

Office of Research Integrity

IRBNet User Manual

August 2021



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. You will find step-by-step instructions and assistance with first-time registration, submission, continuing review, modifications, adverse event reporting, and study closure within this document. If you encounter any problems or have questions regarding the protocol submission process, please contact the Office of Research Integrity.

Office of Research Integrity

West Quad Room 100 (765) 285-5052 orihelp@bsu.edu

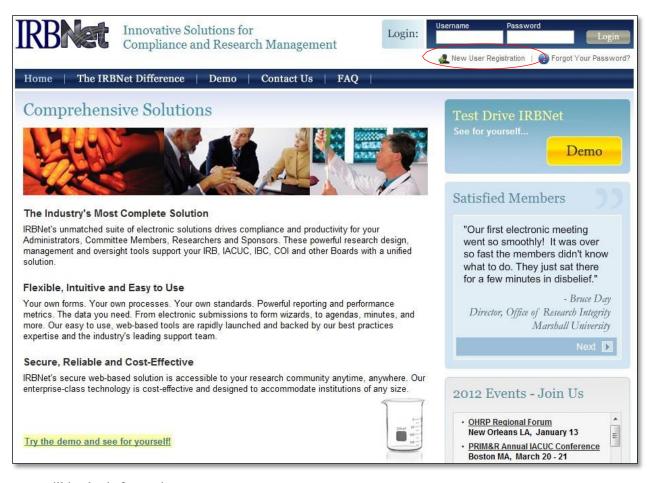
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Registration

- 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."

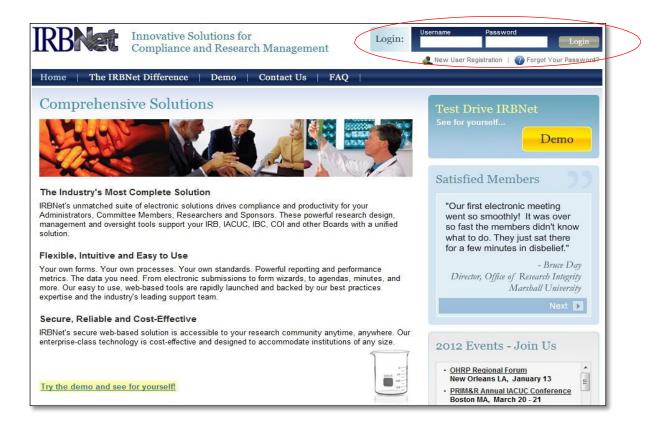


- 4. Fill in the information necessary to create your account.
- 5. After you click **"Continue,"** accept the Terms of Use.
- 6. Select Ball State University. To do this, type "Ball State University" in the "search for an organization" space.
- 7. Click "continue" and enter your contact information. The email address entered will be used to contact you regarding IRB decisions related to 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 email from IRBNet. Click on the provided link sent to you in the email, which will redirect you to IRBNet.org. Type your username and password to log in.



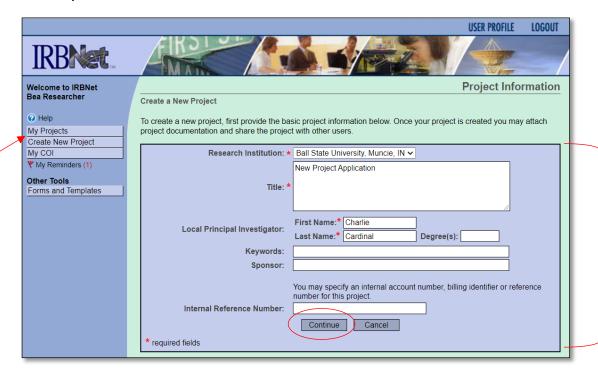
Creating a New Project

1. Navigate to www.irbnet.org and log in 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.

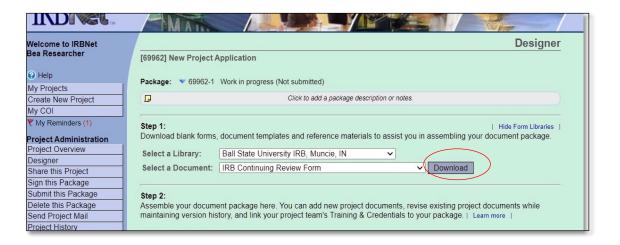




- 2. Select "Create New Project" from the left-hand menu. You should then see a screen that looks like the one below.
- 3. Enter the title of the project and your name. If this is a sponsored study, enter the funding agency's name in the sponsor box. The keywords box may be useful for you if you have several studies and need to find this study later, based upon a specific keyword. Any field marked with an asterisk (*) must be completed.
- 4. Once you are finished, click "Continue."

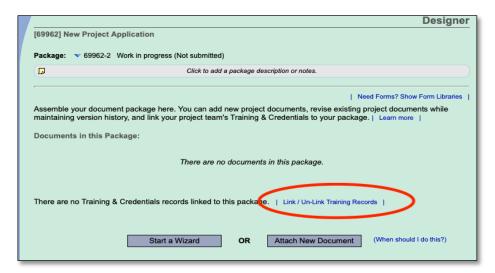


5. You can download any forms you may need via the Document dropdown menu under "Step 1" of this screen. You can return to this menu at a later time, so feel free to skip this for now.

