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.

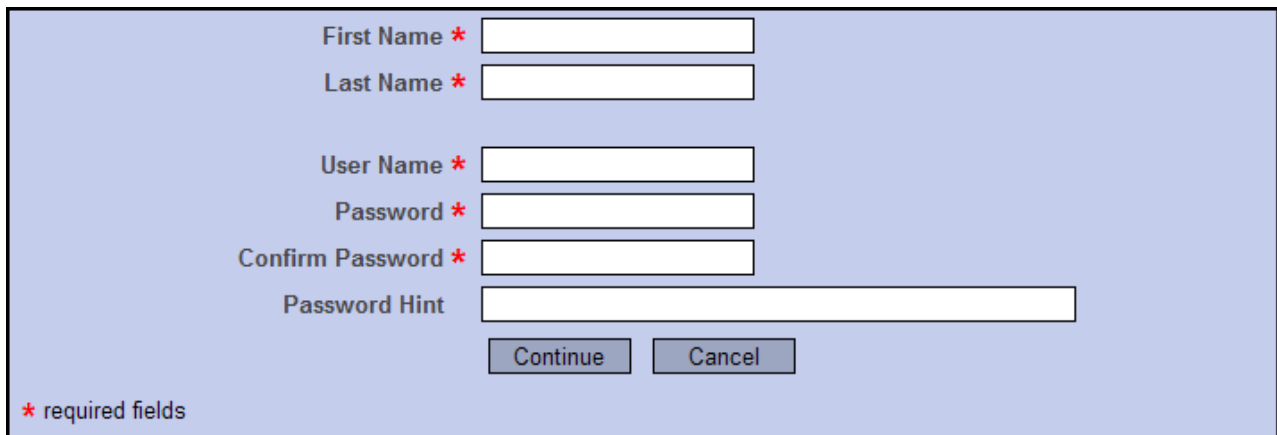_____

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. The hint is optional.

4. Accept the Terms of Use

5. Next, add an affiliation. In the "*Search for an organization*" box, type Marshall University and click "Search". Highlight Marshall University (in the lower box) and click "Continue".
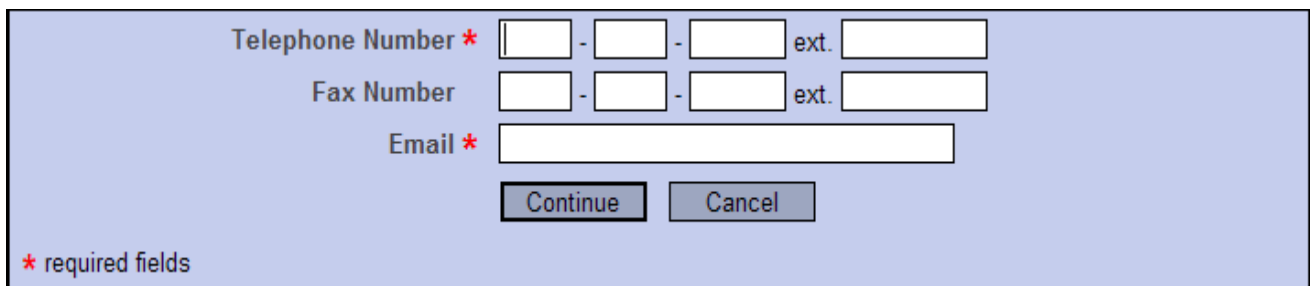
Search for an organization	Marshall University [Search] [Clear]
Organization types to display	☑ Research Institutions ☐ Boards ☐ Sponsors [Display]
Your Organization *	Marshall University, Huntington, WV

If you do not see your organization listed you may **add a new organization.**

[Continue] [Cancel]

* required fields

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

Telephone Number *	[___] - [___] - [___] ext. [_____]
Fax Number	[___] - [___] - [___] ext. [_____]
Email *	[_____]

[Continue] [Cancel]

* required fields

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, a confirmation email will be sent to you. If you do not receive that confirmation email in a short time period then check your spam folder. 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>IRBNet Library</u>

The IRBNet Forms and Templates library contains all the documents needed for an IRB/COI/IACUC submission. This library is available once you log into IRBNet and is located on the left side of the webpage under "Other Tools".

