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.

Contact:

Office of Research Integrity
West Quad Room 200
(765) 285-5052
orihelp@bsu.edu

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Registration

1. Navigate to 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. Click on the provided link that was sent to you in the email, which will redirect you to IRBNet.org. Type your username and password to log in.

10. This will appear the first time you log into IRBNet:

11. Click **“Create a New Project”** if you want to get started on your IRB submission.

12. For the next steps, scroll down to Step 3 in the section on **“Creating your Study”** – page 6 of this user manual.
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 this is a sponsored study, 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 later, based upon a specific keyword.

5. Click “continue”.

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

![Designer page screenshot]

Click the drop down list to select which form you would like to download. Then click “Download”. You can also access all of the forms by clicking the “Forms and Templates” button.

7. Make sure you have completed all pieces of the IRB Application and created separate documents for possible recruitment materials, surveys, media permission forms, letters of support, FERPA release forms, informed consent forms, etc.

**Note:** There are many forms on IRBNet, you only need to download and complete the forms that are relevant for your study. If you have questions about which forms you need, please contact our office.
8. Within the “Designer” page, click “Attach New Document”

9. Click, “Attach New Document” and browse your computer for the file you want to attach. Click “Open” and then a list will appear on IRBNet which includes document type, the title of the document, and the date that the document was last updated on IRBNet. You also have the ability to view, edit, and delete the document.
10. 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.

11. Once all files have been uploaded, you may 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.

12. Select the “**Share this Project**” link, located on the left side of the page. This is located under the “Project Administration” heading.
13. 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.

14. 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:
15. Once you select the organization, 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.

Specify the access that you wish to grant to each user at Ball State 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

16. Once you find the user, 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 by email of their new access to your protocol. **NOTE: The email will automatically be sent to the email address they listed when the registered for IRBNet.**

Search for a User: Cardinal

Search

IRBNet User  Permission Access
Cardinal, Charlie  Full  Write  Read  No Access

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
17. The next step is to navigate to the “Sign this Package” section. Remember, **student PIs must have faculty advisor sign the package before you can submit the package for review.**

18. Within the “Sign Package” page, you will need to select your role in the project. For example, if you are the principal investigator, select this option from the drop down box.

Charlie Cardinal, as Principal Investigator, certify that to the best of my knowledge the information contained in this package is accurate, complete and is ready for submission. The electronic signature is intended to be the legally binding equivalent of a traditional handwritten signature.

To sign on behalf of an institutional official:
- Department Head
- Department Representative
- Institutional Official
- Monitor
- Other Signatory

**Principal Investigator**
- Research Coordinator
- Scientific Reviewer
- Sponsor
- Statistician
- Sub-Investigator
- Team Member

Notice: This page has not been signed.
19. Once you click “Sign,” you will be prompted to provide your IRBNet username and password

![Image of IRBNet login form]

20. Click “Continue” and you will receive an email from IRBNet notifying you 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. **Please note:** We do not allow anyone to sign on behalf of another person. You may not use the “Designee Signature Mode” to sign for another person.

21. A protocol cannot be approved until the PI and the advisor (if applicable) 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.**

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

23. You can select your project from the “My Projects” list after signing in.

24. Look again to the “Project Administration” section and select “Submit this package.”
25. The page below will appear.

- For **Animal Research**, select “Ball State University IACUC, Muncie, IN.”
- For **Research utilizing rDNA, biological materials (i.e. infectious agents) or potentially hazardous agents (i.e. carcinogens)**, select “Ball State University IBC, Muncie, IN.”
  - Please note that IBC is for the Institutional Biosafety Committee and not for Human Subjects Research. If you are conducting Human subjects Research, please submit to the IRB.
- For **Human Subjects Research**, select “Ball State University IRB, Muncie, IN.”

26. Once you highlight the correct option for your project, click **“Continue.”**
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 be notified of your submission and the review process can begin. You will receive a time stamp for the submission.
Minor Revisions (The board determined your project should be unlocked for small changes)

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. All changes in your documents (excluding the application PDF) must be highlighted, otherwise your study won’t be reviewed. You will also need to attach a separate document outlining all of the changes you made.

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.

All changes in your documents (excluding the application PDF) must be highlighted, otherwise your study won’t be reviewed. You will also need to attach a separate document outlining all of the changes you made.
4. Once the changes are made and all documents are attached, click on **“Mark Revisions Complete”** above **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.
Major Revisions (deferred letter – the board determined your study should be resubmitted with major changes)

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 a letter from the IRB Chair on IRBNet indicating that “Modifications are Required”. All changes in your documents (excluding the application PDF) must be highlighted, otherwise your study won’t be reviewed. You will also need to attach a separate document outlining all of the changes you made.

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. 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.

4. Create, complete, and submit the appropriate documents. Reviewers will be interested in seeing changes that you have made from your original documents. For minor changes, (e.g., grammatical changes), simply highlighting the change in the new document is sufficient. However, for larger changes/clarifications, please upload a word document outlining the changes you made.
5. 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 “Attach New Document” tab to browse your computer for other necessary files. Because you have created a new project, you must upload all documents for the IRB to review, as if it was a new study.

6. Click “Sign this Package” under the Project Administration menu on the left. If you are a student, your faculty advisor must sign this new package as well.

7. Once at the “Sign Package” screen, indicate your project role (arrow) and click “Sign”. 
8. Your project is now ready to submit, click “Submit this Package” under the Project Administration menu.

9. Search for and select the proper review body at Ball State University (IACUC, IBC, or IRB) and click “Continue”.
10. Select “Revision” for Submission Type (arrow), and then click “Submit”.

![Image of submission type selection with arrow pointing to "Revision" and "Submit" button highlighted]
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 found in the “Forms and Templates” section of IRBNet.

8. Prepare any additional relevant project documents indicated in the IRB Modification/Amendment Form. This may 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”.

11. Your modification/amendment is now ready to submit, click “Submit this Package” under the Project Administration menu.
12. Search for and select the proper review body. Type in “Ball State University” in the search bar. Click “Search”

13. Select the appropriate board for your study (IRB, IACUC, IBC) and click “Continue”.
14. Select “Amendment/Modification” for Submission Type (arrow), and then click “Submit”.

![Diagram showing the selection process for Submission Type and the notification of the users at Ball State University IRB. The arrow points to the selected option.]
Continuing Review Submission (expedited and full board)

As of January 2019, continuing reviews will typically only be required for full board protocols. Any expedited protocol that was submitted prior to January 2019 will still need a final continuing review to be submitted to the IRB. In certain cases, the IRB may require continuing reviews for expedited protocols submitted after January 2019. 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.

Please note: If you are making any modifications, you will need to fill out and submit the Human Subjects Modification Amendments Form in addition to the Continuing Review Form. You must also include all necessary documentation (see the Modifying an Approved Study, page 24, of this manual for instructions).

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 24, 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**”. **Please note:** If you are a student, your advisor must also sign the package.
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”.

![Image of IRBNet User Manual showing the selection of Continuing Review/Progress Report for Submission Type](image-url)
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 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”. Please note: **If you are a student, your faculty advisor must also sign this package.**

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”.

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.)

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 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.
   b. This can be found 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 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”. Please note: *If you are a student, your faculty advisor must also sign this project.*

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”.

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