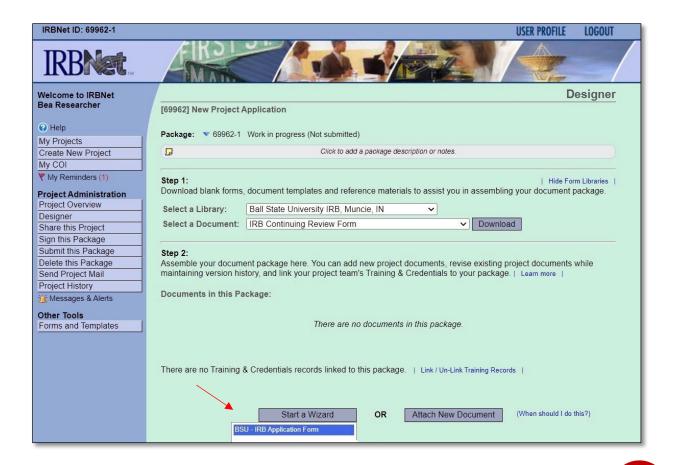




6. Link the CITI training of <u>all key personnel</u> to the package. Refer to page <u>17</u> for detailed instructions.



7. Access a new application form by clicking "Start a Wizard" and selecting the "BSU – IRB Application Form."

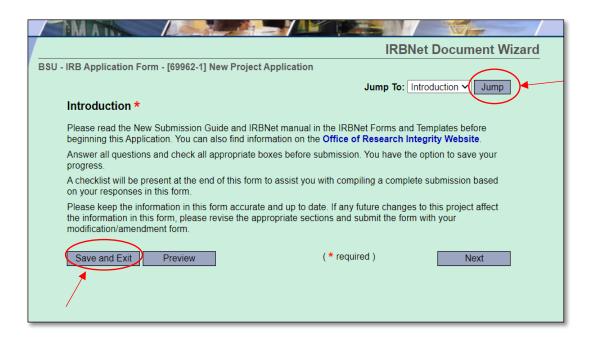




8. Create a new wizard and continue.



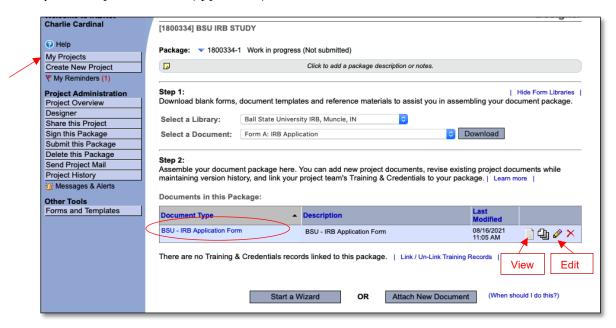
- 9. You should now be viewing the first page (Instructions) of the application form, as depicted below.
- 10. Complete the form as prompted. Anything marked with an asterisk (*) is required. Move to each new page by clicking "Next."
- 11. As you progress throughout the application, you will be able to navigate to different sections via the **"Jump To"** menu in the upper right-hand corner.



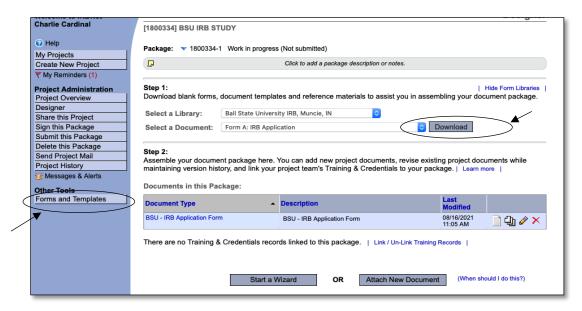
12. If you need to leave the form before it is completed, select "Save and Exit" in the bottom left. You can re-access the form at any time before final submission of your project by selecting the desired protocol from "My Projects" and clicking on the pencil icon.



- 13. Once you hit the **"Save and Exit"** button, you will be taken back to the Designer page. On the Designer page, the Wizard application form (BSU-IRB Application) will now appear as a new document in the package.
- 14. By clicking the document icon (**"View this document"**), you can download a PDF version of your competed Wizard (application) form.

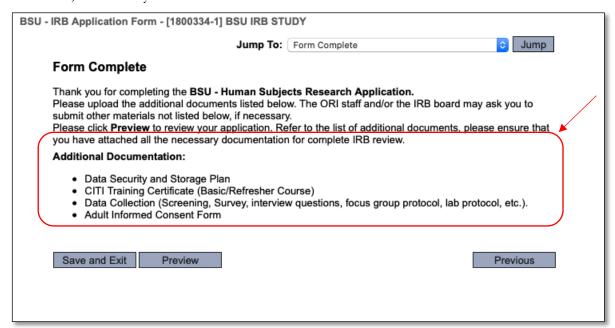


15. Click the drop-down list to select which form you would like to download. Then click "Download." You can also access all of the forms by clicking the "Forms and Templates" button.

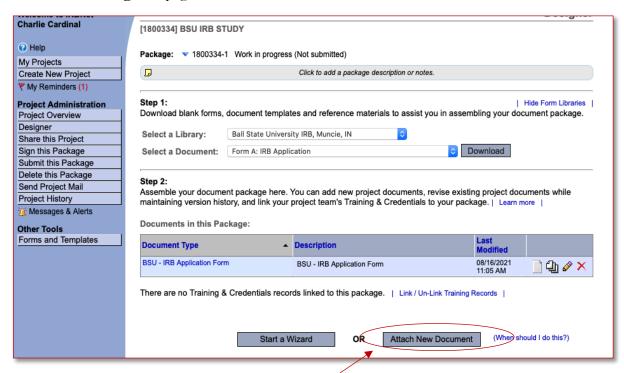




Note: You will see the list of supplementary documents you need to submit at the end of your wizard form. Please note that the IRB may ask you for additional documents not listed, if necessary.

