UNIVERSITY OF SOUTHERN INDIANA

Office of Sponsored Projects and Research Administration

IRBNet User Manual

IRBNet User Manual

The Office of Sponsored Projects and Research Administration is pleased to provide USI 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, modifications, and renewal. If you encounter any problems, or have questions regarding the protocol submission process, please contact the Office of Sponsored Projects and Research Administration.

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Wright Administration Building • Suite 104
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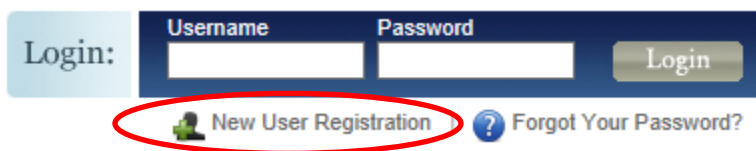eslynn@usi.edu

Table of Contents

Registering with IRBNet

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. Click **continue** and accept the Terms of Use

6. Select University of Southern Indiana. To do this, type **University of Southern Indiana** in the **search for an organization** space.

Add Affiliation

Specify the organization with which you are affiliated. If you are affiliated with more than one organization, you may add additional affiliations after you complete the registration process by logging in to IRBNet and accessing your User Profile.

Search for an organization   University of Southern Indiana   Search   Clear
Organization types to display   ☑ Research Institutions   ☐ Boards   ☐ Sponsors   Display

Your Organization *

University of Southern Indiana (USI), Evansville, IN

If you do not see your organization listed you may **add a new organization.**

Continue   Cancel

* required fields

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 to your future protocol(s) so make sure it is one you can check OFTEN.

Your Contact Information

Specify your contact information at University of Southern Indiana (USI), Evansville, IN. The email address that you specify will be used for communications related to University of Southern Indiana (USI) projects.

Telephone Number * [ ] - [ ] - [ ] ext. [ ]
Fax Number [ ] - [ ] - [ ] ext. [ ]
Email * [ ]
Verify Email * [ ]

Continue   Cancel

* required fields

8. Confirm that all information that you have entered is correct, and confirm that you are listed as a **Researcher** at the University of Southern Indiana.

Confirm Registration Information

Please review your information and click "Register" to complete the registration process. After you have registered, you may update your account information, and add or update affiliations at any time by logging in to IRBNet and accessing your User Profile.
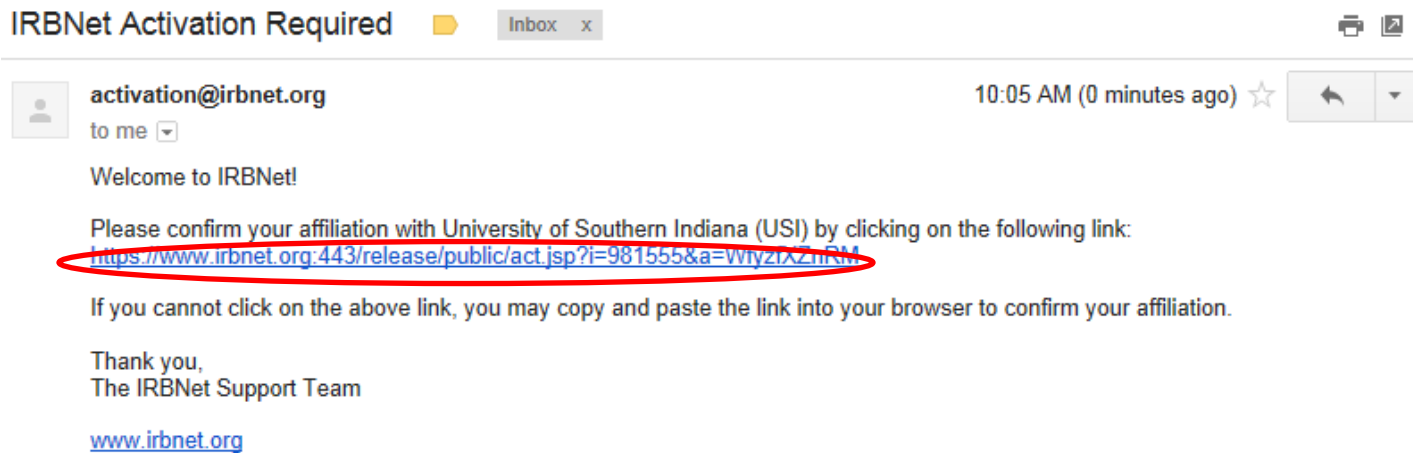
Register   Cancel
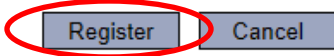
User Account Information and Password (Edit)

