User Manual

The Office of Research Integrity is pleased to provide Ball State researchers with this manual to assist them in using our online protocol submission system, IRBNet. Within this document you will find step by step instructions and assistance with first-time registration, submission, continuing review, modifications, adverse event reporting, and study closure. If you encounter any problems, or have questions regarding the protocol submission process, please contact the Office of Research Integrity.

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Registration

1. Navigate to [http://www.irbnet.org](http://www.irbnet.org)

2. Look for the login box, located in the upper right portion of the website.

3. Click on “New User Registration” (as circled).

4. Fill in the information necessary to create your account.

5. After you click “continue” accept the Terms of Use.
6. Select Ball State University. To do this, type "Ball State University" in the "search for an organization" space.
7. Click continue and enter your contact information. The e-mail address entered will be the one used to contact you regarding IRB decisions related your future protocol(s).
8. Confirm all the information that you have entered, and be sure that you are listed as a "Researcher" at Ball State University.
9. After completing your registration, you will receive an e-mail from IRBNet. Use the provided link within this e-mail to finalize your registration.
Creating your study

1. Navigate to www.irbnet.org and login using the username and password you created from the previous section. If you have not created an account, please follow the necessary steps in the “Registration” section of this manual.
2. On the left side of the page, select “Create New Project”.

3. The following screen will appear:
4. Enter the title of the project and your name. If the study is sponsored, please enter the funding agency’s name in the sponsor box. The keywords box may be useful for you if you have several studies and need to find this study at a later time based upon a specific keyword.

5. Click “continue”.

6. You will be taken to the “Designer” page, and the following screen will appear:

   **Step 1:**
   Download blank forms, document templates and reference materials to assist you in assembling your document package.
   - Select a Library: Ball State University IRB, Muncie, IN
   - Select a Document: IREI Human Subjects Research Application and Narrative v. 3

   **Step 2:**
   Assemble your document package. In addition to adding project documents to your package, IRBNet also allows you to link your project team’s Training & Credentials to your package.
   Documents in this Package:
   - There are currently no documents in this package.

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

   [Add New Document]

   All forms are located in the Library manager on IRBNet:

   ![IRBNet Library](image)

7. Make sure you have completed all pieces of the Human Subjects Research Application and Protocol Form and created separate documents for possible recruitment materials, surveys, and informed consent forms.
8. Within the “Designer” page, click “Add New Document”

   **Step 1:**
   Download blank forms, document templates and reference materials to assist you in assembling your document package.

   Select a Library: Ball State University IRB, Muncie, IN
   Select a Document: IRB Human Subjects Research Application and Narrative v. 3

   **Step 2:**
   Assemble your document package. In addition to adding project documents to your package, IRBNet also allows you to link your project team’s Training & Credentials to your package.

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

   There are no Training & Credentials records linked to this package. | [Link / Un-Link Training Records](#) |

9. Once you click, “Add New Document”, this screen will appear:

   You may attach documents to this package by clicking the “Browse...” button to locate a document and then by clicking “Attach”. The “Document Type” and optional “Description” are informational fields to assist you in managing your attached documents.

   ![Document Attachment Screen](image)

10. Within this Document Type, select “Application Form”.

11. Browse for the file on your computer and click “Attach”.

12. If you have additional materials (such as a file containing recruitment materials, survey questions, consent forms, proof of CITI training, letter of support, etc), complete these steps again. For document type, select the name that best represents what is in the additional document, or choose “Other” and type what the document is in the “Description” box.
13. Once all files have been uploaded, you need to share your study with others. **Student PI’s must share the project with faculty advisor before submitting.** This could also include other advisors or colleagues. To share your project with another person, the person must be registered with IRBNet.

14. Select the “Share this Project” link, located on the left side of the page. This is located under the “Project Administration” heading.

15. The following screen will appear, and you select the first option, “Share”:

You may share this project with other Researchers, Committee Members, Administrators and Sponsors. You may also send a complete copy of this project to a Principal Investigator at another site if this is a multi-site project. You may also transfer ownership of this project to another individual.

- **Share:** Use this option if you wish to share your project with other Researchers, Committee Members, Administrators or Sponsors at your own institution or any other institution. For example, you may wish to share this project with other members of your research team so that you may collaborate in the design and development of the project, or with a selected Committee Member or Administrator to solicit feedback prior to submitting your project for review. You may provide any individual with **Full, Write or Read** access.