Other Tools
Track Training
Forms and Templates
Library Manager
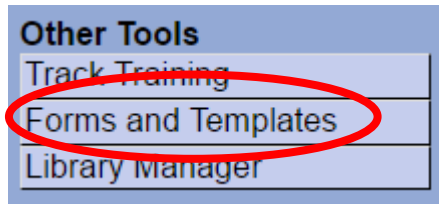
From the "Select a Library" drop down list you will first select the library that corresponds with the board to which you will be submitting. Below is the drop down list of the available board libraries:

Select a Library: Marshall University (MUSOM) Conflict of Interest Committee, Huntington, WV - Documents for Committee Members ▾

Marshall University (MUSOM) Conflict of Interest Committee, Huntington, WV - Documents for Committee Members
Marshall University (MUSOM) Conflict of Interest Committee, Huntington, WV - Documents for Researchers
Marshall University IACUC, Huntington, WV - Documents for Committee Members
Marshall University IACUC, Huntington, WV - Documents for Researchers
Marshall University Institutional Review Board #1 (Medical), Huntington, WV - Documents for Researchers
Marshall University Institutional Review Board #2 (Social/Behavioral), Huntington, WV - Documents for Researchers

**Note: The bottom 2 libraries are for the IRB.**

Once you select the appropriate library you will see all the available forms and templates. Please keep in mind that these are just templates, so once editing is complete you will need to save the document to your hard drive. Then in the following sections you will be provided instructions for uploading a document into your package.

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3. Submission Instructions

To submit a study for initial review, you must first Create a New Project 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 (Submission Checklist) can be found in the Forms and Templates library in IRBNet (see Section 2 for library instructions).

To create your first package:

1. Go to www.irbnet.org and login using the user name and password you previously created. On the navigation bar to your left, click the button titled "Create New Project".
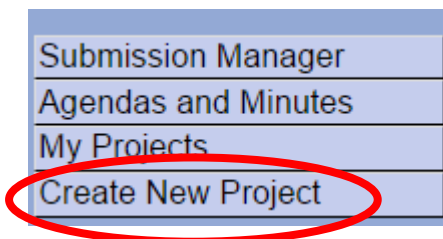

2. Pick a title for your study (see picture below). Enter the first and last name of the Principal Investigator. If you are a student then you would enter your professor's name. The "Keywords" and "Sponsor" boxes are for your reference only and will assist you later if you need to search through your studies to find one pertaining to a specific topic. Click the "Continue" button when finished.

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3. You will be brought to a screen called the *Designer* page. This is where you can also access the forms and templates by clicking on the "Select a Library" dropdown list and select your IRB (#1 or #2). Then click on the "Select a 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.

4. At this point, there will be a message stating there are no documents attached to this study (see picture below) and two button options below it ("Start a Wizard" or "Attach New Document"). To add a document, click "Attach New Document" and select the document from your computer.

Documents in this Package:
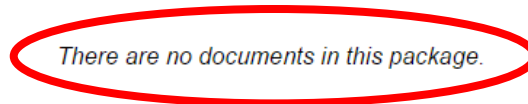
There are no documents in this package.

There are no Training & Credentials records linked to this package. | Link / Un-Link Training Records |

Start a Wizard   **OR**   Attach New Document   (When should I do this?)

5. Once the document is selected you will see that it has been attached to the study (as in the box below). Under "Document Type" click the drop down arrow and pick the best match for the document you are uploading. For example, if it is the application, select 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.

Documents in this Package:

Document Type	Description	Last Modified	
▼ (please select)	IRB2 Application 071316.docx	05/30/2017 03:20 PM	

6. Repeat steps 4 & 5 until all documents have been uploaded to your package.

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7. 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".

Project Administration
Project Overview
Designer
Share this Project
Sign this Package
Submit this Package
Delete this Package
Send Project Mail
Reviews
Project History
Create a New Package
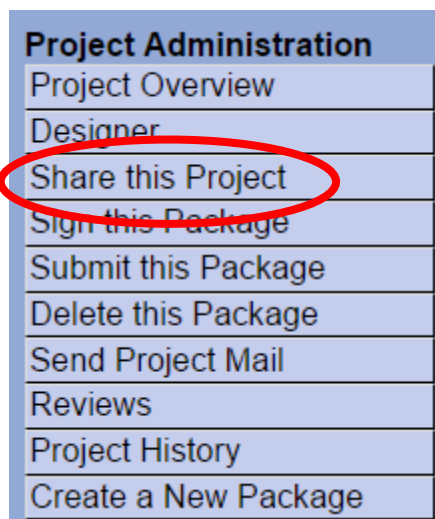
8. On the next page this is the information you will see and you should choose "Share":