Username	joe.researcher
First Name	Joe
Last Name	Researcher

Affiliations

Researcher at University of Southern Indiana (USI), Evansville, IN (Edit)

9. Finalize your registration by clicking **Register** when everything is complete.

10. After completing your registration, you will receive an e-mail from IRBNet. Use the provided link within this e-mail to finalize your registration.

IRBNet Activation Required   Inbox x

activation@irbnet.org   10:05 AM (0 minutes ago)
to me

Welcome to IRBNet!

Please confirm your affiliation with University of Southern Indiana (USI) by clicking on the following link:
https://www.irbnet.org:443/release/public/act.jsp?i=981555&a=Wfyzfxznrm

If you cannot click on the above link, you may copy and paste the link into your browser to confirm your affiliation.

Thank you,
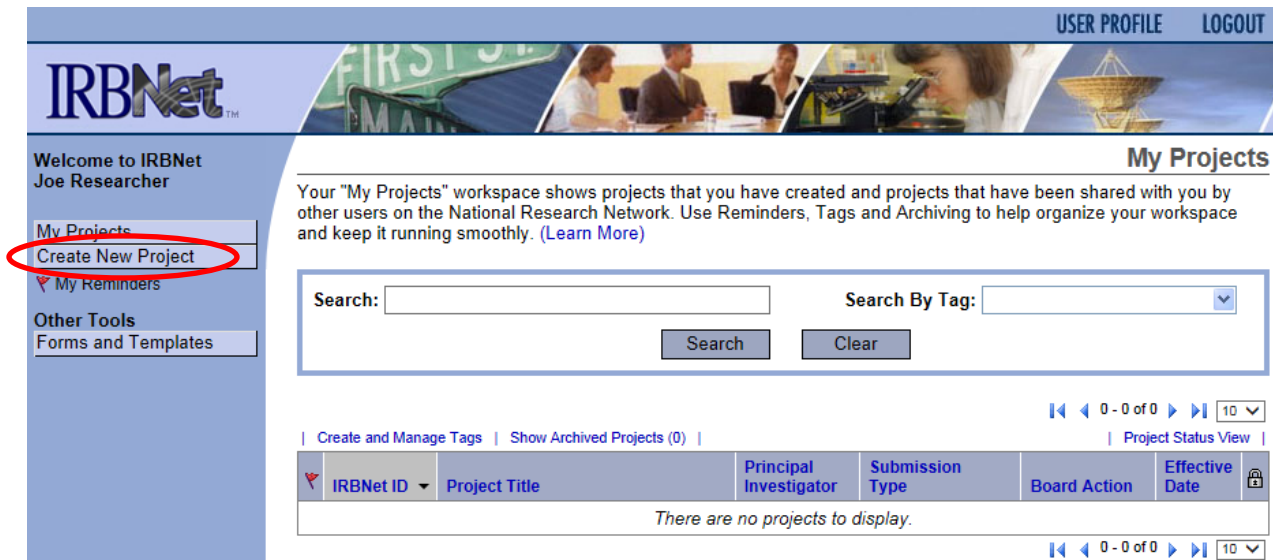The IRBNet Support Team

www.irbnet.org

Project Creation

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,** under "My Projects."