- **Multi-site:** Use this option only if your project is a multi-site project and you wish to send a complete and independent copy of this project to a Principal Investigator at another site. The local Principal Investigator will be able to obtain project documents from the lead site 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 project at every local site. The other local Principal Investigators will also be able to monitor the progress of this project at every local site (including your own).

- **Transfer:** Transfer your ownership of this project to another user. In doing so you will relinquish all access to this project and the designated user will be granted **Full** access.
16. The following screen will appear, and you can search for the organization with which the person you would like to share the project with is affiliated:

You may share this project with other IRBNet users. Sharing a project consists of three steps:

1. Select an organization to display a list of IRBNet users at that organization.
2. Specify the access that you wish to grant each user at that organization.
3. Save your changes.

17. Once the organization is selected, you will need to search for the specific user using the page below. Please pay attention to the different sharing levels. You may want an advisor or a colleague to have a particular level of access.
18. Once the user is found, you may grant the appropriate level of access. Within the “Comments” box, you can enter any additional comments that will be included in the e-mail to the specified IRBNet user which notifies them of their new access to your protocol.

Search for a User: Cardinal

<table>
<thead>
<tr>
<th>IRBNet User</th>
<th>Permission Access</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cardinal, Charlie</td>
<td>○ Full ○ Write ○ Read ○ No Access</td>
</tr>
</tbody>
</table>

One User found.

Each user will be automatically notified that they have been granted access to this project. You may also specify additional comments to be included in this notification:

Your Comments

Save Cancel

19. The next step is to navigate to the “Sign this Package” section. Remember, student PI’s must have faculty advisor sign the package before you can submit the package for review.
20. Within the “Sign Package” page, you will need to select your role in the project. If you are the principal investigator, select this option from the drop down box.

21. Once you click “Sign,” you will receive a notification from IRBNet that you have signed the package. Anyone else that you selected to share the project with will receive an email notifying them of your signature too. Similarly, when your advisor signs the package, you will receive an email notification.

22. Once everyone has signed the package, you need to submit the package. A package cannot be submitted until everyone has signed the package. **If you have an advisor, the advisor must sign the package before you submit the package to the IRB for review.**

23. Unless all signatures are handled at once, you will likely need to access IRBNet at another time once you receive notification that everyone has signed the package. Sign back into your IRBNet account.

24. You can select your project from the list after signing in.

25. Look again to the “Project Administration” section and select “Submit this package.”
26. The page below will appear. You want to be sure to select “Ball State University IRB, Muncie, IN.” Once this is highlighted, click “Continue.”

IRBNet supports multiple models of review. Using the IRBNet “Submit” feature, you may electronically submit this document package to either a single Board, or to multiple Boards. Each Board you submit to will be notified of your submission and given access to view your electronic documents. Each Board will also be permitted to electronically record their review decision, which will be stored as a permanent part of your project record. You will be automatically notified when the review decision is electronically recorded.

Please select a Board:

27. You need to select the submission type, select “New Project” from the dropdown box. If you would like to include any comments that will be sent to the reviewers, feel free to do so. Click “Submit.”

28. The reviewers will now be notified of your submission and the review process can begin. You will receive a time stamp for the submission.
Minor Revisions (Unlock)

Minor modifications may be necessary after the applicable committee has reviewed your initial protocol submission. This section of the user manual will guide principal investigators in the steps necessary to submit minor modifications. You will receive an e-mail indicating that your project has been unlocked and modifications are required.

1. Login to www.irbnet.org with your username and password, and then click on the “My Projects” button on the left side navigation menu.

2. Select the project you wish to modify.
3. Click on “Unlocked – Revisions Pending” in red to the right of the Package number. On the next screen you will complete the requested changes.

4. Once the changes are made, click on “Mark Revisions Complete” to the right of Unlocked – Revisions Pending and View History to resubmit the revised study.

5. After you have locked your submission, reply to the e-mail you received from a member of the Office of Research Integrity to let them know you have made the requested changes.
Modification Submission (deferred letter)

Modifications may be necessary after the Institutional Review Board has reviewed your initial protocol submission. This section of the user manual will guide principal investigators in the steps necessary to submit modifications. You will receive an e-mail from the IRB Chair indicating that “Modifications are Required”.

1. Login to www.irbnet.org with your user name and password, and then click on the “My Projects” button on the left side navigation menu.

