

Office of Research Integrity

IRBNet User Manual

3/20/2019





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

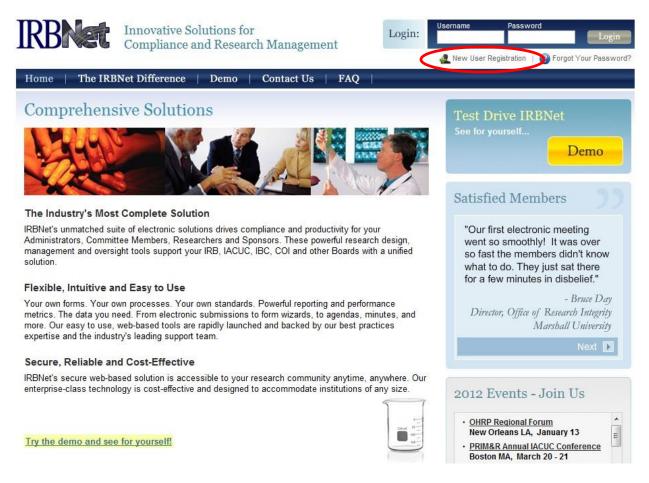
Contents

Registration3	
Creating your study 5	
Minor Revisions (Unlock) 16	
Modification Submission (Deferred letter)	19
Modifying an Approved Study	24
Annual Continuing Review Submission (Expedited and Full Board)	31
Adverse Events Submission	38
Final Report Submission (Expedited and Full Board)	45



Registration

1. Navigate to http://www.irbnet.org



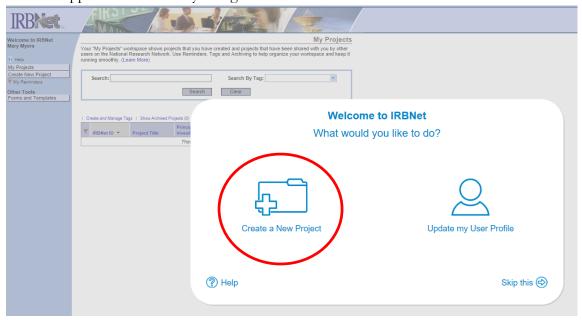
- 2. Look for the login box, located in the upper right portion of the website.
- 3. Click on "New User Registration" (as circled).



- 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:

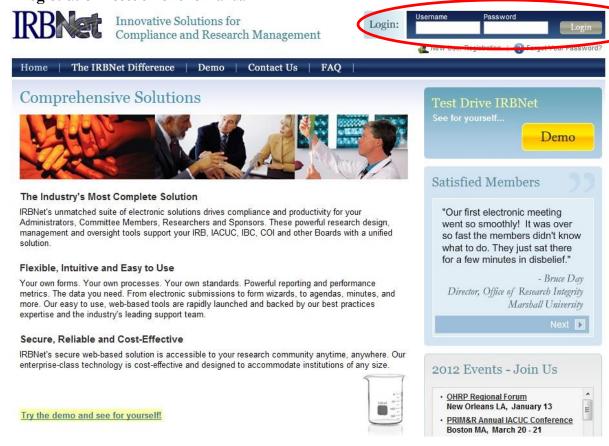


- 11. Click "Create a New Project" if you want to get started on your IRB submission.
- 12. For the next steps, scroll down to Step 3 in the section on "Creating your Study" page 6 of this user manual.



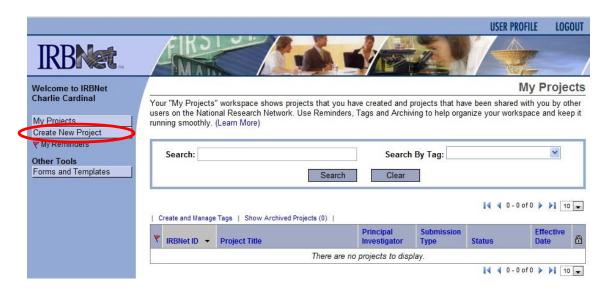
Creating your study

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:

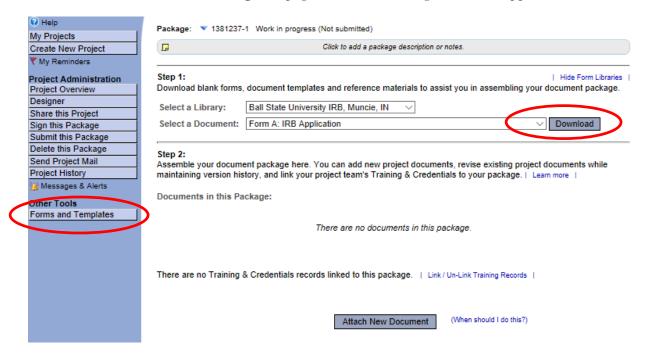
Create a New Project

To create a new project, first provide the basic project information below. Once your project is created you may attach project documentation and share the project with other users.

