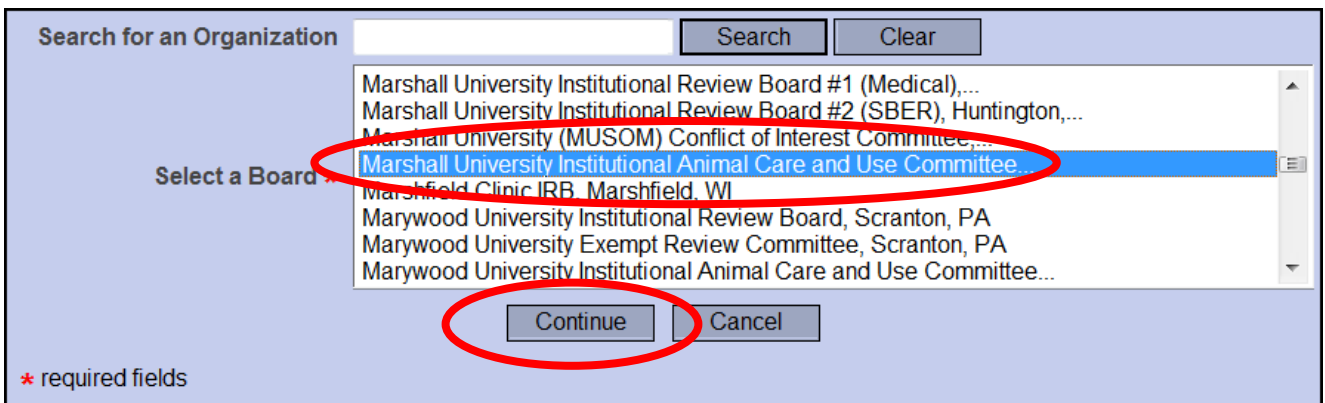[Attach] [Cancel]

* required fields

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

6. 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 (i.e. Principal Investigator).

7. Once you have signed, click the "Submit this Package" button on the navigation bar. All MU boards will appear on the list so just highlight the IACUC board and click "Continue".
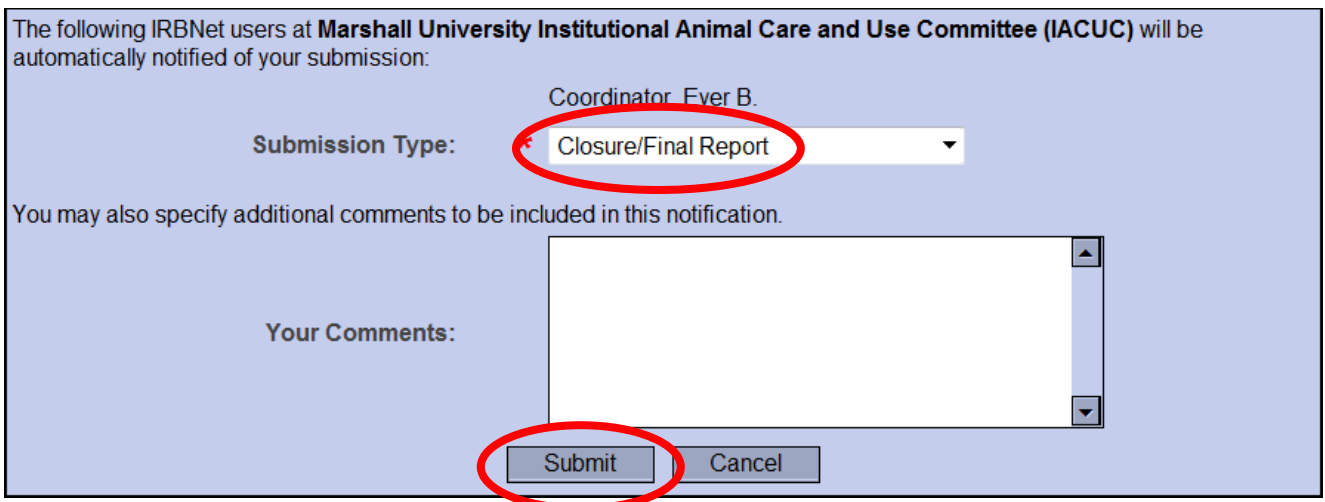

8. On the final screen, in the "Submission Type" drop-down menu, choose "Close/Final Report". You can leave comments in the Comment box, but they are not required. Finally, click the Submit button.

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.