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:	University of Southern Indiana (USI), Evansville, IN
Title: *	
Local Principal Investigator:	**First Name:** * _____ **Last Name:** * _____ **Degree(s):** _____
Keywords:	
Sponsor:	
	You may specify an internal account number, billing identifier or reference number for this project.
Internal Reference Number:	
	Continue Cancel

* required fields

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

5. Click **Continue** and you will be taken to the Designer page and this screen.

Designer

[558287-1] IRBNet Usability Study

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

Select a Library: USI Institutional Review Board, Evansville, IN ▾

Select a Document: **READ ME FIRST - Step 1 - How to register on IRBNet ▾   Download

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

Documents in this Package:

There are currently no documents in this package.

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

Add New Document

6. All forms are located in the Library on IRBNet. To download all necessary forms, click on the "Forms and Templates" tab.
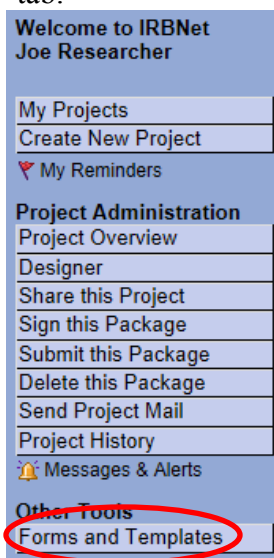
7. You will be taken to this screen:

Forms and Templates

These libraries have been made available to you by your Boards so that you can easily download blank forms, document templates and reference materials to assist you in your work.

Select a Library: USI Institutional Review Board - Documents for Researchers ∨

Documents in this Library:

Document Description	Last Updated	
*Application Form A - Type 1 Research (Exempt)	03/10/2014 12:09 PM	
*Application Form B - Type 2 or 3 Research (Expedited or Full Board)	03/10/2014 12:09 PM	
*Application Form C - Amendment	03/10/2014 12:09 PM	
*Continuing Review Form	03/10/2014 12:09 PM	
Co-Investigator Information	02/20/2014 03:14 PM	
Exempt Application Example	02/20/2014 03:05 PM	
Informed Consent for Audio, Video, or Photographs Template	02/20/2014 03:11 PM	
Informed Consent for Online or Web Based Surveys Template	02/20/2014 03:12 PM	
Informed Consent for Parent/Guardian Template	02/20/2014 03:13 PM	
Informed Consent Template	01/24/2013 03:19 PM	
Informed Consent Verbal Script Template	02/20/2014 03:10 PM	
Minor Assent Template	12/09/2013 12:22 PM	

8. Download any files by clicking the paper icon next to the title, complete all necessary fields, and save to your computer to upload.

9. Make sure you have completed all sections of the IRB Application Form and created all separate documents for possible recruitment materials, surveys, and informed consent forms.

10. Once all necessary forms have been completed, click **My Projects** and select your current project.

11. Navigate to the **Designer** page to upload application and all supporting documents.

12. Once you click, **Add New Document**, this screen will appear.

13. In the Document Type drop-down box, select **Application Form**.

14. Browse for the file on your computer and click **Attach**.

15. Attach all supporting documents such as surveys, interview questions, CITI Training Completion Reports, site verification letters, etc. as separate documents and label them as such. Your completed designer page might look something like this:

16. Once all files have been uploaded, you may need to share your study with others.
Student PIs (principal investigators) must share their project with a faculty advisor
before submitting so they can add their signature. A PI might also share with other
advisors or colleagues. To share your project with another person, they must be registered
with IRBNet.

17. Select the **Share this Project** tab located on the left side of the page.
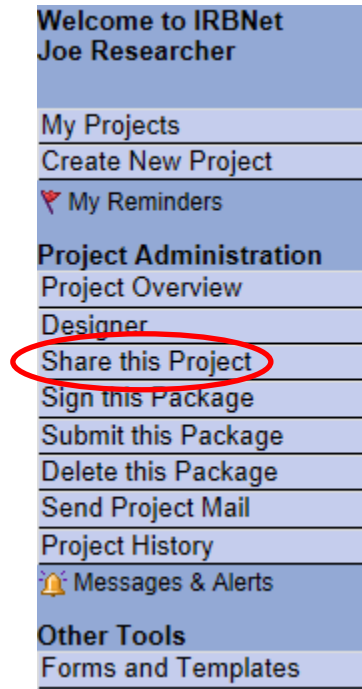
18. The following screen will appear, select the first option **Share.**

Share Project

[558287-1] IRBNet Usability Study

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.