Research Institution:	Ball State University, Muncie, IN
Title: **	
Local Principal Investigator: Keywords: Sponsor:	First Name:* Last Name:* Degree(s):
Internal Reference Number:	You may specify an internal account number, billing identifier or reference number for this project. Continue Cancel
* required fields	



- 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:



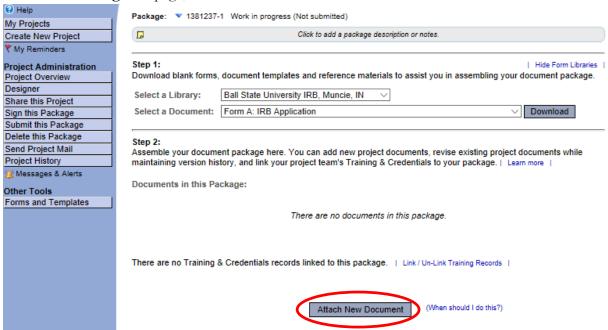
Click the drop down list to select which form you would like to download. Then click "**Download**". You can also access all of the forms by clicking the "**Forms and Templates**" button.

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"

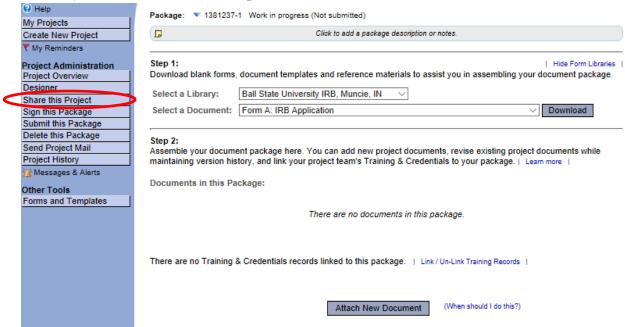


9. Click, "Attach New Document" and browse your computer for the file you want to attach. Click "Open" and then a list will appear on IRBNet which includes document type, the title of the document, and the date that the document was last updated on IRBNet. You also have the ability to view, edit, and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

Select a Library: Select a Document:	Ball State University IRB, Muncie, IN Form A: IRB Application Download					
maintaining version his	story, and link your	You can add new project documents, revise exis project team's Training & Credentials to your pa				
Document Type	•	→ Description Last Modified				
▼ (please select)	Form A- IRB HSR Application and Protocol Form v 01/23/2019 9-fillable-1-8-9 (1).pdf 05:47 PM					
(picase select)						
,,	Credentials recor	rds linked to this package. Link/Un-Link Trainin	n Records			



- 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**<u>must</u> 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.

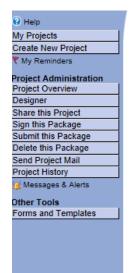




13. The following screen will appear, and you select the first option, "Share":

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:



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

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

Organization types to display ✓ Research Institutions ☐ Boards ☐ Sponsors ☐ Display	
4Dclass, Beijing, China	^
A.T. Still University, Mesa, AZ	
Abilene Christian University, Abilene, TX	
Select an Organization* Abt SDBI New York NV	
ADI SRDI, New YOR, NY	
Abused Adult Resource Center, Bismarck, ND	
Ackerman Academy of Dermatopathology, New York, NY	
Action Counseling Services, Roswell, NM	~
Select Organization	
* required fields	
required lietus	



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 <u>minimum</u> 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

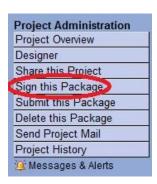
16. Once you find the user, you may grant the appropriate level of access. Within the "Comments" box, you can enter any additional comments that will be included in the e-mail to the specified IRBNet user, which notifies them by email of their new access to your protocol. NOTE: The email will automatically be sent to the email address they listed when the registered for IRBNet.

IRBNet User	Permi	ssion	Access			
Cardinal, Charlie	⊚ Fu	11 (Write	Read	0	No Access
			One U	ser found.		
Each user will be automatically not comments to be included in this no		iey ha	ave been	granted acce	ss to	this proj
		iey ha	ave been	granted acce	ss to	this projec
		ney ha	ave been	granted acce	ss to	this projec
	otification:	ney ha	ave been (granted acce	ss to	this projec

Cancel



17. The next step is to navigate to the "Sign this Package" section. Remember, **student PIs must** have faculty advisor sign the package <u>before</u> 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.

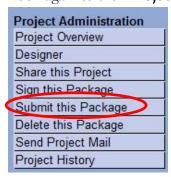




19. Once you click "Sign," you will be prompted to provide your IRBNet username and password

Please provide your IRBNet username and password to continue.
Username: Password:
Continue

- 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."

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	
	Only show My Default Boards	
	Ball State University IACUC, Muncie, IN Ball State University IBC, Muncie, IN	٨
	Ball State University IRB, Muncie, IN	
Select a Board *		
		_
	Continue	
* required fields		

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**."

The following users at Ball State University	IRB will be automatically notified of your submission:
	Currie, Sandra Dickin, D Clark Klenner, James Mangelli, Chris Myers, Mary Pardieck, Grace Yoder, Grace
Submission Type: *	▼
You may also specify additional comments to	be included in this notification.
Your Comments:	
	Submit Cancel

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)

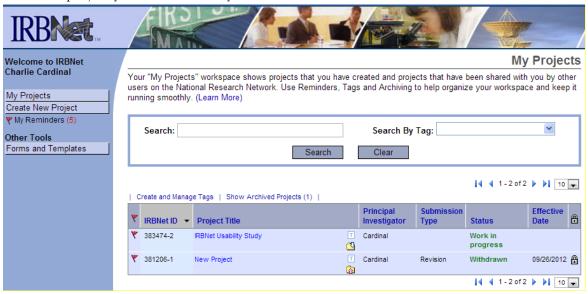
Minor modifications may be necessary after the applicable committee has reviewed your initial protocol submission. This section of the user manual will guide principal investigators in the steps necessary to submit minor modifications. You will receive an e-mail indicating that your project has been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