- **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.
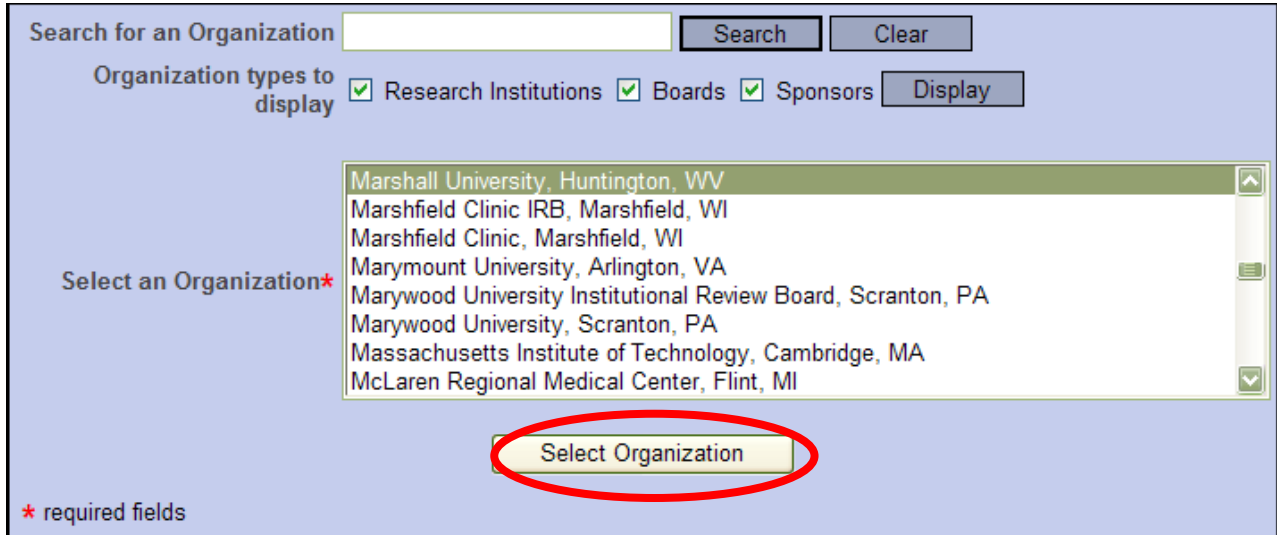
- **Multi-site:** Use this option only if your study is a multi-site study and you wish to send a complete and independent copy of this study to a Principal Investigator at another site. The local Principal Investigator will receive their own independent copy of all study documents and may modify their 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.

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9. 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.

10. You will be brought to a screen in which you can search for a user. The top of the page describes the different types of access that you can specify. Use the search tool at the bottom of the page and type in the **last name** of the person in which you want to share your study. If you do not find them in the system then they have not yet registered on IRBNet. Specify the access that you wish to grant to each user at Marshall University. You should grant each user only the minimum level of access necessary to perform their work on this project.

- **Signature Only (Read):** Users whose only role is to sign off on project documentation should be granted "Read" access. Users with Read access can view project documentation, communicate with the project team and add their signature. This would typically include advisors, department heads, and other individuals who are required to sign off on the project documentation prior to submission but do not otherwise have a day-to-day role on the project.

- **Read:** Users that are granted "Read" access can view project documentation, collaborate with other users and add their signature, but may not edit project documents or perform any other administrative functions.

- **Write:** Users that are granted "Write" access can view and edit project documents, collaborate with other users and add their signature, but may not grant access to other users, submit packages for review or perform any other administrative functions.

- **Full:** Users that are granted "Full" access can perform all functions without restriction. This includes editing project documents, sharing the project with other users, submitting document packages for review and deleting document packages. Only Project Owners with day-to-day responsibility for the project should be granted Full access. Users with Full access will receive automatic email copies of all project notifications and alerts that are sent to the Project Owners.

Search for a User: [   ] [Search]

[Save] [Cancel]

For instance, a search for last name Stanley would show the following:

Search for a User: stanley [Search]

User	Access Type			
Jules, Stanley	○ Full	○ Write	○ Read	● No Access
Stanley, Jackie	○ Full	○ Write	○ Read	● No Access
	2 Users found, displaying all Users.			

11. Once you have shared the study with a research team member then they will receive an email notification regarding their access to the study. That team member can now attach documents and perform the tasks according to the access level granted.

12. When all documents are uploaded and you have shared your study then you need to sign your package electronically. To do this, click the "Sign this Package" button on the left side navigation bar.
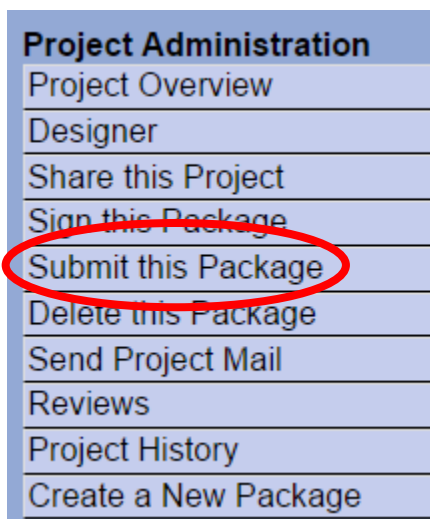
Project Administration
Project Overview
Designer
Share this Project
Sign this Package
Submit this Package
Delete this Package
Send Project Mail
Reviews
Project History
Create a New Package