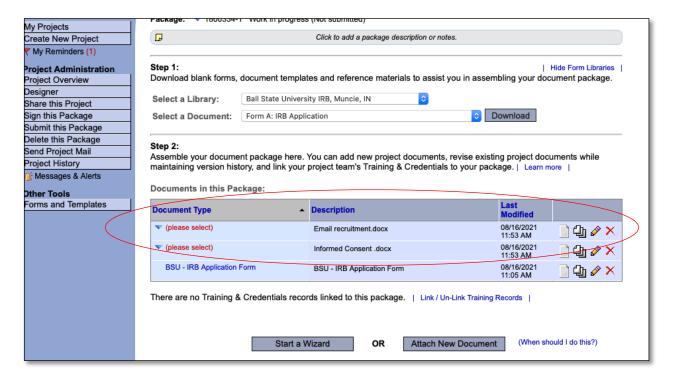


16. Within the "Designer" page, click "Attach New Document."





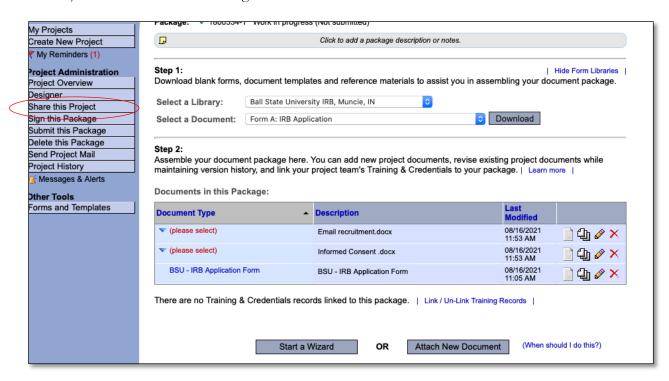
- 17. Click, "Attach New Document" and browse your computer for the file you want to attach. Click "Open," and then a list will appear on IRBNet, including document type, the title of the document, and the date that the document was last updated on IRBNet. You are also able to view, edit, and delete the document.
- 18. 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 one that best represents what is in the additional document, or choose "Other" and type what the document is in the "Description" box.



- Make sure you have completed all pieces of the IRB Application and create separate documents for possible recruitment materials, surveys, media permission forms, letters of support, FERPA release forms, informed consent forms, etc.
- If you have questions about which forms you need, please contact our office.
- 19. Once all files have been uploaded, you may need to share your study with others. To share your project with another person, the person must be registered with IRBNet.



20. Select the "**Share this Project**" located on the left side of the page. This is located underthe "Project Administration" heading.



21. 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.

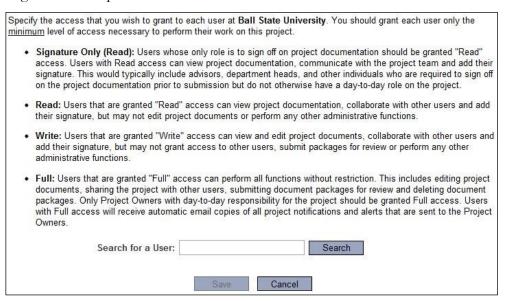
- Share: Use this option if you wish to share your project with other Researchers, Committee Members,
 Administrators or Sponsors at your own institution or any other institution. For example, you may wish to share this
 project with other members of your research team so that you may collaborate in 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.



22. 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.

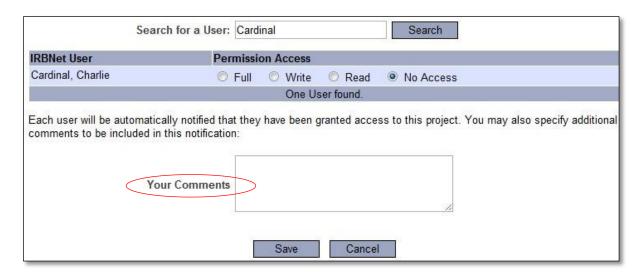


23. Once you select the organization, you will need to search for the specific user using the page below. Please pay attention to the different sharing levels. You may want an advisor or a colleague to have a particular level of access.

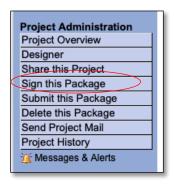




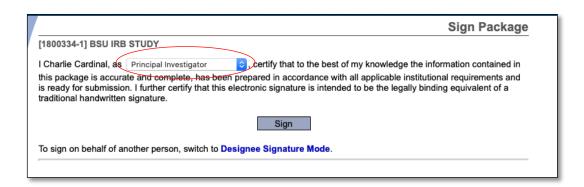
24. Once you find the user, you may grant the appropriate level of access. Within the "Comments"box, you can enter any additional comments that will be included in the email to the specified IRBNet user, which notifies them by email of their new access to your protocol. Note: The email will automatically be sent to their IRBNet- registered emails.



25. The next step is to navigate to the "Sign this Package" section.



26. Within the "**Sign this Package**" page, you will need to select your role in the project. For example, if you are the principal investigator, choose this option from the dropdown box.





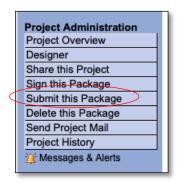
27. Once you click "Sign," you will be prompted to provide your IRBNet username and password.



28. 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 the notification as well.

Note: The ORI does not allow anyone to sign on behalf of another person. You may not use the "Designee Signature Mode" to sign for another person.

- 29. A protocol cannot be approved until the PI and co-PI (if applicable) have signed the package.
- 30. 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.
- 31. You can select your project from the "My Projects" list after signing in.
- 32. Look again to the "Project Administration" section and select "Submit this package."



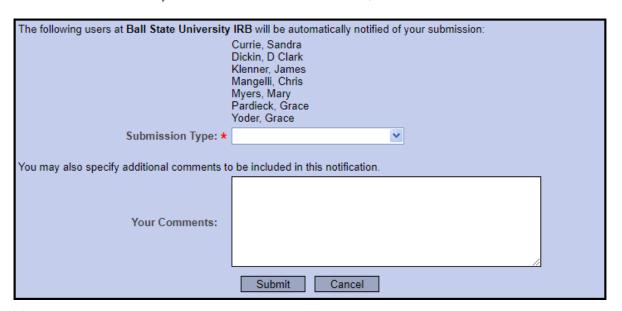
- 33. The page below will appear.
 - For Animal Research, select "Ball State University IACUC, Muncie, IN."
 - For Research utilizing rDNA, biological materials (i.e., infectious agents) or potentially hazardous agents (i.e., carcinogens), select "Ball State UniversityIBC, Muncie, IN."
 - Please note 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."