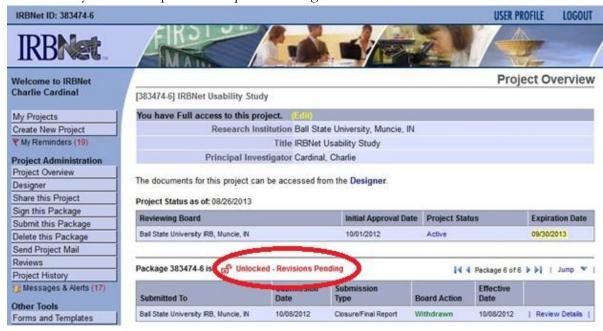




2. Select the project you wish to modify.

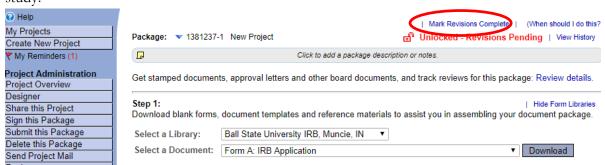


3. Click on "Unlocked – Revisions Pending" in red to the right of the Package number. On the next screen you will complete the requested changes.



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.

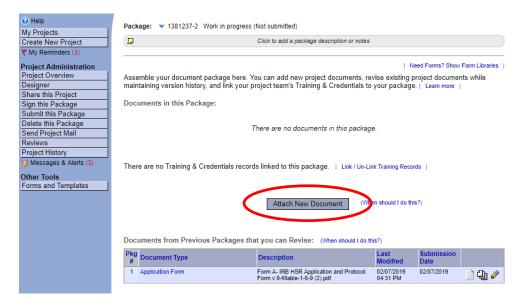
IRBNet	file		1					
Welcome to IRBNet	7					ı	Ny Projec	ts
My Projects Create New Project Way Reminders (5) Other Tools Forms and Templates		ts" workspace shows projects t ional Research Network. Use R y. (Learn More)			to help organi			
	Create and Mana	ge Tags Show Archived Projects	(1) [14 4 1-20	of 2 > >1 10	•
	W IRRNALID	Project fide	Annes.	Principal Investigator	Submission Type	Status	Effective Date	8
	¥ 383474-2	RBNet Usability Study		Cardinal	New Project	Deferred		
	₹ 381206-1	New Project	Ū	Cardinal	Revision	Withdrawn	09/26/2012	a



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.

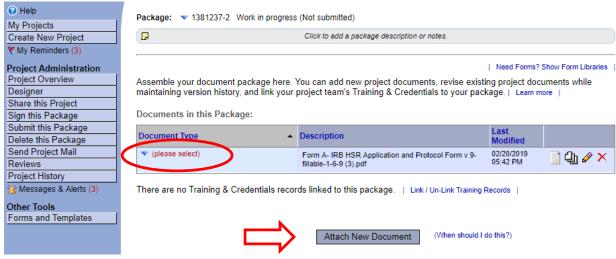


4. Create, complete, and submit the appropriate documents. Reviewers will be interested in seeing changes that you have made from your original documents. For minor changes, (e.g., grammatical changes), simply highlighting the change in the new document is sufficient. However, for larger changes/clarifications, 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.

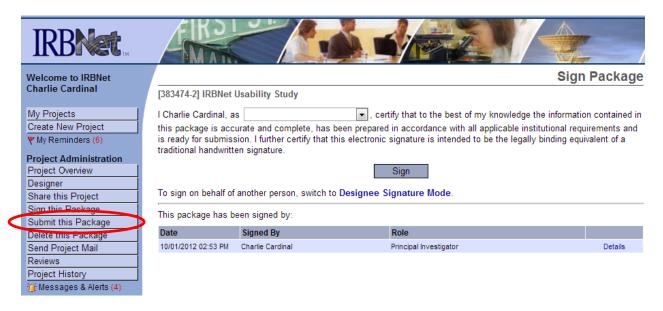


- 6. Click "Sign this Package" under the Project Administration menu on the left. If you are a student, your faculty advisor must sign this new package as well.
- 7. Once at the "Sign Package" screen, indicate your project role (arrow) and click "Sign".





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".

Please select a Board:

Search for an Organization	Search Clear
	✓ Only show My Default Boards
	Ball State University IACUC, Muncie, IN Ball State University IBC, Muncie, IN
	Ball State University IRB, Muncie, IN
Select a Board *	
	•
	Continue Cancel
* required fields	



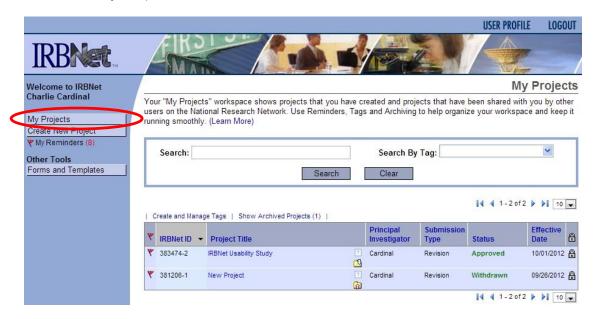
10. Select "Revision" for Submission Type (arrow), and then click "Submit".