13. The next page will provide a 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. You will be prompted to insert your login information for security purposes. **Also, we do not use the designee signer mode.**

I Bruce Day, CIP, as [_____ ▼], certify that to the best of my knowledge the information contained in this package is accurate and complete, has been prepared in accordance with all applicable institutional requirements and is ready for submission. I further certify that this electronic signature is intended to be the legally binding equivalent of a traditional handwritten signature.
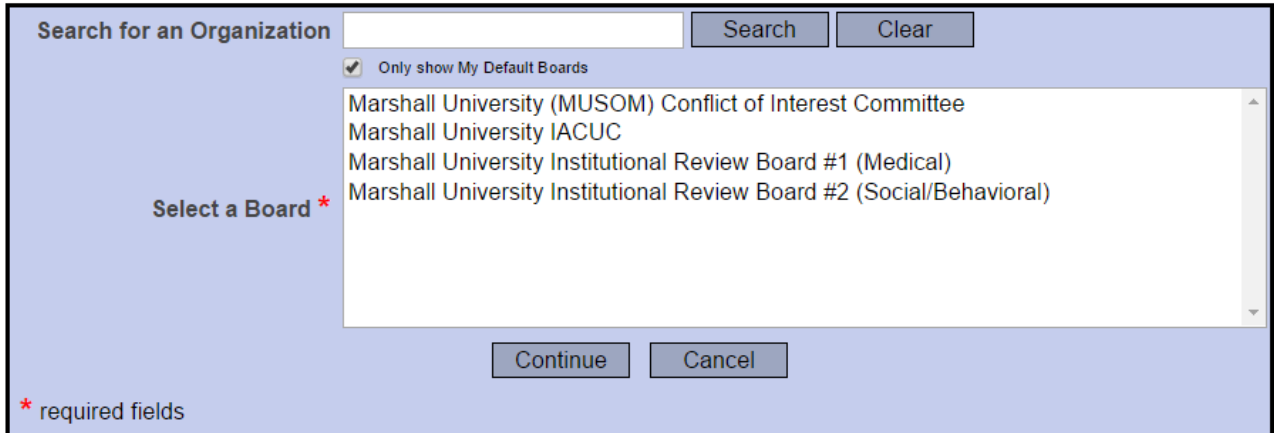
[Sign]

14. (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.)

15. Once you (and your professor, if applicable) have signed, click the "Submit this Package" button on the left side navigation bar.
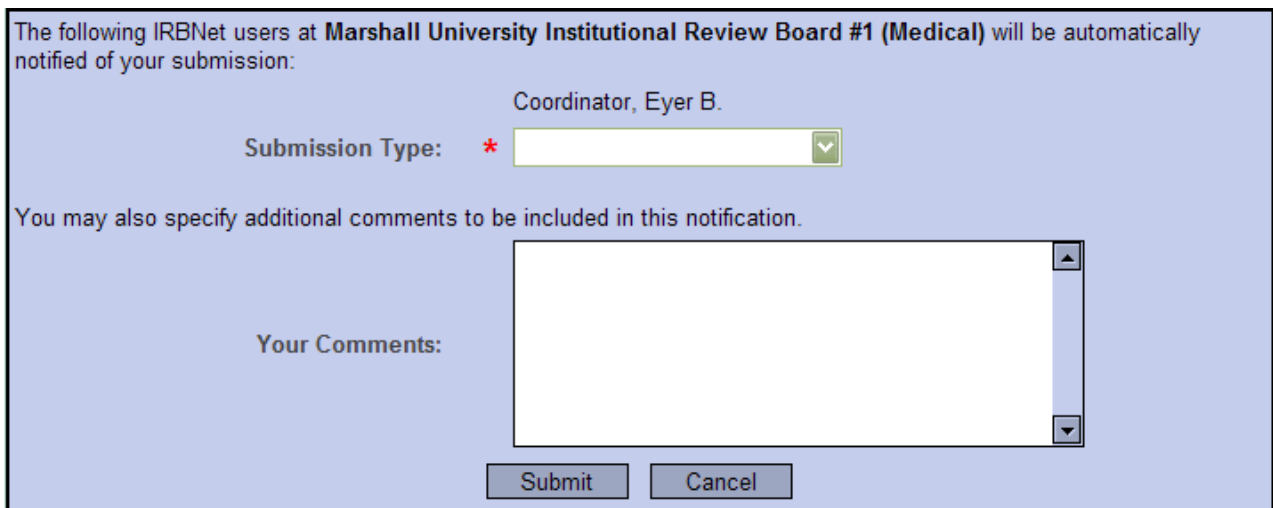
Project Administration
Project Overview
Designer
Share this Project
Sign this Package
Submit this Package
Delete this Package
Send Project Mail
Reviews
Project History
Create a New Package

All MU boards will appear on the list so highlight the board to which you will be submitting. Click "Continue".