34. Once you highlight the correct option for your project, click "Continue."

IRBNet supports multiple models of review. Using the "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:	
Search for an Organization	Search Clear
Select a Board *	Only show My Default Boards Ball State University IACUC, Muncie, IN Ball State University IBC, Muncie, IN Ball State University IRB, Muncie, IN
* required fields	

35. You need to select the submission type, select "New Project" from the dropdown box. If you would like to include any comments sent to the reviewers, feel free to do so. Click "Submit."



36. The reviewers will be notified of your submission and the review process can begin.

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Linking Your CITI Training Certificate to IRBNet and Your Study Package

All researchers need to link their CITI training certificate to their IRBNet profile. By doing so, the IRB can track researchers' training records and expiration dates. Contact our office if you have any questions on which training courses are needed for your project.

- 1. Once you have completed your CITI training course(s), save the CITI training certificate(s) to your personal device. You can reference our CITI training user manual for assistance with this process.
- 2. Log in to **IRBNet**.
- 3. Click **User Profile** in the top right corner of the screen.



4. Scroll down to "Training & Credentials" and click Add a New Training & Credentials

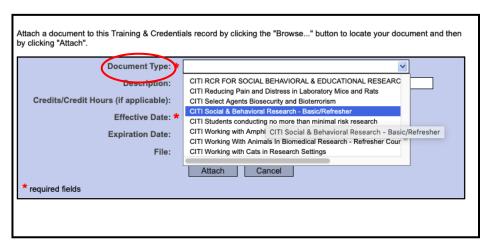
Training & Credentials

IRBNet allows your to track and share your training records, certifications, resumes and other personal credentials. Once added to your profile, your training and credentials can be easily linked to your projects from the Designer, are accessible by your project teams and can be quickly accessed and tracked by the boards that review your projects. Some boards also permit you to directly submit your training and credentials without requiring you to link these records to specific projects.

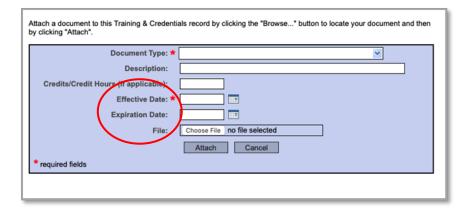
Add a New Training & Credentials Record



1) In the "**Document Type"** drop-down menu, select the certificate or training you want to upload (e.g., CITI Social & Behavioral Research - Basic/Refresher).



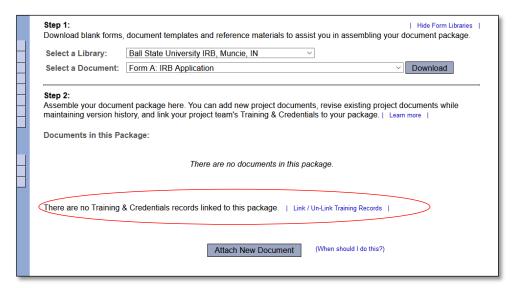
- 2) Enter your "Effective Date" and "Expiration Date," if applicable.
- 3) Click on **"Choose File"** and search your computer for your certificate/training file to upload.
- 4) Click on the "Attach" button.



Note: The project PI <u>and</u> all personnel listed on the project must provide the CITI certificates.

- 5. Next, reference the following to retrieve linked CITI certifications from your account or key personnel's accounts:
 - 1) Click "My Projects" on the left-hand side of the screen and select the project title you are working on.
 - 2) Under Project Administration, click "Designer."
 - 3) Under Step 2 of the Designer screen, you will see "There are no Training & Credentials records. | Link / Un-Link Training Records |."





4) Click "| Link / Un-Link Training Records |" and check the certificate(s) you want to link. You can link and unlink the certificates of your personnel as well.

Note: For the names of your personnel to show in the list, the project must be shared with them. Please see page 12 for assistance with this process.

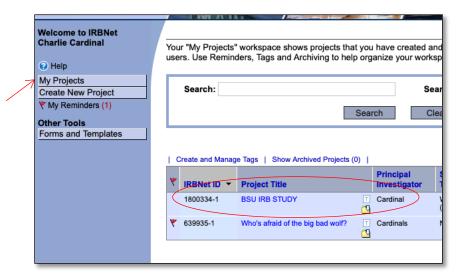
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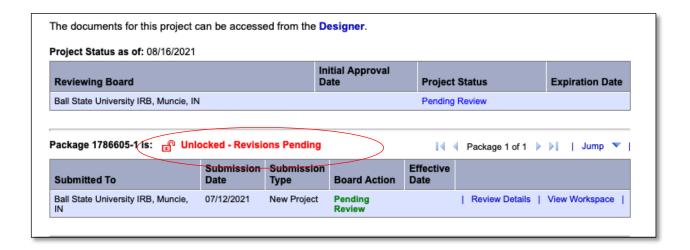
Pre-review Revisions

When you submit your application, the IRB administrator will pre-review your project to ensure your application is complete and clearly written prior to being reviewed by the Board reviewers. You will receive an email indicating that your project has been unlocked, along with a list of feedback. <u>All changes in your documents (except the application) must be highlighted. You also need to attach a separate word document outlining all the changes you have made.</u>

- 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.