The following users at Ball State University	IRB will be automatically notified of your submission:
	Currie, Sandra Dickin, D Clark Klenner, James Mangelli, Chris Myers, Mary Pardieck, Grace Yoder, Grace
Submission Type: *	<u> </u>
You may also specify additional comments to	Other Reportable Event Protocol Deviation/Violation Publication Response/Follow-Up Revision Unanticipated Problem (UP)
	Submit Cancel

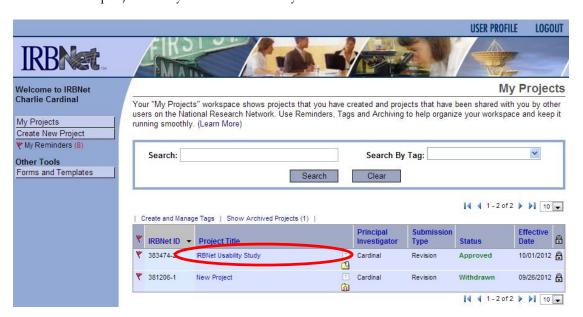


Modifying an Approved Study

- 1. Login to www.irbnet.org using your username and password.
- 2. Select "My Projects" on the left side of the screen.

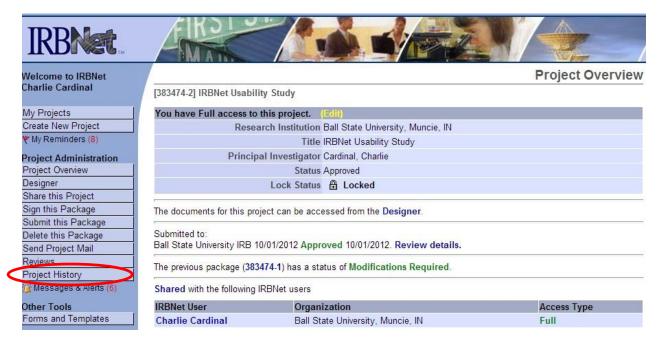


3. Select the project that you want to modify.



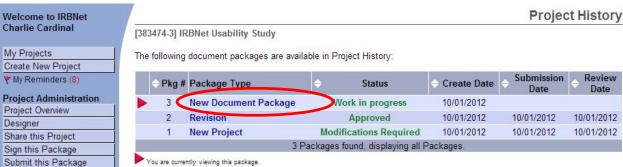


4. Click on "Project History" under the Project Administration menu.



5. Click "Create New Package" at the bottom of the page.



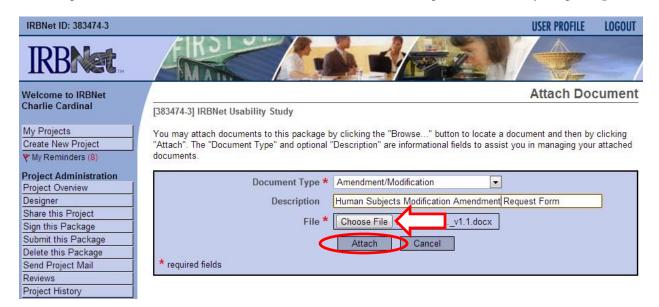


- 7. Fill out and complete the **IRB Modification/Amendment Form**.
 - This can be found in the "Forms and Templates" section of IRBNet.
- 8. Prepare any additional relevant project documents indicated in the IRB Modification/Amendment Form. This may include: Informed consent documents, parental submission 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.

Welcome to IRBNet				Design
Charlie Cardinal	[383474-3] IRBNet Usa	ability Study		
My Projects	Step 1:	1.		re en
Create New Project	Download blank forms,	document templates and reference materi	als to assist you in a	ssembling your document package
♥ My Reminders (8)	Select a Library:	Ball State University IRB, Muncie, IN	•	
Project Administration	Select a Document:	Child Assent (Sample)	•	Download
Project Overview	Select a Document:	Child Assent (Sample)		Download
Designer	j.			
Share this Project	Step 2:			
Sign this Package		ent package. In addition to adding project o	documents to your pa	ackage, IRBNet also allows you to
Submit this Package	link your project team's	Training & Credentials to your package.		
Delete this Package	New and Revised Do	cuments in this Package:		
Send Project Mail				
Reviews		Th		2
Project History	There are currently no documents in this package.			
Messages & Alerts (6)				
Other Tools	5000 5500 5000			
Forms and Templates	There are no Training &	Credentials records linked to this packag	e. Link / Un-Link Trair	ning Records
	IRBNet allows you to re your package. Learn r			
		Add New Doc	cument (When hould	d I do this?)