Please select a Board:

Search for an Organization		Search	Clear

☑ Only show My Default Boards

Select a Board *

Marshall University (MUSOM) Conflict of Interest Committee
Marshall University IACUC
Marshall University Institutional Review Board #1 (Medical)
Marshall University Institutional Review Board #2 (Social/Behavioral)

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 Study). 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:

Submit   Cancel

17. Once you hit the Submit button, you will be given a confirmation showing the time the package 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.

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4. <u>Revision Instructions</u> (When the IRB deems "Modifications are Required")

If you have submitted a package and the IRB has deemed that "Modifications are Required" then you need to submit a revision package. Once you have the study open just click on the "Create a New Package" button on the left side navigation bar.
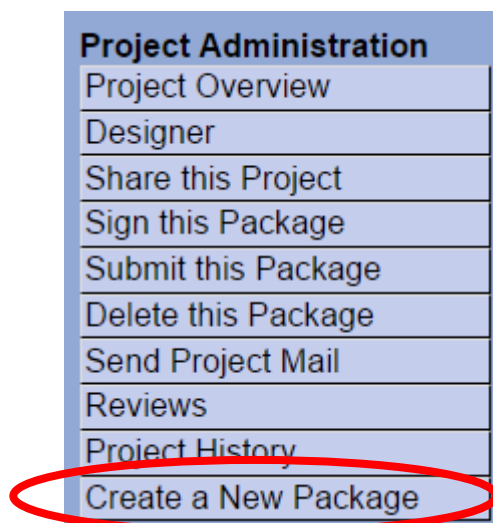
1. You will be brought to the *Designer* page so you can add new documents. Initially there will not be any documents in the package. Click "Attach New Document" and upload the required documents for the revision.

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2. Once a document has been selected from your computer you will see that the document has been attached to the study (see the box below). Under "Document Type" click the drop down arrow and pick the best match for the document you are uploading. If it is the application, select 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.

3. Once all documents have been uploaded and the package has been signed by the principal investigator, click the "Submit this Package" button on the left side navigation bar. All MU boards will appear on the list so highlight the board to which you will be submitting. Click "Continue".

4. Under "Submission Type" select "Revision" for this type of package. The "Your Comments" section is optional so when finished just Click "Submit".
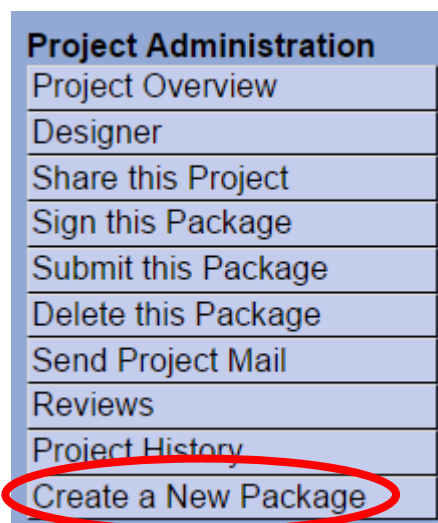

5. Once you hit the Submit button, you will be given a confirmation showing the time the package was submitted. Keep in mind that this study is now locked. You will be contacted if corrections are needed. If nothing additional is required then everyone with full access will be notified via email once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

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5. Continuing Review/Annual Update Instructions

To submit a continuing review package:

To submit a package 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 create a new package to an already existing study. Once you have the study open just click on the "Create a New Package" button on the left side navigation bar.

Project Administration
Project Overview
Designer
Share this Project
Sign this Package
Submit this Package
Delete this Package
Send Project Mail
Reviews
Project History
Create a New Package

1. You will be brought to the *Designer* page so you can add the required documents for a continuing review. Initially there will not be any documents in package. Click "Attach New Document" and upload the required documents for the continuing review package.

Documents in this Package:

There are no documents in this package.

There are no Training & Credentials records linked to this package. | Link / Un-Link Training Records |

Start a Wizard   OR   Attach New Document   (When should I do this?)

_____

2. Once a document has been selected from your computer you will see that the document has been attached to the package (see the box below). Under "Document Type" click the drop down arrow and pick the best match for the document you are uploading. If it is the application, select 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.

Documents in this Package:

Document Type	Description	Last Modified	
▼ (please select)	IRB2 Application 071316.docx	05/30/2017 03:20 PM	

3. Once all documents have been uploaded and the package has been signed by the principal investigator, click the "Submit this Package" button on the left side navigation bar. All MU boards will appear on the list so highlight the board to which you are submitting. Click "Continue".