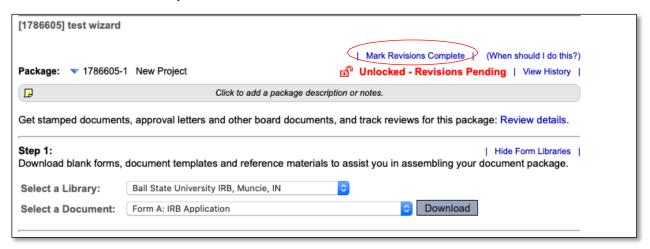


3. Click on **"Unlocked – Revisions Pending"** in red to the right of the Package number. On the next scree, you will complete the requested changes.





4. Once the changes are made and all documents are attached, relock your project by clicking 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 email you received from the ORI administrator to let them know you have made the requested changes.

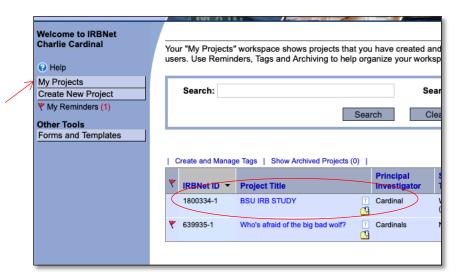
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Minor Revisions

Minor modifications may be necessary after the applicable committee has reviewed your protocol. The board determined your project should be unlocked for small changes. You will receive an email indicating that your project has been unlocked and modifications are required. All changes in your documents (excluding the IRB application) 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.

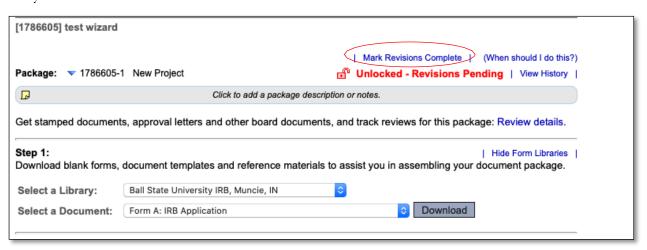


3. Click on "Unlocked – Revisions Pending" in red to the right of the Package number. On the next screen you will complete the requested changes.





4. Once the changes are made and all documents are attached, relock your project by clicking on "Mark Revisions Complete" above Unlocked – Revisions Pending to resubmit the revised study.



5. After you have locked your submission, reply to the email you received from a member of the Office of Research Integrity to let them know you have made the requested changes.

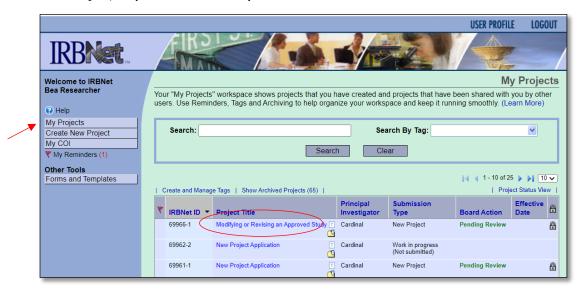
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Major Revisions

When the IRB board determines your study should be resubmitted with major changes, you will receive a deferred letter from the IRB on IRBNet with the list of modifications required. All changes in your documents (excluding the IRB application) must be highlighted. You will also need to upload a separate word document outlining all of the changes you have 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.

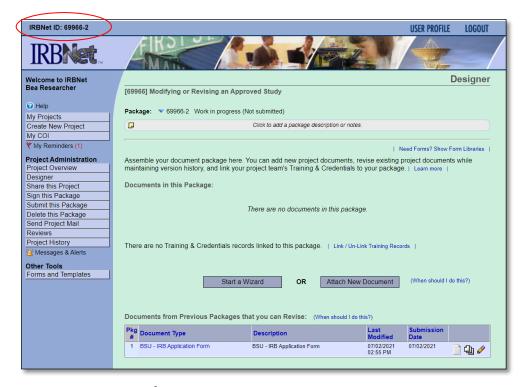


3. Next, click "Create a New Package" on the left.

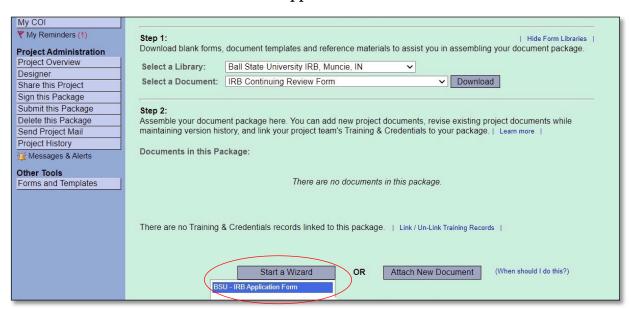




- a. You should now be viewing a new package like the one below. Although it is a "new" package, it is still affiliated with the original submission.
- b. You can verify that you have successfully created a new package by making sure the "dash number" of your IRBNet ID number has increased by one from the previous submission. In this case, we increased from [69966-1] to [69966-2].



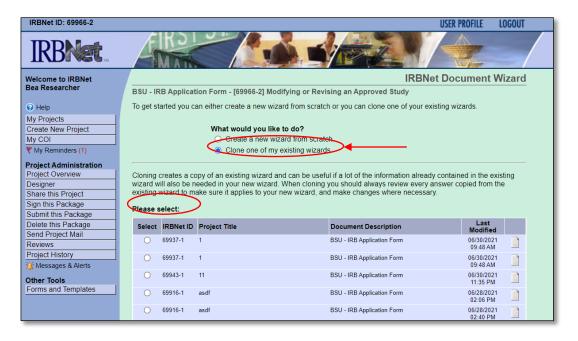
4. Click on "Start a Wizard" → "BSU – IRB Application Form."