10. In the Document Type box, select the category the bests 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.

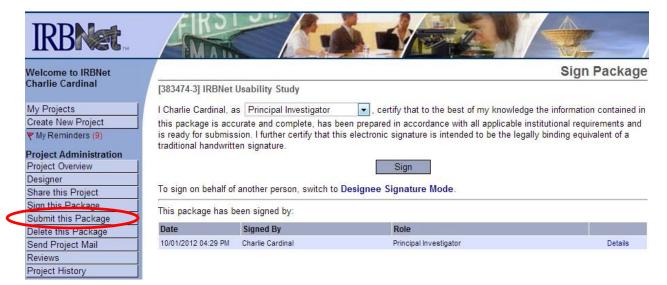




13. Once at the Sign Package screen, indicate your project role (arrow) and click "Sign".



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"

Please select a Board:



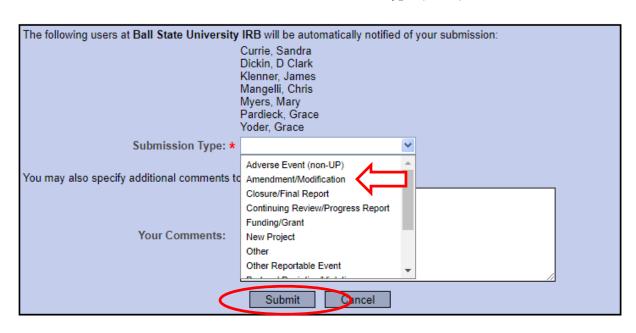
13. Select the appropriate board for your study (IRB, IACUC, IBC) and click "Continue".

Please select a Board:

Search for an Organization	Search Clear				
	✓ Only show My Default Boards				
	Ball State University IBC, Muncie, IN	^			
	Ball State University IRB, Muncie, IN				
Select a Board *					
		Ţ.			
Continue					
* required fields					



14. Select "Amendment/Modification" for Submission Type (arrow), and then click "Submit".





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 the Continuing Review Form. You must also include all necessary documentation (see the *Modifying an Approved Study*, page 24, of

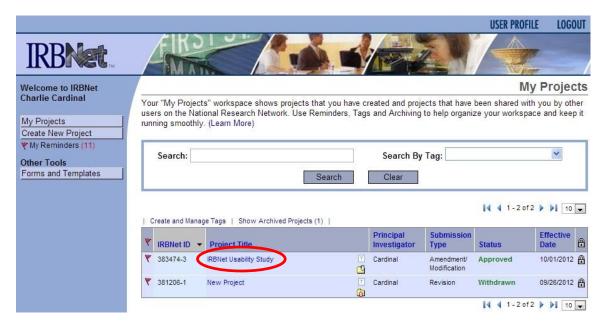
You must also include all necessary documentation (see the *Modifying an Approved Study*, page 24, of this manual for instructions).

- 1. Login to <u>www.irbnet.org</u> with your username and password.
- 2. Select "My Projects" on the left side of the screen.

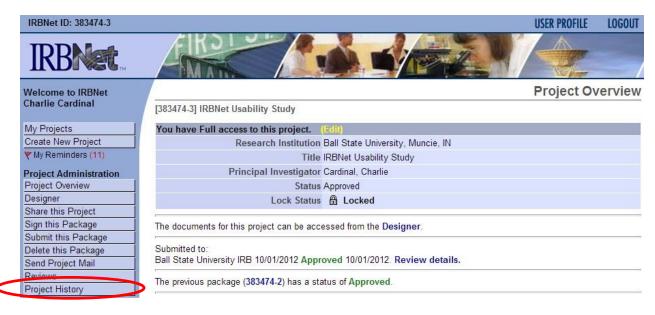
			USER PROFILE	LOGOUT
IRBNet.	The state of the s			-
Welcome to IRBNet			My P	rojects
Charlie Cardinal		ejects that you have created and projects that have		
My Projects	users on the National Research Network. running smoothly. (Learn More)	Use Reminders, Tags and Archiving to help organ	ize your workspace a	and keep it
Create New Project	, , , , , , , , , , , , , , , , , , , ,			
My Reminders (11)				
Other Tools	Search:	Search By Tag:		~
Forms and Templates		Search Clear		
			[4 4 1-2 of 2 ▶	10 -



3. Select the project for which you want to submit a continuing review.

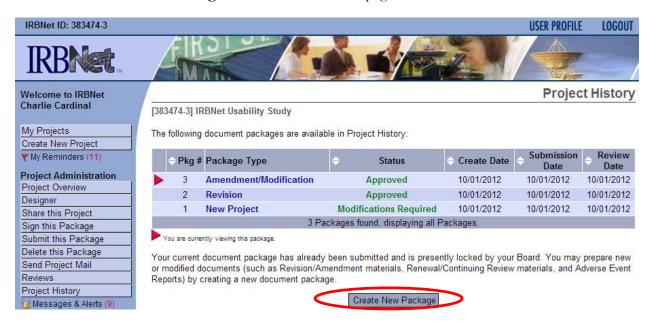


4. Select "Project History" under the Project Administration menu.





5. Click "Create New Package" at the bottom of the page.



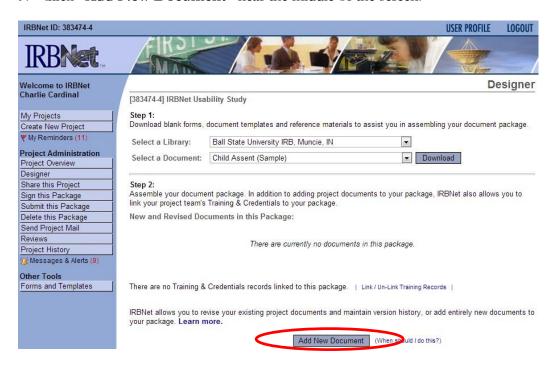
6. "New Document Package" will appear, click this to be taken to the Designer page.



