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](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”.

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.

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. IRBNet Library

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”.

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 Drop Down List]

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.
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.
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.

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.

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

- **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 those 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.
8. 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.

9. You will be brought to a screen in which you can search for a user. Use the search tool 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.

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

Note: See next page for a description of Full, Write, and Read access.
Below is chart that describes the different level of access for any package. Grant the permissions you desire keeping in mind what level of access members of the research team 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.

10. 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.
11. 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.**

12. *(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.)*

13. Once you (and your professor, if applicable) have signed, 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”.

14. 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.

15. 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.
4. **Revision Instructions** (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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**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**

---

There are no documents in this package.

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

[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 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.

Documents in this Package:

<table>
<thead>
<tr>
<th>Document Type</th>
<th>Description</th>
<th>Last Modified</th>
</tr>
</thead>
<tbody>
<tr>
<td>(please select)</td>
<td>IRB2 Application 071316.docx</td>
<td>05/30/2017 03:20 PM</td>
</tr>
</tbody>
</table>

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”.

Please select a Board:
4. Under “Submission Type” select “Revision” for this type of package. The “Your Comments” section is optional so when finished just Click “Submit”.

![Image of IRBNet submission process]

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.
5. **Continuing Review 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.

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 |
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.

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:
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”.

![Image of IRBNet submission interface]

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.
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.

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”.
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”.

<table>
<thead>
<tr>
<th>Submission Type</th>
<th>Coordinator, Eyer B.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Your Comments</td>
<td></td>
</tr>
</tbody>
</table>

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.
7. 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 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 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.
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.

<table>
<thead>
<tr>
<th>Document Type</th>
<th>Description</th>
<th>Last Modified</th>
</tr>
</thead>
<tbody>
<tr>
<td>[please select]</td>
<td>IRB2 Application 071316.docx</td>
<td>05/30/2017 03:20 PM</td>
</tr>
</tbody>
</table>

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”.
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. **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.

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 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│
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.

![Document in 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”.

![Select a Board]

* 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.