2. Select the project that you wish to modify.
3. The screen below will appear, click on “Designer” under the “Project Administration” tab on the left side of the page.

4. Click “Add New Document” to submit a revised document with requested changes (Note: changes should be made according to the deferral letter sent to the IRBNet e-mail address you provided).
5. Your project will be locked and you will be unable to edit documents that have already been submitted. Click “Create New Package” to submit a revised version of the documents requested.

6. Create, complete, and submit the appropriate documents. Reviewers will be interested in seeing changes that you have made from your original document. For minor changes, (e.g., grammatical changes), simply highlighting the change in the new document is sufficient. However, larger changes require a new document to be uploaded in its place.
7. In the document type menu, select the most appropriate match for the document you are uploading. If there is no match, select “Other” from the menu. Select the “Choose File” tab to browse your computer for desired file (arrow). Click the “Attach” button to upload the file to your package.

![Attach Document](Image)

8. Click the “Sign this Package” under the Project Administration menu on the left.
9. Once at the “Sign Package” screen, indicate your project role (arrow) and click “Sign”.

10. Your project is now ready to submit, click “Submit this Package” under the Project Administration menu.
11. Search for and select the proper review body at Ball State University (IRB, IACUC, IBC) and click “Continue”.

12. Select “Revision” for Submission Type (arrow), and then click “Submit”.

Submit Package
Modifying an Approved Study

1. Login to www.irbnet.org using your username and password.
2. Select “My Projects” on the left side of the screen.
3. Select the project that you want to modify.
4. Click on “Project History” under the Project Administration menu.

5. Click “Create New Package” at the bottom of the page.
6. “New Document Package” will appear, click this to be taken to the Designer page.

7. Fill out and complete the IRB Modification/Amendment Form.
   a. This can be obtained in the “Forms and Templates” section of IRBNet.
8. Prepare any additional relevant project documents indicated in the IRB Modification/Amendment Form. This could include: Informed consent documents, parental submission documents, surveys, recruitment letters or e-mails, introductory scripts, and any additional documentation that will assist the committee in understanding the changes you are making to the study. All changes must be highlighted, otherwise your study won’t be reviewed.
9. Click “Add New Document” near the middle of the screen.
10. In the Document Type box, select the category that best matches the document you are uploading. If you are uploading the modification amendment form, select “Amendment/Modification”. If you are uploading supporting documentation, pick the best match. If there is no match select “other”. Click “Choose File” (arrow) to browse your computer for the desired file. Once found, click “Attach” to upload the file to your package.

11. Repeat steps 9 and 10 for all additional supporting documents until they have been added to your package.

12. Click “Sign this Package” under the Project Administration menu on the left side of the screen.
13. Once at the **Sign Package** screen, indicate your **project role** (arrow) and click “**Sign**”.

13. Your modification/ amendment is now ready to submit, click “**Submit this Package**” under the **Project Administration** menu.
14. Search for and select the proper review body at Ball State University (IRB, IACUC, IBC) and click “Continue”.

15. Select “Amendment/Modification” for Submission Type (arrow), and then click “Submit”.

Submit Package
Continuing Review Submission (expedited and full board)

Projects may be approved for one or two years. You will be notified before your project expires. To continue working on a project you must submit and be approved for a continuing review before the expiration date.

1. Login to www.irbnet.org with your username and password.
2. Select “My Projects” on the left side of the screen.
3. Select the project for which you want to submit a continuing review.
4. Select “Project History” under the Project Administration menu.

5. Click “Create New Package” at the bottom of the page.
6. “New Document Package” will appear, click this to be taken to the Designer page.

7. Fill out and complete the IRB Continuing Review form.
   a. This can be obtained in the Forms and Templates section of IRBNet.

8. If you are making any modifications, you will need to fill out and submit the Human Subjects Modification Amendments Form in addition the Continuing Review Form. You must also include all necessary documentation (see the Modifying an Approved Study, page 20, of this manual for instructions).

9. Click “Add New Document” near the middle of the screen.
10. In the Document Type box, select the category that best matches the document you are uploading. If you are uploading the IRB Continuing Review Form, select “Continuing Review/Progress Report”. If you are uploading supporting documentation, pick the best match, if there is no match, select “Other”. Click “Choose File” (arrow) to browse your computer for the desired file. Once found, click “Attach” to upload the file to your package.