Please select a Board:

Search for an Organization		Search	Clear

☑ Only show My Default Boards

Marshall University (MUSOM) Conflict of Interest Committee
Marshall University IACUC
Marshall University Institutional Review Board #1 (Medical)
Marshall University Institutional Review Board #2 (Social/Behavioral)

Select a Board *

Continue   Cancel

* required fields

_____

4. Under "Submission Type" select "Continuing Review/Renewal" for this type of package. The "Your Comments" section is optional so when finished just click "Submit".


5. Once you hit the Submit button, you will be given a confirmation showing the time the package 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.

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6. Modification/Amendment/Deviation Instructions

To submit a Modification/Amendment package:

To submit a Modification/Amendment or Protocol Deviation package, you must first open the study. Keep in mind that you **do not** want to create a new project. You want to create a new package to an already existing study. Once you have the study open just click on the "Create a New Package" button on the left side navigation bar.
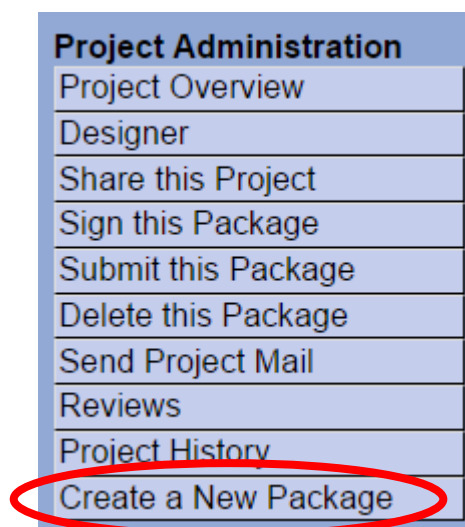
1. You will be brought to the *Designer* page so you can add the required documents for an amendment or protocol deviation. Initially there will not be any documents in package. Click "Attach New Document" and upload the required documents.

2. Once a document has been selected from your computer you will see that the document has been attached to the package (see the box below). Under "Document Type" click the drop down arrow and pick the best match for the document you are uploading. If it is the application, select 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.

Documents in this Package:

Document Type ▲	Description	Last Modified	
▼ (please select)	IRB2 Application 071316.docx	05/30/2017 03:20 PM	📄 🗗 ✏ ✕

3. Once all documents have been uploaded and the package has been signed by the principal investigator, click the "Submit this Package" button on the left side navigation bar. All MU boards will appear on the list so highlight the board to which you are submitting. Click "Continue".

Please select a Board:

Search for an Organization	[ ] [Search] [Clear]
	☑ Only show My Default Boards
Select a Board *	Marshall University (MUSOM) Conflict of Interest Committee Marshall University IACUC Marshall University Institutional Review Board #1 (Medical) Marshall University Institutional Review Board #2 (Social/Behavioral)
	[Continue] [Cancel]

* required fields

_____

4. Under "Submission Type" select "Modification/Amendment" or "Protocol Deviation" (whichever is applicable). The "Your Comments" section is optional so when finished just click "Submit".
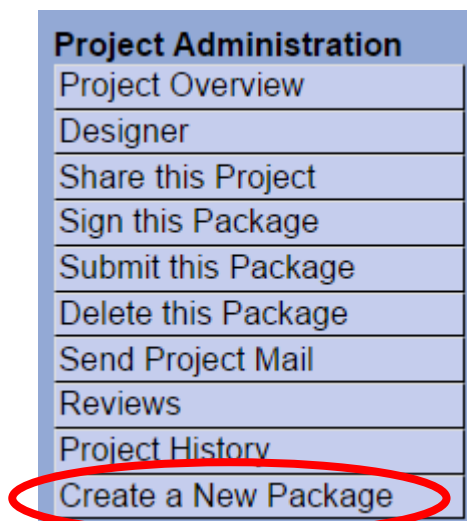

5. Once you hit the Submit button, you will be given a confirmation showing the time the package was submitted. Keep in mind that this study is now locked. You will be contacted if corrections are needed. If nothing additional is required then everyone with full access will be notified via email once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

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7. <u>Adverse Event Reporting Instructions</u>

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 create a new package to an already existing study. Once you have the study open just click on the "Create a New Package" button on the left side navigation bar.

Project Administration
Project Overview
Designer
Share this Project
Sign this Package
Submit this Package
Delete this Package
Send Project Mail
Reviews
Project History
Create a New Package

1. You will be brought to the *Designer* page so you can add the required documents for the submission of an AE/SAE. Initially there will not be any documents in package. Click "Attach New Document" and upload the required documents.

Documents in this Package:

There are no documents in this package.

There are no Training & Credentials records linked to this package. | Link / Un-Link Training Records |

Start a Wizard   **OR**   Attach New Document   (When should I do this?)

2. Once a document has been selected from your computer you will see that the document has been attached to the package (see the box below). Under "Document Type" click the drop down arrow and pick the best match for the document you are uploading. If it is the application, select 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.