19. 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 (University of Southern Indiana).

Share Project

[558287-1] IRBNet Usability Study

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

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

Search for an Organization		Search	Clear

Organization types to display: ☑ Research Institutions ☐ Boards ☐ Sponsors Display

Select an Organization*

University of Southern Indiana (USI), Evansville, IN
University of Southern Mississippi, Hattiesburg, MS
University of St. Thomas (UST), Houston, TX
University of St. Thomas, Saint Paul, MN
University of Tennessee - Knoxville, Knoxville, TN
University of Tennessee Health Science Center, Memphis, TN
University of Tennessee, Knoxville, TN
University of Texas - Houston, Houston, TX

Select Organization

* required fields

20. Once the organization is selected, you will need to search for the specific user using the page below. (User must have their own IRBNet account in order to share with them). Please pay attention to the different sharing levels. You may want an advisor or colleague to have a particular level of access.

Share Project

[558287-1] IRBNet Usability Study

Specify the access that you wish to grant to each user at **University of Southern Indiana (USI)**. 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]

21. Once the user is found, you may grant appropriate level of access. Within the comments box, you can enter any additional comments that will be included in the e-mail to the specified IRBNet user which notifies them of their new access to your protocol. Then click **Save.**

Search for a User: Rusher [Search]

IRBNet User	Permission Access
Rusher, Lane	○ 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]

22. Click the **Sign this Package** tab on the left side of the page. Remember, student PI's must have a faculty advisor sign the package *before* they can submit the package for review.
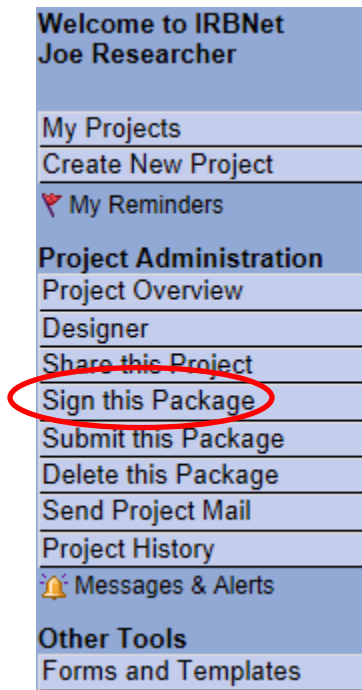
23. Select your role in the project. If you are the principal investigator, select this option from the drop down box.
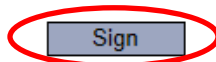
24. Once you click **Sign,** you will receive a notification from IRBNet that you have signed the package. Anyone else that you selected to share the project with will receive an e-mail notifying them of your signature too. Similarly, when your advisor signs the package, you will receive an email notification.

25. A package cannot be submitted until everyone has signed the package. **If you have a faculty sponsor, the sponsor must sign the package before you submit the package to the IRB for review.**

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

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

28. Under Project Administration select **Submit this Package.**
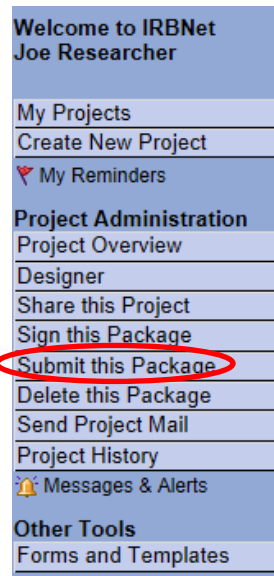
29. The page below will appear. Make sure to select **University of Southern Indiana IRB, Evansville, IN** and click **Continue.**

30. Select **New Project,** from the dropdown box. Feel free to add any comments and click **Submit.**

31. This will lock your project and the Office of Sponsored Projects and Research Administration will be notified of your submission so the review process can begin. *You will receive a time stamp for the submission.*

32. If you have forgotten to add a necessary document or need to make a quick change to a recently submitted project package, please contact our office at rcr@usi.edu or (812) 465-7000.