11. Repeat steps 9 and 10 for all additional supporting documents until they have been added to your package (if necessary).

12. Click “Sign this Package” under the Project Administration menu on the left side of the screen.
13. Once at the **Sign Package** screen, indicate your **project role** (arrow) and click “**Sign**”.

14. Your Annual Continuing Review is now ready to submit, click “Submit this Package” under the **Project Administration** menu.
15. Search for and select the proper review body at Ball State University (IRB, IACUC, IBC) and click “Continue”.

16. Select “Continuing Review/Progress Report” for Submission Type (arrow), and then click “Submit”.

Submit Package

The following IRBNet users at Ball State University IRB will be automatically notified of your submission:

Byers, Bryan
Mangilli, Chris
Mulcahey, John
Weaver, Jennifer

Submission Type: * Continuing Review/Progress Report

You may also specify additional comments to

Your Comments: 

Submit
Adverse Events Submission

NOTE: Non-serious adverse events (i.e. loss of non-identifiable data) must be submitted to the Office of Research Integrity within 5 business days. **Serious adverse events** (i.e. loss of identifiable data, injury, and/or death) must be reported within 24 hours.

1. Login to [www.irbnet.org](http://www.irbnet.org) with your username and password.
2. Select “My Projects” on the left side of the screen.

3. Select the project for which you want to submit an adverse event.
4. Select “Project History” under the Project Administration menu.

5. Click “Create New Package” at the bottom of the page.
6. “New Document Package” will appear, click this to be taken to the Designer page.

7. Fill out and complete the IRB Adverse Event form.
   a. This can be obtained in the Forms and Templates section of IRBNet.
8. Click “Add New Document” near the middle of the screen.
9. In the Document Type box, select the category that best matches the document you are uploading. If this is an adverse event or serious adverse event select “Adverse Event Report”. If this is an Unanticipated Problem select “Unanticipated Problem Report”. Click “Choose File” (arrow) to browse your computer for the desired file. Once found, click “Attach” to upload the file to your package.

10. Click “Sign this Package” under the Project Administration menu on the left side of the screen.
11. Once at the **Sign Package** screen, indicate your **project role** (arrow) and click “Sign”.

12. Your Adverse Event form is now ready to submit, click “Submit this Package” under the **Project Administration** menu.
13. Search for and select the proper review body at Ball State University (IRB, IACUC, IBC) and click “Continue”.

![Image of search interface]

**UNANTICIPATED PROBLEM SUBMISSION SEE STEP 14**

**SERIOUS ADVERSE EVENT AND ADVERSE EVENT SUBMISSION SEE STEP 15**

14. Select “Unanticipated Problem (UP)” for Submission Type (arrow), and then click “Submit”. *(ORI must be contacted within 5 days of the unanticipated problem.)*

![Image of submission interface]
15. Select “Adverse Event (non-UP)” for Submission Type (arrow), and then click “Submit”. *(ORI must be contacted within 24 hours of the unanticipated problem.)*
Final Report Submission (Expedited and Full Board)

When your project is complete, you will submit a final report submission to close your project on IRBNet.

1. Login to [www.irbnet.org](http://www.irbnet.org) with your username and password.
2. Select “My Projects” on the left side of the screen.

3. Select the project for which you want to submit a Final Report.
4. Select "Project History" under the Project Administration menu.

5. Click "Create New Package" at the bottom of the page.
6. “New Document Package” will appear, click this to be taken to the Designer page.

7. Fill out and complete the IRB Final Report form.
   a. This can be obtained in the Forms and Templates section of IRBNet.
7. Click “Add New Document” near the middle of the screen.
9. In the Document Type box, select the category that best matches the document you are uploading. If you are uploading the IRB Final Report, select “Closure/Final Report”. Click “Choose File” (arrow) to browse your computer for the desired file. Once found, click “Attach” to upload the file to your package.

10. Click “Sign this Package” under the Project Administration menu on the left side of the screen.
11. Once at the **Sign Package** screen, indicate your **project role** (arrow) and click **“Sign”**.

12. Your Final Report/ Study Closure form is now ready to submit, click **“Submit this Package”** under the **Project Administration** menu.
13. Search for and select the proper review body at Ball State University (IRB, IACUC, IBC) and click “Continue”.

![Search for an Organization](image)

14. Select “Closure/Final Report” for Submission Type (arrow), and then click “Submit”.

![Submit Package](image)