- 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.

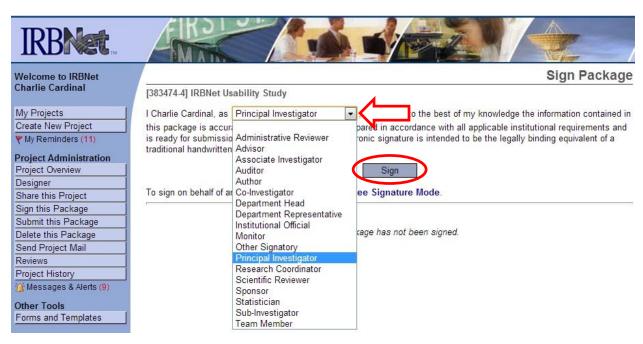
Welcome to IRBNet	Attach Document
Charlie Cardinal	[383474-4] IRBNet Usability Study
My Projects Create New Project W My Reminders (11)	You may attach documents to this package by clicking the "Browse" button to locate a document and then by clicking "Attach". The "Document Type" and optional "Description" are informational fields to assist you in managing your attached documents.
Project Administration Project Overview Designer Share this Project Sign this Package Submit this Package Delete this Package Send Project Mail Reviews	Description Annual Continuing Review Form File * Choose Filev1.1.docx * required fields
Project History	



- 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".

Please select a Board:

Search for an Organization	Search Clear	
	✓ Only show My Default Boards	
	Ball State University IACUC, Muncie, IN Ball State University IBC, Muncie, IN	*
	Ball State University IRB, Muncie, IN	
Select a Board *		
	Continue	
* required fields		



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

Submission Type: *	Continuing Review/Progress Report	*	
You may also specify additional comments to	Adverse Event (non-UP) Amendment/Modification Closure/Final Report	III >	
Your Comments:	Continuing Review/Progress Report Funding/Grant New Project Other Other Reportable Event	•	
	Submit Cancel		



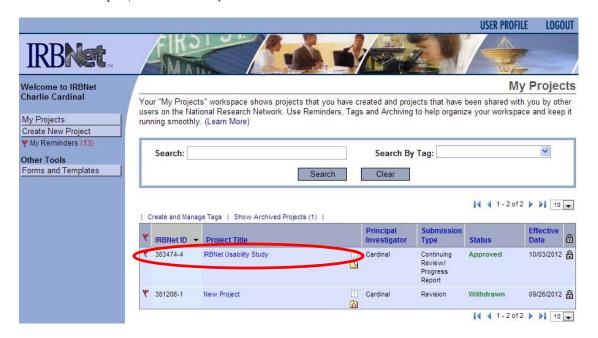
Adverse Events Submission

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.

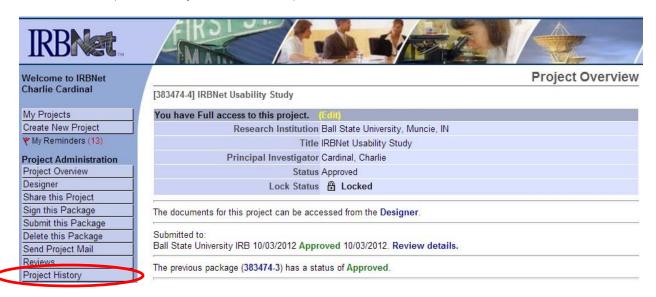


3. Select the project for which you want to submit an adverse event.

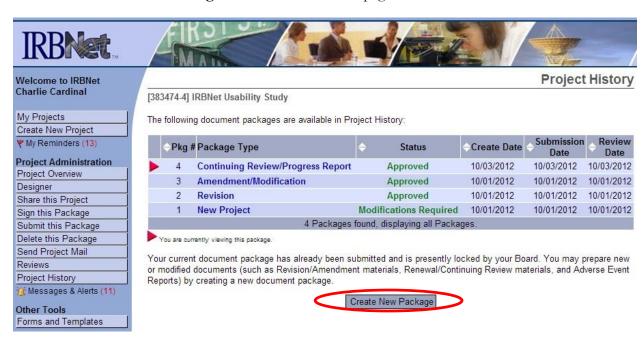




4. Select "Project History" under the Project Administration menu.



5. Click "Create New Package" at the bottom of the page.

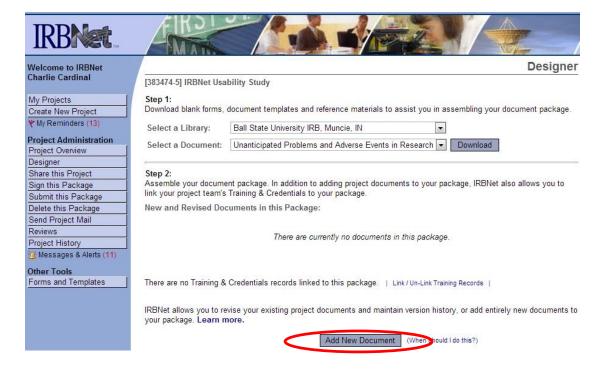




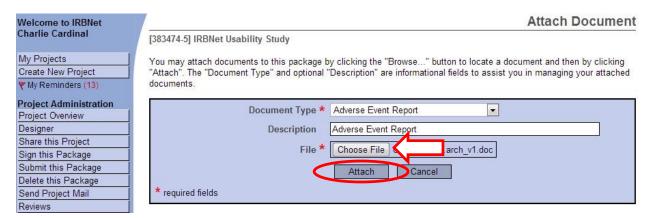
6. "New Document Package" will appear, click this to be taken to the Designer page.