Making Requested Revisions

Minor 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 minor modifications. You will receive an e-mail indicating that your project has been unlocked if modifications are required.

1. Login to www.irbnet.org with your username and password then click on the **My Projects** button on the left side of the screen. Select the project you wish to modify.

2. If revisions are needed you will see the "Unlocked-Revisions Pending" in red. Click on "Review Details" in blue to see what revisions are requested.

3. To view requested changes, click on the most recent letter from the USI Institutional Review Board.

Review Details

[558287-1] IRBNet Usability Study
USI Institutional Review Board, Evansville, IN

Submission Details	
Submitted To	USI Institutional Review Board, Evansville, IN
Submitted by	Joe Researcher
Submission Date	01/10/2014
Submission Type	New Project
Local Board Reference Number	2014-1-SA

Review Details:

Agenda	Review Type	Board Action	Effective Date	Expiration Date
Unassigned	Exempt Review	Information Required	01/10/2014	

Board Documents:

Document Type	Description	Last Modified	View
Acknowledgment Not Complete Letter	Acknowledgment Not Complete Letter	01/10/2014 12:39 PM	

4. This will bring up a .pdf file of the requested modifications which you can save for your files. Go back to the "Unlocked-Revisions Pending" page to make all necessary changes. When you make changes to a document that is already uploaded, **make modifications directly to that document** and highlight all changes.

5. Once the changes are made, click on **Mark Revisions Complete** to resubmit the revised study. Keep in mind that your project will be locked and you will be unable to make any further changes after **Mark Revisions Complete** is clicked.

Designer

[558287-1] IRBNet Usability Study

This package is: 🔓 Unlocked - Revisions Pending | View History | Mark Revisions Complete | (When should I do this?)

Get stamped documents, approval letters and other board documents, and track reviews for this package: **Review details**.

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

Select a Library: [USI Institutional Review Board, Evansville, IN ⌄]
Select a Document: [**READ ME FIRST - Step 1 - How to register on IRBNet ⌄] Download

Step 2:
Assemble your document package. In addition to adding project documents to your package, IRBNet also allows you to link your project team's Training & Credentials to your package.
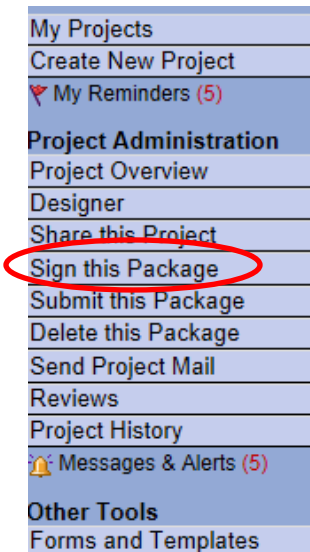
Documents in this Package:

Document Type	Description	Last Modified			
Application Form	IRBNet Usability Study.pdf	01/10/2014 11:31 AM		✏	✕
Consent Form	Informed Consent.doc	01/10/2014 11:35 AM		✏	✕
Letter	Site Verification Letter.docx	01/10/2014 11:36 AM		✏	✕
Other	Survey.docx	01/10/2014 11:37 AM		✏	✕
Training/Certification	CITI Training Completion Report.docx	01/10/2014 11:38 AM		✏	✕

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

Add New Document

6. If all items from the initial review are correct, your application will then be sent to a reviewer. Keep in mind that reviewers have up to seven business days to complete their review and might comment with additional revisions. In that case, return to step 1 to modify your application again. Allow yourself **at least 3 weeks** to get approval prior to project start date.

7. Upon completion of review you will either get a 'Modifications Required' letter or an 'Approval' letter. You will receive a notification email and can view the letter upon clicking **Review Details** on the Designer page.