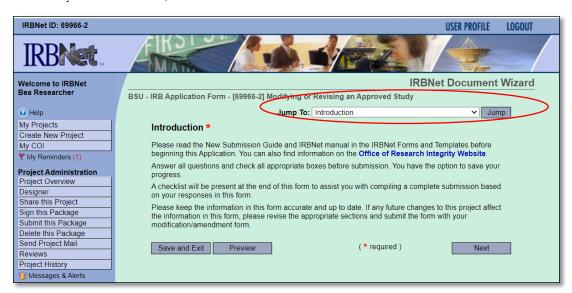


5. Click "Clone one of my existing wizards."

a. A list of past documents will appear. Select the application form from the submission that you are modifying or revising.

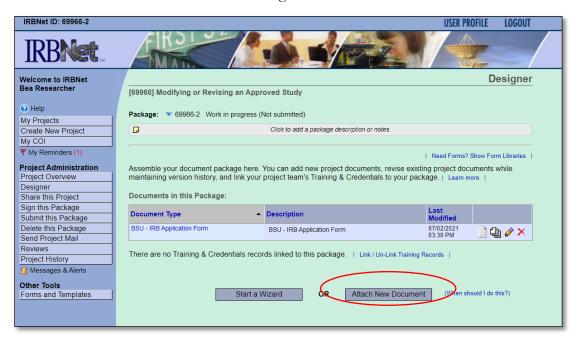


- 6. You will be brought to the start of the application you selected.
 - a. Use the **"Jump"** feature in the top-right to navigate to the section(s) of the application that you are modifying.
 - b. Make any necessary changes to the application form.
 - c. When you are finished, click "Save and Exit" on the bottom-left.

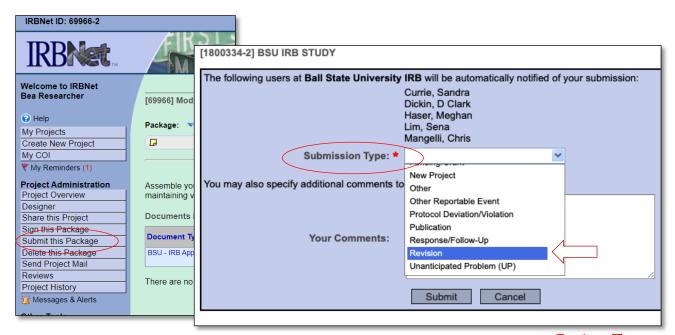




- 7. In addition to reflecting any modifications within your application form, you are to also upload a word document outlining all of the changes you have made.
- 8. Upload the completed modification form and any other necessary documents by clicking on "Attach New Document" in the bottom-right.



9. Once you are finished updating your application form and uploading any other necessary documents, share (if applicable), sign, and submit your revision to the IRB. Please refer to page 11 for the rest of steps. Please be sure to mark the submission type as revision.





Modification/Amendment after Approval

If you want to modify your study after approval, you must submit a modification/amendment form with updated application and documents. All changes in your documents (excluding the application) must be highlighted.

- 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.

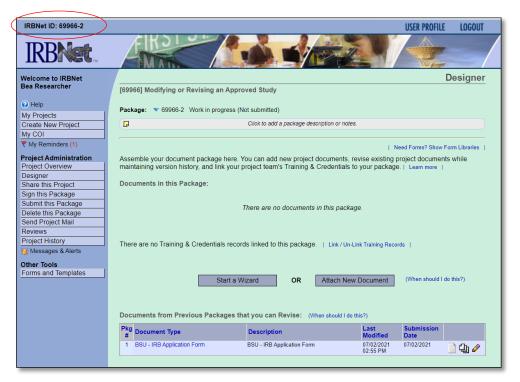


3. Next, click "Create a New Package" on the left.

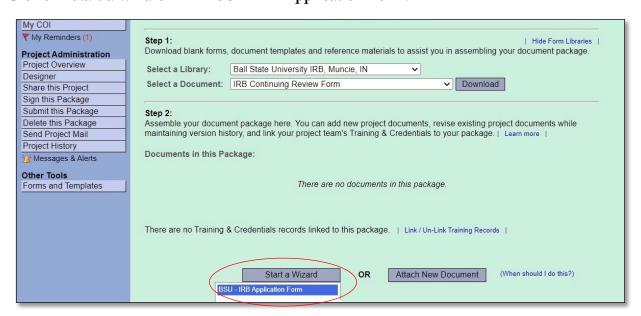




- a. You should now be viewing a new package like the one below. Although it is a "new" package, it is still affiliated with the original submission.
- b. You can verify that you have successfully created a new package by making sure the "dash number" of your IRBNet ID number has increased by one from the previous submission. In this case, we increased from [69966-1] to [69966-2].



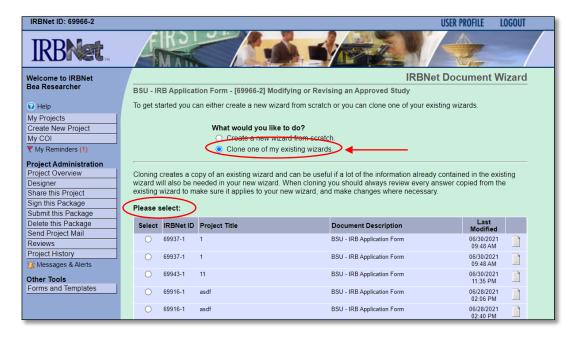
4. Click on "Start a Wizard" → "BSU – IRB Application Form."



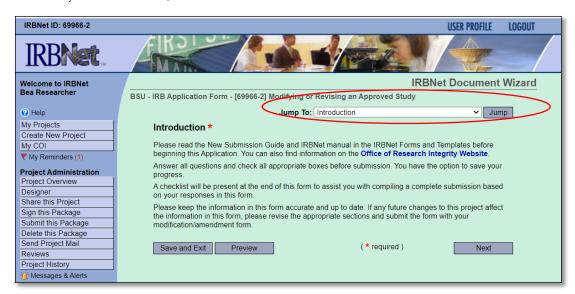


5. Click "Clone one of my existing wizards."

b. A list of past documents will appear. Select the application form from the submission that you are modifying or revising.

