

# IRBNet User's Guide Instructions for Online Submissions of Research Proposals to the Institutional Review Board (IRB)

#### www.irbnet.org

If you have any questions regarding the submission of an IRB proposal, contact:

Alvernia.irb@alvernia.edu 610-685-3338

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#### Section I Registering with IRBNet

- 1. Go to <a href="http://www.irbnet.org">http://www.irbnet.org</a>.
- 2. Click on the "New User Registration" link in the upper right-hand corner of the screen.
- 3. Create your username and password. Fill out the required information. Your password must contain 8 characters. Click "Continue".
- 4. Read and accept the Individual User Terms of Use.
- 5. To add your organization, type "Alvernia" into the "Search for an Organization" box. Ensure only "Research Institutions" is checked. Click "Display" or "Search". Select "Alvernia University, Reading, PA" from the organization box. Then click "Continue"
- 6. Enter your contact information. Enter the email address you would like to receive communications through the IRBNet system. (e.g. notification of committee decisions, communications from your research team or committee administrator). Click "Continue".
- 7. Review your provided information and edits as necessary. When you are satisfied, click "Register".

An email will be sent to the address you provided in Step 6 with "IRBNet Activation Required" in the subject line. You will need to click on the link provided in this registration email in order to activate your account

Clicking on the link will take you to IRBNet homepage.

## Section II Uploading Training & Credentials

- 1. "Log-in" to http://www.irbnet.org/ using your username and password. (First time users must register in IRBNet. See Section I)
- 2. Click on "User Profile" (top right corner)
- 3. Scroll down to "Training & Credentials"
- 4. Click "Add New Record" and upload your CITI Certificate as proof of human subjects training. (To complete the CITI training please visit the IRB section of the MyAlvernia Portal to see AU CITI Training Instructions)

Proof of completion of training is a <u>required document</u> for proposal submissions to the IRB. <u>ALL PERSONAL</u> listed on the proposal <u>MUST</u> provide proof and later link to each project.

## Section III Creating a New Project

1. "Log-in" to <a href="http://www.irbnet.org/">http://www.irbnet.org/</a> using your username and password. (First time users must register in IRBNet. See Section I)

The default page will be "My Projects", where you will have access to all the projects you have created or that have been shared with you from other researchers.

- 2. Click "Create New Project" button on the left bar, fill in the relevant information about your project, and click "Continue". Asterisk fields are required to be completed. An Internal Reference number is not needed, this section is for administrative use only.
- 3. You will now be on the Designer Page where you will access, download, and submit forms and any guidance documents needed to help assemble a new project package.

Documents required for acceptance of your submission:

- 1. Completed Application form
- 2. Research Proposal
- 3. Training and Certifications that apply
- 4. Consent Forms
- 5. Electronic Signature of PI, Co-PIs, & Advisors

Access and Download forms: For supporting documents on the Designer Page, go to "Select a Library" drop down menu and select "Alvernia University Institutional review Board, Reading, PA". Select a document and then click "Download". Open and/or save to your computer file or desktop. Complete the form(s) required for submitting a research proposal to the IRB. Repeat this step for additional forms/documents.

You may also click "Forms and templates" on the left menu to access templates and guidance documents guidance documents from the IRBnet library.

To attach your documents, click "Add New Document" from the Designer Page, select the appropriate Document Type, add a description of the document (the document description should be a helpful description). Click "Browse" to look for the document where it is saved on your computer. Click on the document, click "open" so the file is moved into the "file" field. The click "Attach".

Your attached document will appear under "Step 3" on the Designer Page. The icons to the right side of the attached document allow you to view the document, update the document by replacing it with a new version, or delete the document. (See <u>Section VIII</u>)

<sup>\*\*</sup>Certificates must be uploaded to each team member's user profile and linked to projects.

#### <u>Section IV</u> Sharing Project with Other Users

- 1. You may share this project with your research team. Click the "Share this Project" button on the left bar, and then click the blue "Share" link to grant access to this project.
- 2. From the organization box select "Alvernia University, Reading, PA". Click "Select Organization" and search for registered users with whom you'd like to share this project (e.g., co-investigators, research assistants, faculty advisor, committee members, collaborative researcher from another institution, etc.)

To "Share" your project with someone, she/he must be registered with IRBNet. You may enter the person's name with whom you would like to share your project in the "Search for a User" box. You can do this by typing all or part of their first or last name and clicking "Search." You can search for multiple names by inserting a comma between names.