Documents in this Package:

Document Type		Description	Last Modified	
▼ (please select)		IRB2 Application 071316.docx	05/30/2017 03:20 PM	

3. Once all documents have been uploaded and the package has been signed by the principal investigator, click the "Submit this Package" button on the left side navigation bar. All MU boards will appear on the list so highlight the board to which you are submitting. Click "Continue".

Please select a Board:

Search for an Organization		Search	Clear

☑ Only show My Default Boards

Marshall University (MUSOM) Conflict of Interest Committee
Marshall University IACUC
Marshall University Institutional Review Board #1 (Medical)
Marshall University Institutional Review Board #2 (Social/Behavioral)

Select a Board *

Continue   Cancel

* required fields

_____

4. Under "Submission Type" select "Adverse Event (non-UP)" or "Unanticipated Problem (UP)" (whichever is applicable). The "Your Comments" section is optional so when finished just click "Submit".

5. Once you hit the Submit button, you will be given a confirmation showing the time the package 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.

8. How to Share a Study

If you have need to share a study with a new study member then it must either be done as part of the original submission or as part of a new package. If you desire to add a new research member then click on the "Create a New Package" button on the left side navigation bar.
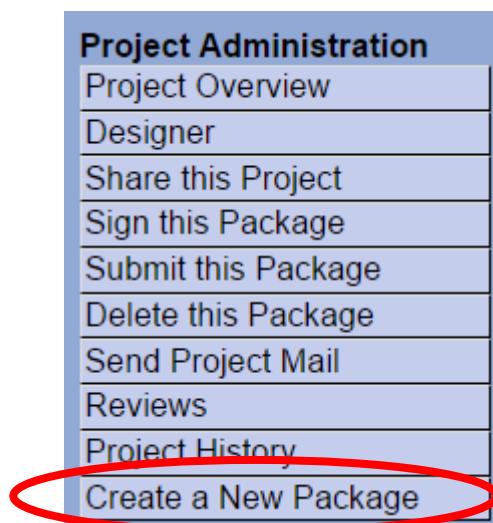
1. You will be brought to the *Designer* page so you can add the documents for that new researcher. Initially there will not be any documents in the package. When adding someone to a study you must include their CV/Resume, current CITI certificate, and Attachment C. Click "Attach New Document" and upload the required documents for the package.
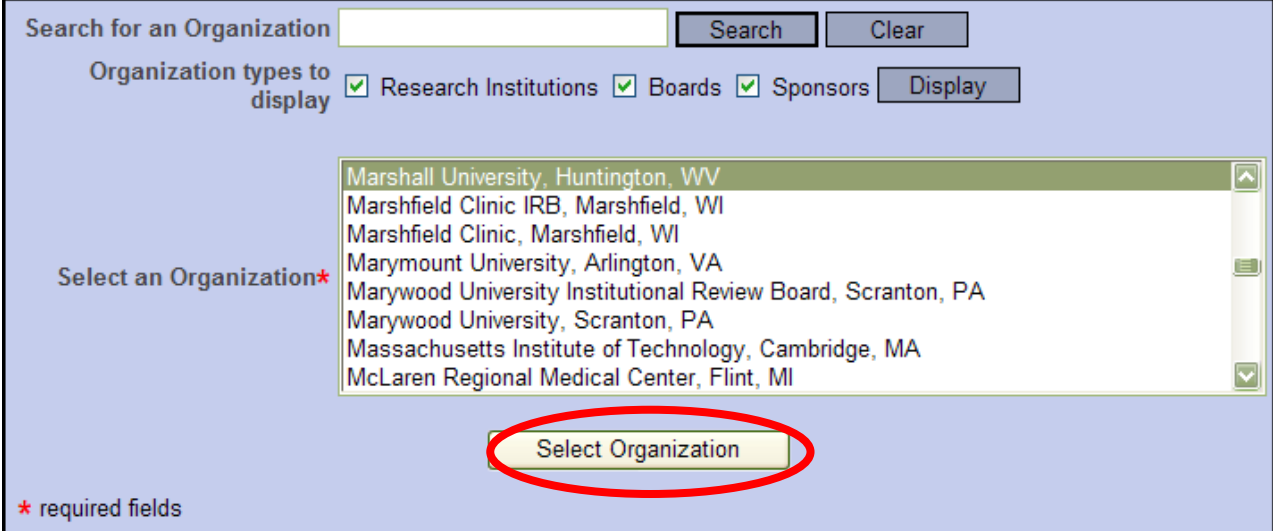
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2. Now it is time to share the study. On the left side navigation bar, click the "Share this Project" button. On the Share Study screen, choose "Share".

Project Administration

Project Overview
Designer
Share this Project
Sign this Package
Submit this Package
Delete this Package
Send Project Mail
Reviews
Project History
Create a New 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.