Project Overview

[558287-1] IRBNet Usability Study

You have Full access to this project. (Edit)	
Research Institution	University of Southern Indiana (USI), Evansville, IN
Title	IRBNet Usability Study
Principal Investigator	Researcher, Joe

The documents for this project can be accessed from the **Designer**.

Project Status as of: 01/20/2014

Reviewing Board	Board Ref #	Initial Approval Date	Project Status	Expiration Date
USI Institutional Review Board, Evansville, IN	2014-1-SA	01/20/2014		01/20/2015

Package 558287-1 is: 🔒 Locked |◀ ◀ Package 1 of 1 ▶ ▶| | Jump ▼ |

Submitted To	Submission Date	Submission Type	Board Ref #	Board Action	Effective Date	
USI Institutional Review Board, Evansville, IN	01/10/2014	New Project	2014-1-SA	Approved	01/20/2014	Review Details

Shared with the following IRBNet users:

IRBNet User	Organization	Access Type
Researcher, Joe	University of Southern Indiana (USI), Evansville, IN	Full

8. This will take you to the page where you can view letters from the Institutional Review Board. If you see a **Modifications Required** letter, click the paper icon next to it and go back to step 4 in this section of the guidelines book. Your application will be unlocked to allow you to make changes.

9. If you see an **Approval Letter** click the paper icon next to it to open your letter and save it for your files. Once your project has been approved it will be locked so you can no longer make changes to it.

Modifying an Approved Study (Form C)

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 you wish to modify.

4. You will be taken to this screen, click on the **Project History** tab.

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

6. **Work in Progress (Not Submitted)** will appear, click this to be taken to the Designer page.

7. From the drop list, you will select **Application Form C**. Download this form, fill out all necessary fields and click **Add New Document**.

8. From the drop-down Document Type box, select **Amendment/Modification**. Click **Browse** to find the document you wish to upload.

9. Name the document and finish by clicking **Attach**. This will take you back to the **Designer** page where you can add more supporting documents if necessary.

10. When all necessary documents have been uploaded, click **Sign this Package** on the left hand side of the screen.

11. At the **Sign Package** screen, indicate your project role and click **Sign**.

12. Once signed, click **Submit this Package** on the left hand side of the screen.

13. Make sure **USI Institutional Review Board** is selected and click **Continue**.

Submit Package

[558287-3] IRBNet Usability Study

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

Please select a Board:

| Search for an Organization | [   ] | Search | Clear |

☑ Only show My Default Boards

USI Institutional Review Board, Evansville, IN

Select a Board *

Continue   Cancel

* required fields

14. Select **Amendment/Modification** from the drop-down box and click **Submit**.

Submit Package

[558287-4] IRBNet Usability Study

The following IRBNet users at **USI Institutional Review Board** will be automatically notified of your submission:

Deeg, Rebecca
Lynn, Emily
Rusher, Lane

Submission Type: * Amendment/Modification ▼

You may also specify additional comments to be included in this notification.

Your Comments:

Submit   Cancel

What is Continuing Review?

Regulations state that the IRB must conduct Continuing Review of an approved Expedited and Full Board Review study at intervals appropriate to the degree of risk, but not less than once per year.

The purpose of this process is to review an entire study and determine that the anticipated risks and benefits are reflected in the actual experience of subjects and that the safeguards in place at the time of original approval are, in fact, adequate to ensure the safety of subjects.

How the Process Works:

1. An email notice is sent from IRBNet to the principal investigator, co-investigators, coordinators and faculty sponsors prior to the annual review date.

2. The continuing review form can be found in IRBNet under forms and templates.

3. The continuing review form must be completed and uploaded in IRBNet (see instructions on how to do this in IRBNet User Manual) before the expiration date for processing and review.

4. The continuing review form can be used to provide updates on a project, renew a project, or close a project.

It is the principal investigator's responsibility to complete the continuing review form in a timely manner or the study may be inactivated by the IRB Board.

Projects involving high risk may require more frequent review. The IRB may require frequent review or reports on a specific number of cases. IRB expiration dates and/or project update dates will be announced at the time of project approval.