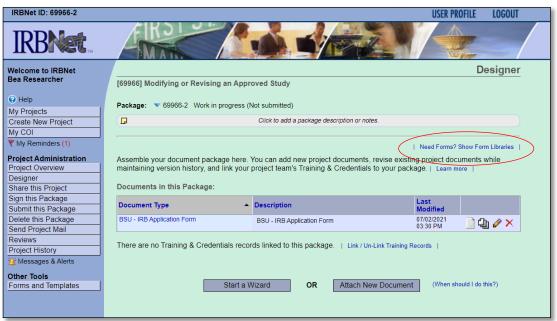


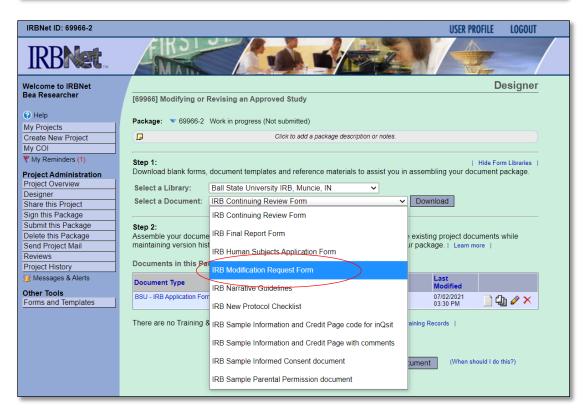
- 6. You will be brought to the start of the application you selected.
 - d. Use the "Jump" feature in the top-right to navigate to the section(s) of the application that you are modifying or revising.
 - e. Make any necessary changes to the application form.
 - f. When you are finished, click "Save and Exit" on the bottom-left.





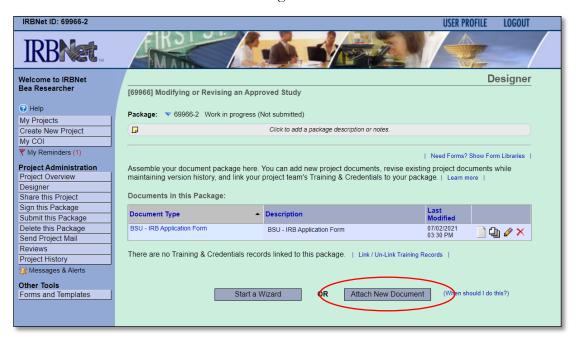
- 7. In addition to reflecting any modifications within your application form, you are to also upload an amendment/modification form.
 - a. Download this and any other relevant forms from the document library by clicking on "| Need Forms? Show Form Libraries |" in the top-right.



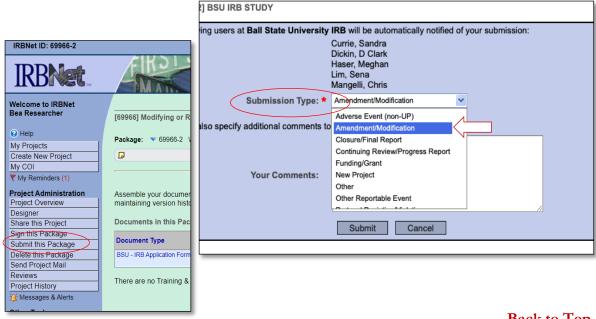




8. Upload the completed modification form and any other necessary documents by clicking on "Attach New Document" in the bottom-right.



9. Once you are finished updating your application form and uploading any other necessary documents, share (if applicable), sign, and submit your modification to the IRB. Please refer to page 11 for the rest of steps. Please be sure to mark the submission type as amendment/modification.



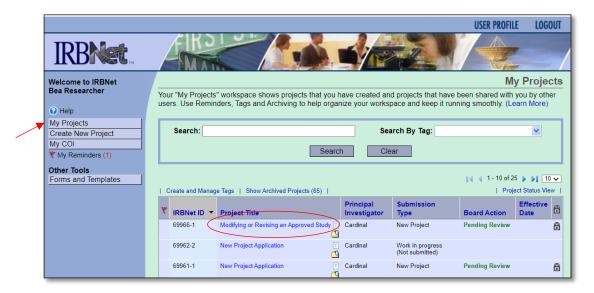


Continuing Review Submission (expedited and full board)

As of January 2019, continuing reviews will typically only be required for full board protocols. Any expedited protocol submitted prior to January 2019 will still need a final continuing review 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 need to create another package as an amendment/modification. See the Modification/Amendments after Approval, page 28, 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.



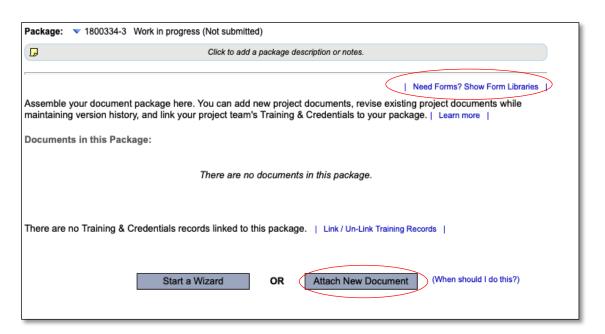


4. Next, click "Create a New Package" on the left.



- 5. Fill out and complete the IRB Continuing Review form.

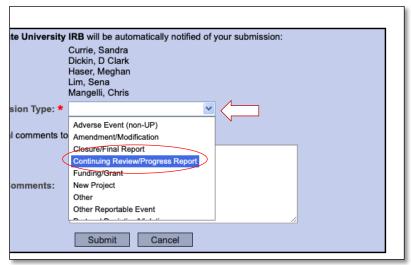
 Download this and any other relevant forms from the document library by clicking on "| Need Forms? Show Form Libraries |" in the top-right.
- 6. Upload the completed modification form and any other necessary documents by clicking on "Attach New Document" in the bottom-right.





