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.

Contact:
Office of Sponsored Projects and Research Administration
Wright Administration Building • Suite 104
Evansville, IN 47712
Phone (812) 228-5149

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# Table of Contents

- Registering with IRBNet................................................................. 1
- Project Creation ........................................................................... 5
- Making Requested Revisions......................................................... 16
- Modifying an Approved Study (Form C).......................................... 20
- What is Continuing Review? .......................................................... 26
- Renewing an Approved Study or Submitting a Progress Report (Continuing Review Form) ........................................... 27
- Closing an Approved Study/Final Review (Continuing Review Form) .......... 33
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.

Registration

New User Account Information

All users must be REGISTERED to access IRBNet. Registration is free.
The first step is to enter your basic account information and create your IRBNet Username and Password.

<table>
<thead>
<tr>
<th>First Name *</th>
<th>Username *</th>
<th>Password *</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Password Hint

* required fields

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

**IRBNet: Individual User Terms of Use**

To register on IRBNet, you must read and agree to these Terms of Use, including any future amendments (collectively, the "Agreement").

1. **Acceptance of Terms.**
   This Agreement governs your participation as an individual user of IRBNet. IRBNet is a service provided by Research Datavware, LLC and both the company and service name are used interchangeably in this Agreement. In addition, when using particular IRBNet owned or operated services, you shall be subject to any posted guidelines or rules applicable to such services which may be posted from time to time. All such guidelines or rules are hereby incorporated by reference into this Agreement. IRBNet may also offer other services that are governed by different Terms of Use.

   If this Agreement or any future changes are unacceptable to you, your sole remedy is to terminate your use of the Service. If you do not accept and abide by this Agreement, you may not use the services offered by IRBNet. By accessing or using the Service, you confirm your acceptance of, and agree to be bound by, this Agreement and any future changes to this Agreement. You agree to use the Service only in accordance with this Agreement. Nothing in this Agreement shall be deemed to confer any third party rights or benefits.

2. **Modification of Terms.**
   Although we may attempt to notify you via your submitted e-mail address when major changes to the Agreement are made, you should visit this page periodically to review these terms. IRBNet may, in its sole discretion, modify or revise these terms and conditions and policies at any time without notice to you, and you agree to be bound by such modifications or revisions.

   **Accept**  **Reject**
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.

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.
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.

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**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](image1)

**User Account Information and Password**

<table>
<thead>
<tr>
<th>Username</th>
<th>Joe.researcher</th>
</tr>
</thead>
<tbody>
<tr>
<td>First Name</td>
<td>Joe</td>
</tr>
<tr>
<td>Last Name</td>
<td>Researcher</td>
</tr>
</tbody>
</table>

**Affiliations**

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

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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.

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**IRBNet Activation Required**

activation@irbnet.org

Welcome to IRBNet!

Please confirm your affiliation with University of Southern Indiana (USI) by clicking on the following link:


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.

![Image of the Create a New Project Screen]

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.

![Image of the Designer 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**

**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.

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:

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

![Attach Document](image)

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.

![Required fields](image)

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:

![Designer](image)
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

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

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

1. Select an organization to display a list of IRENet 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

Organization types to display

- Research Institutions
- Boards
- Sponsors

Select an Organization

*required fields

Select Organization
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.

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.
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.

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.
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.
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](http://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.

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.

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

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

   ![Create New Package button](image)

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**.

15. Select **Continuing Review/Progress Report** from the drop-down box and click **Submit**.
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 button](image)

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.

Please select a Board

Search for an Organization

Select a Board *

* required fields

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.

Your Comments:

Submit