- 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 the bests 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.

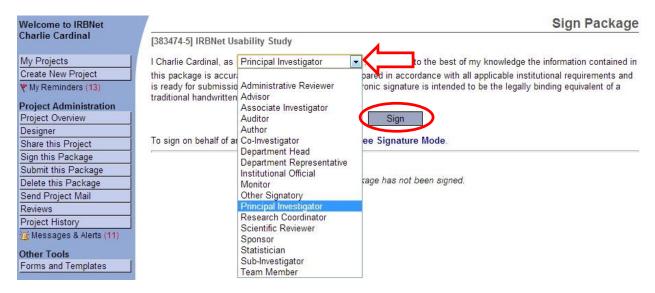


10. Click "Sign this Package" under the Project Administration menu on the left side of the screen.

Welcome to IRBNet				D	esi	igne
Charlie Cardinal	[383474-5] IRBNet Usa	bility Study				
My Projects Create New Project	Step 1: Download blank forms,	document templates and reference materials	s to assist you in assembling your o	documen	t pac	ckage.
♥ My Reminders (13)	Select a Library:	Ball State University IRB, Muncie, IN	•			
Project Administration Project Overview	Select a Document:	Child Assent (Sample)	▼ Download			
Designer						
Share this Project Sign this Package Submit this Package Delete this Package	link your project team's	ent package. In addition to adding project doo Training & Credentials to your package. cuments in this Package:	cuments to your package, IRBNet a	ilso allov	ıs yo	u to
Send Project Mail	♦ Document Type	→Description	-Last Modified	34		
Reviews Project History	Adverse Event Report	ort Adverse Event Report	10/05/2012 04:30 PM			×
Messages & Alerts (11)	There are no Training &	Credentials records linked to this package.	Link / Un-Link Training Records			



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**.



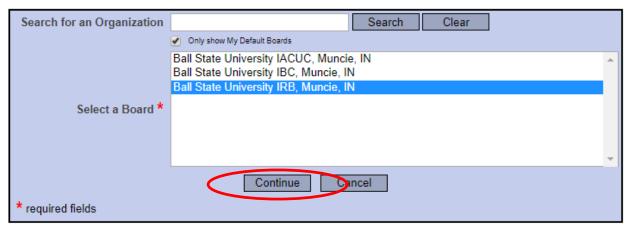
12. Your Adverse Event form is now ready to submit, click "Submit this Package" under the Project Administration menu.

Welcome to IRBNet				Sign Package
Charlie Cardinal	[383474-5] IRBNet	Usability Study		
My Projects	I Charlie Cardinal, a	s Principal Investigator	certify that to the best of my knowledge the	information contained in
Create New Project	this package is acc	urate and complete, has be	en prepared in accordance with all applicable institu	itional requirements and
My Reminders (14)	is ready for submise traditional handwritt		s electronic signature is intended to be the legally b	inding equivalent of a
Project Administration	traditional nanowitt	on signature.		
Project Overview			Sign	
Designer	1		10 m	
Share this Project	To sign on behalf of	another person, switch to	Designee Signature Mode.	
Sign this Package	This package has b	san aigned bur		
Submit this Package	This package has b			
Delete this Package	Date	Signed By	Role	
Send Project Mail	10/05/2012 04:33 PM	Charlie Cardinal	Principal Investigator	Details



13. Search for and select the proper review body at Ball State University (IRB, IACUC, IBC) and click "Continue".

Please select a Board:

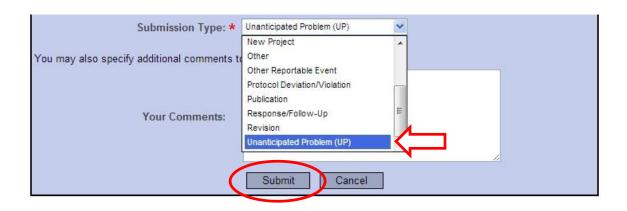


UNANTICIPATED PROBLEM SUBMISSION SEE STEP 14

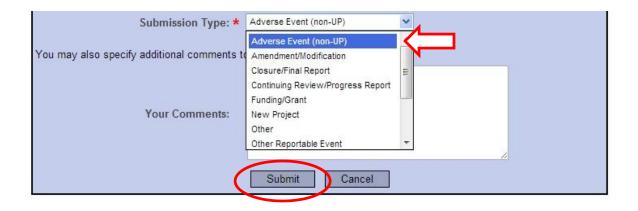
SERIOUS ADVERSE EVENT AND ADVERSE EVENT SUBMISSIOM SEE STEP 15



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.)





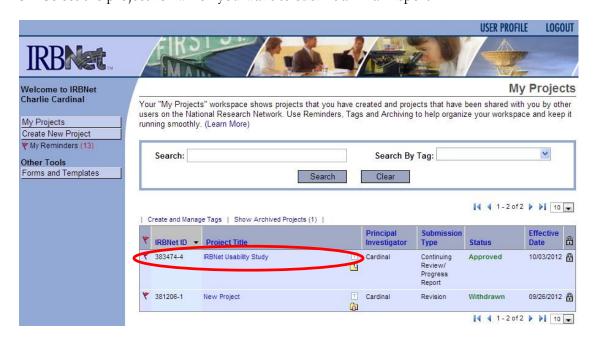
Final Report Submission (Expedited and Full Board)

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.