7. Once you are finished updating your uploading continuing review and other necessary documents, share (if applicable), sign, and submit your revision to the IRB. Refer to <u>page 11</u> for the rest of steps. Please be sure to mark the submission type as continuing review.





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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, and then click on the "My Projects" button on the left side navigation menu.
- 2. Select the project you wish to submit an adverse event.

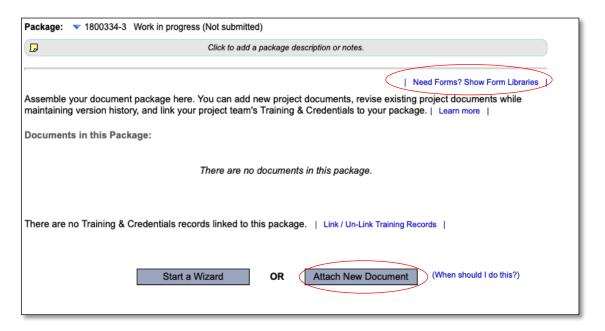


3. Next, click "Create a New Package" on the left.





- 4. Fill out and complete the "Adverse Event Report" or "Unanticipated Problem Report." Download this and any other relevant forms from the document library by clicking on "| Need Forms? Show Form Libraries |" in the top-right.
- 5. Upload the completed form and any other necessary documents by clicking on "Attach New Document" in the bottom-right.

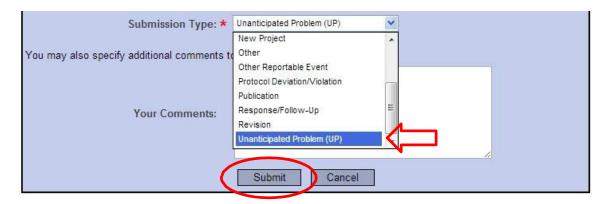


6. Once you are finished updating your uploading continuing review and other necessary documents, share ((if applicable), sign, and submit your revision to the IRB. Refer to page 11 for the rest of steps.

UNANTICIPATED PROBLEM SUBMISSION SEE STEP 7SERIOUS ADVERSE EVENT AND ADVERSE EVENT SUBMISSIOM SEE STEP 8

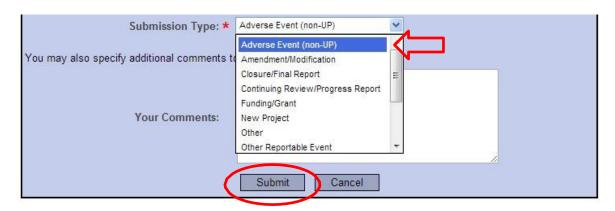
7. Select "Unanticipated Problem (UP)" for Submission Type (arrow), and then click "Submit."

Note: ORI must be contacted within 5 days of the unanticipated problem.





8. Select "Adverse Event (non-UP)" for Submission Type (arrow), and then click "Submit." Note: ORI must be contacted within 24 hours of the unanticipated problem.



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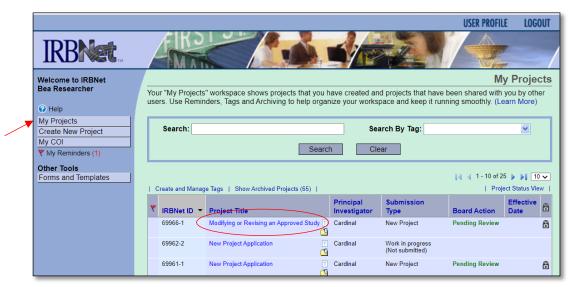


Final Report Submission (Expedited and Full Board)

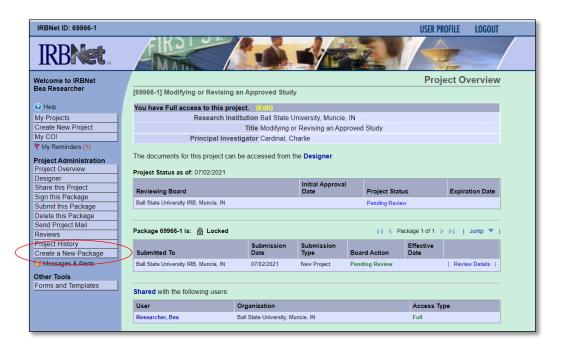
When your project is complete, you will submit a final report submission to close your project on IRBNet.

Note: It is not mandatory, but exempt and expedited studies with no expiration date are also recommended to submit a final report.

- 1. Login to <u>www.irbnet.org</u> 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.



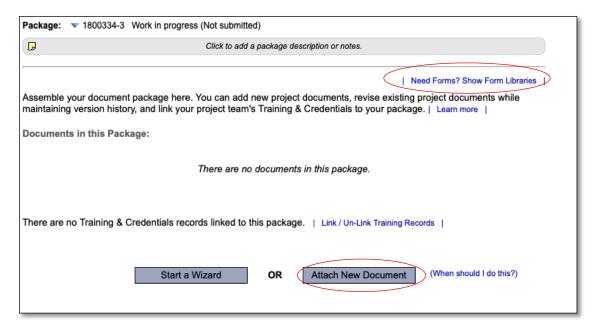
4. Next, click "Create a New Package" on the left.





- 5. Fill out and complete the IRB Final Report.

 Download this and any other relevant forms from the document library by clicking on "| Need Forms? Show Form Libraries |" in the top-right.
- 6. Upload the completed modification form and any other necessary documents by clicking on "Attach New Document" in the bottom-right.



7. Once you are finished updating your uploading continuing review and other necessary documents, share (if applicable), sign, and submit your revision to the IRB. Refer to <u>page 11</u> for the rest of steps. Please be sure to mark the submission type as Closure/Final Report.