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3. 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.

4. You will be brought to a screen in which you can search for a user. The top of the page describes the different types of access that you can specify. Use the search tool at the bottom of the page and type in the **last name** of the person in which you want to share your study. If you do not find them in the system then they have not yet registered on IRBNet. Specify the access that you wish to grant to each user at Marshall University. You should grant each user only the minimum level of access necessary to perform their work on this project.

- **Signature Only (Read):** Users whose only role is to sign off on project documentation should be granted "Read" access. Users with Read access can view project documentation, communicate with the project team and add their signature. This would typically include advisors, department heads, and other individuals who are required to sign off on the project documentation prior to submission but do not otherwise have a day-to-day role on the project.

- **Read:** Users that are granted "Read" access can view project documentation, collaborate with other users and add their signature, but may not edit project documents or perform any other administrative functions.

- **Write:** Users that are granted "Write" access can view and edit project documents, collaborate with other users and add their signature, but may not grant access to other users, submit packages for review or perform any other administrative functions.

- **Full:** Users that are granted "Full" access can perform all functions without restriction. This includes editing project documents, sharing the project with other users, submitting document packages for review and deleting document packages. Only Project Owners with day-to-day responsibility for the project should be granted Full access. Users with Full access will receive automatic email copies of all project notifications and alerts that are sent to the Project Owners.

Search for a User: [   ] [Search]

[Save]   [Cancel]

For instance, a search for last name Stanley would show the following:

Search for a User: stanley [Search]

User	Access Type			
Jules, Stanley	○ Full	○ Write	○ Read	⦿ No Access
Stanley, Jackie	○ Full	○ Write	○ Read	⦿ No Access
2 Users found, displaying all Users.				

5. Once you have shared the study with a research team member then they will receive an email notification regarding their access to the study. That team member can now attach documents and perform the tasks according to the access level granted.

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9. 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 create a new package to an already existing study. Once you have the study open just click on the "Create a New Package" button on the left side navigation bar.

Project Administration
Project Overview
Designer
Share this Project
Sign this Package
Submit this Package
Delete this Package
Send Project Mail
Reviews
Project History
Create a New Package
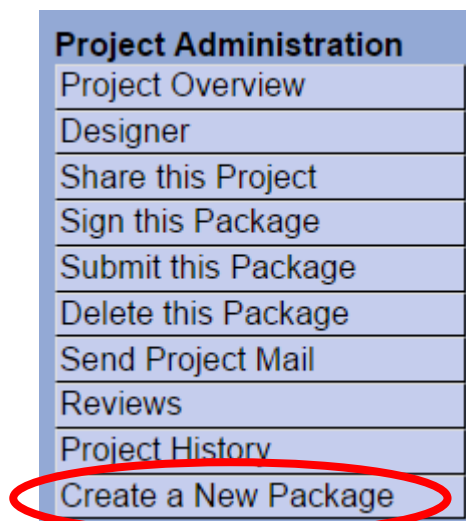
1. You will be brought to the *Designer* page so you can add the required documents for a closure request. Initially there will not be any documents in package. Click "Attach New Document" and upload the Closure Request form. You can upload a study summary if desired.

Documents in this Package:

There are no documents in this package.

There are no Training & Credentials records linked to this package. | Link / Un-Link Training Records |

Start a Wizard OR Attach New Document (When should I do this?)

2. Once a document has been selected from your computer you will see that the document has been attached to the package (see the box below). Under "Document Type" click the drop down arrow and pick the best match for the document you are uploading. If it is the Closure Request Form, select the "Closure/Final Report" choice. If the type of document you are submitting (i.e. the summary) is not in the list then choose "Other" and enter the type of document in the Description filed.

New and Revised Documents in this Package: | All Project Documents |

☆	Document Type	▲	Description	Last Modified
	▼ Closure/Final Report		Closure Request Form	02/19/2018 09:06 AM
	▼ Other		Closure report summary for longitudinal study	02/19/2018 09:06 AM

There are no Training & Credentials records linked to this package.

3. Once all documents have been uploaded and the package has been signed by the principal investigator, click the "Submit this Package" button on the left side navigation bar. All MU boards will appear on the list so highlight the board to which you are submitting. Click "Continue".

Please select a Board:

Search for an Organization	[ ] Search Clear
	✔ Only show My Default Boards
Select a Board *	Marshall University (MUSOM) Conflict of Interest Committee Marshall University IACUC Marshall University Institutional Review Board #1 (Medical) Marshall University Institutional Review Board #2 (Social/Behavioral)
	Continue Cancel
* required fields	

4. Under "Submission Type" select "Close/Final Report". The "Your Comments" section is optional so when finished just click "Submit".

5. Once you hit the Submit button, you will be given a confirmation showing the time the package 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.