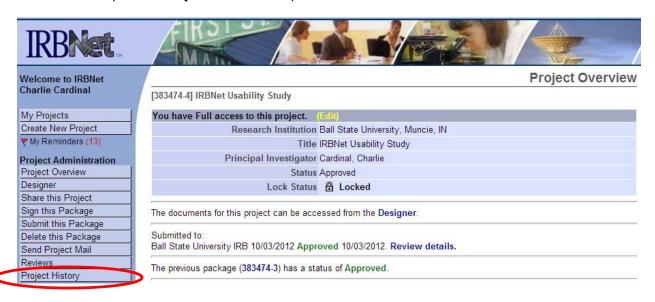


3. Select the project for which you want to submit a Final Report.

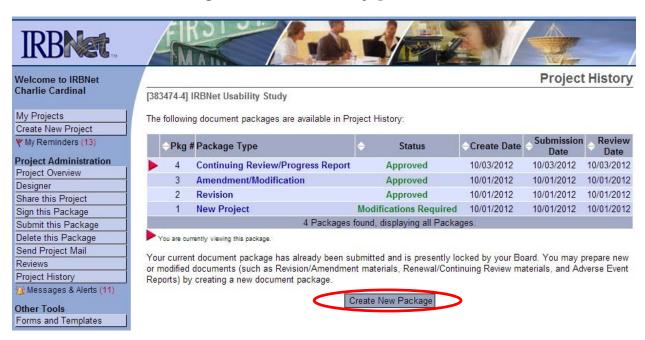




4. Select "Project History" under the Project Administration menu.



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.

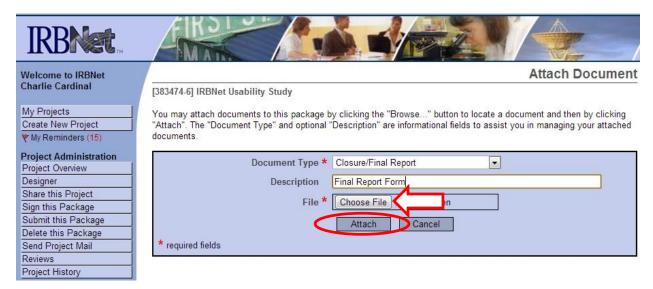


- 7. Fill out and complete the IRB Final Report form.
 - b. This can be found in the Forms and Templates section of IRBNet.
- 8. Click "Add New Document" near the middle of the screen.





9. In the Document Type box, select the category the bests 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.

IRBNet.	EKS!			
Welcome to IRBNet Charlie Cardinal				Designer
My Projects Create New Project W My Reminders (15) Project Administration Project Overview	[383474-6] IRBNet Usa Step 1: Download blank forms, Select a Library: Select a Document:	document templates and reference mate Ball State University IRB, Muncie, IN Child Assent (Sample)	erials to assist you in assembling your Download	r document package.
Designer Share this Project Sign this Package Submit this Package Delete this Package Send Project Mail	link your project team's New and Revised Doo	ent package. In addition to adding project Training & Credentials to your package. cuments in this Package:		also allows you to
Reviews Project History	Document Type ▼ Closure/Final Repor	Description t Final Report Form	10/08/2012 10:27 AM) Ø×

rage has not been signed.

11. Once at the **Sign Package** screen, indicate your **project role** (arrow) and click **"Sign"**. Please

12. Your Final Report/ Study Closure form is now ready to submit, click "Submit this Package" under the **Project Administration** menu.

Institutional Official

Research Coordinator

Scientific Reviewer

Team Member

Other Signatory

Monitor

Sponsor Statistician Sub-Investigator

Delete this Package

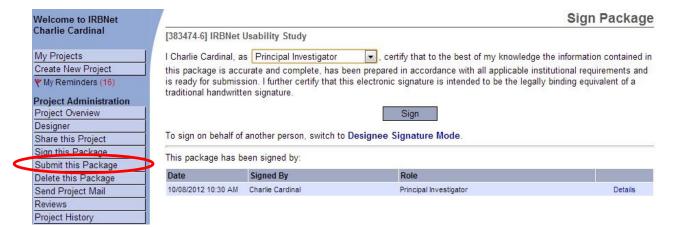
Messages & Alerts (13)

Forms and Templates

Send Project Mail

Project History

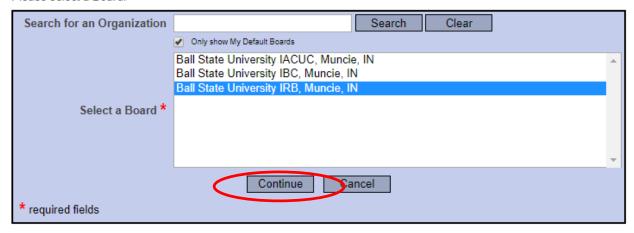
Reviews





13. Search for and select the proper review body at Ball State University (IRB, IACUC, IBC) and click "Continue".

Please select a Board:



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