Renewing an Approved Study or Submitting a Progress Report (Continuing Review Form)

1. Upon approval, your project will expire on the date given by the IRB. You will receive an automatically generated email reminder from IRBNet when this date is approaching to allow you time to renew your project if necessary.

2. Login to www.irbnet.org using your username and password.

3. Select **My Projects** on the left side of the screen.

4. Select the project you wish to renew.

5. You will be taken to this screen, click on the **Project History** tab.

6. Click **Create New Package** at the bottom of the page.

Your current document package has already been submitted and is presently locked by your Board. You may prepare new or modified documents (such as Revision/Amendment materials, Renewal/Continuing Review materials, and Adverse Event Reports) by creating a new document package.

7. **Work in Progress (Not Submitted)** will appear, click this to be taken to the **Designer** page.

8. From the drop-down box, select **Continuing Review Form**, download this, fill out all necessary fields, and click **Add New Document**.

9. From the drop-down Document Type box, select **Continuing Review/Progress Report**. Click **Browse** to find the document you wish to upload.

10. Name the document and finish by clicking **Attach**. This will take you back to the
Designer page where you can add more supporting documents if necessary.

11. When all necessary documents have been uploaded, click **Sign this Package** on the left
hand side of the screen.

12. At the **Sign Package Screen**, indicate your project role and click **Sign**.

13. Once signed, click **Submit this Package** on the left hand side of the screen.

14. Make sure **USI Institutional Review Board** is selected and click **Continue**.

Submit Package

[558287-3] IRBNet Usability Study

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

Please select a Board:

Search for an Organization		Search	Clear
	☑ Only show My Default Boards		
Select a Board *	USI Institutional Review Board, Evansville, IN		
	Continue	Cancel	
* required fields			

15. Select **Continuing Review/Progress Report** from the drop-down box and click **Submit**.

Submit Package

[558287-4] IRBNet Usability Study

The following IRBNet users at **USI Institutional Review Board** will be automatically notified of your submission:

Deeg, Rebecca
Lynn, Emily
Rusher, Lane

Submission Type: * Continuing Review/Progress Report

You may also specify additional comments to be included in this notification.

Your Comments:

Submit   Cancel

Closing an Approved Study/Final Review (Continuing Review Form)

1. When all data is collected and has been disseminated, you will need to submit a **Final Report**.

2. Login to www.irbnet.org using your username and password.

3. Select **My Projects** on the left side of the screen.

4. Select the project you wish to renew.

5. You will be taken to this screen, click on the **Project History** tab.

6. Click **Create New Package** at the bottom of the page.

Your current document package has already been submitted and is presently locked by your Board. You may prepare new or modified documents (such as Revision/Amendment materials, Renewal/Continuing Review materials, and Adverse Event Reports) by creating a new document package.

Create New Package

7. **Work in Progress (Not Submitted)** will appear, click this to be taken to the **Designer** page.

8. From the drop-down box, select **Continuing Review Form**, download this, fill out all necessary fields, and click **Add New Document**.

9. From the drop-down Document Type box, select **Closure/Final Report**. Click **Browse** to find the document you wish to upload.

10. Name the document and finish by clicking **Attach**. This will take you back to the Designer page where you can add more supporting documents if necessary.

11. When all necessary documents have been uploaded, click **Sign this Package** on the left hand side of the screen.

12. At the **Sign Package** screen, indicate your project role and click **Sign**.

13. Once signed, click **Submit this Package** on the left hand side of the screen.

14. Make sure **USI Institutional Review Board** is selected and click **Continue**.

Submit Package

[558287-3] IRBNet Usability Study

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

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15. Select **Continuing Review/Progress Report** from the drop-down box and click **Submit**.

Submit Package

[558287-5] IRBNet Usability Study

The following IRBNet users at **USI Institutional Review Board** will be automatically notified of your submission:

Deeg, Rebecca
Lynn, Emily
Rusher, Lane

Submission Type: * Closure/Final Report

You may also specify additional comments to be included in this notification.

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