#### Grant each user a level of access:

**Read:** User many only view project documents. Recommended for research assistants.

Write: User may add/delete/edit project documents, collaborate with other users, and add their signatures: but cannot grant access to other users, submit the project or perform any other administrative functions.

**Full:** User may perform all functions without restrictions, add/edit/delete project documents, grant access to other users, and submit the project. Individuals with full access to a project will receive auto-notifications when an action has been taken regarding the project. [It is recommended that only researchers with day to day responsibility be granted full access.]

Selected users will be notified automatically via email that a project has been shared with them. You may also enter comments in the comment box to be included within the email.

- 3. Click "Save"
- 4. After you share your project with your team members you need to link their Training and Credentials (T&C). On the Designer page click the "Link/ Un-link Training Records" (blue text in the middle of the page) and select the appropriate T&C for each team members.

## **Section V Submitting Project Signatures**

Signatures are required before the package is submitted. The principal investigator, co-investigators, and advisors MUST sign the package before the IRB will accept your submission.

- 1. Click the "Sign This Package" button on the left menu.
- 2. Choose your project role from the drop-down menu by clicking the arrow on the box.
- 3. Then click the "Sign" button.

#### <u>Section VI</u> <u>Submitting a New Project</u>

- 1. Click "Submit This Package" button on the left bar.
- 2. Select 'Alvernia University, Reading, PA" or type all or part of University name in the "Search for Organization" box.
- 3. Select "Alvernia University, Reading, PA". Then click the "Continue" button.
- 4. In the Submission Type drop down menu, select "New Project" and click "Submit".

Once a decision is made by the IRB, an automatic email will be sent to everyone who has full access. The letter and any supporting documents can be printed. (See <u>Section IX</u>)

Projects are only submitted after you click the "Submit Button". Make sure the Project Status Column, located at the top of the Submission detail Page, is labeled "Pending Review". Projects not submitted will be labeled "Work in Progress" until submitted.

Did you submit an incomplete package?

The project package is <u>locked</u> upon submission. If you need access to this package for additions or revisions prior to review, please contact IRB:

Alvernia.irb@alvernia.edu 610-685-3338

## Submitting Signatures for Advisors

1. "Log-in" to <a href="http://www.irbnet.org/">http://www.irbnet.org/</a> using your username and password. (First time users must register in IRBNet. See Section I)

The default page will be "My Projects", where you will have access to all the projects you have created or that have been shared with you from other researchers.

- 2. Click the project title to open, this will then bring you to the **Submission Detail** page
- 3. Review any necessary study details and documents
- 4. Next from the left-hand menu click "Sign this Package"
- 5. Use the dropdown list to select the appropriate role and click "Sign" Note: If you have previously signed this package, the system will ask you if you wish to sign it again. If you need to re-sign the package for any reason, click "OK"
- 6. Enter your username and password to validate your identity and click "Continue"
- 7. Your electronic signature has been applied to the contents of this package. IRBNet will send a notification to all users who have full access to this project.

## Submitting a Subsequent Package in a Project

Use these instructions for the following submission types (for projects that were originally submitted through IRBNet:

- a. Conditional Approvals with Required Revisions
- b. Modifications/Amendments for an approved study.
- c. Incomplete
- d. Continuing reviews for an approved study.
- 1. Log-in to <u>www.irbnet.org</u>. This will take you to the "My Projects" page. This is where all of the projects that you have access to will be housed.
- 2. Click on the **Title** of the project that you would like to amend, renew, etc. (If the project is not listed on you "My Projects" page then you should contact your committee administrator.) Then click on "**Project History**".
- 3. Create a new project if the approved project was **not** submitted in IRBNet originally.
- 4. Click on the "Create New Package" button to add an additional package to your IRBNet project. (The additional package will have a new number, such as 116011-2).

Supporting documents can be uploaded to the new package via two methods, described below:

**a.** You may attach (add) a new document (use this option when the document you are adding is <u>NOT</u> a revised or updated version of an existing project document):

Select "Alvernia University, Reading, PA" from the "Select a Library" drop down menu. Select a document and then click "download". Open and/or save to your computer file or desktop. Complete the form(s) required. Repeat this step for additional forms/documents.

All required forms are to be downloaded, completed and saved to your computer. Completed forms, proposal and other documents should then be "UPLOADED" into your IRBNet package.

To attach your documents, click "Add New Document" from the Designer Page, select the appropriate Document Type, add a description of the document (the document description should be a helpful description). Click "Browse" to look for the document where it is saved on your computer. Click in the document, click "open" so the file is moved into the "file: field. Then click "Attach"

b. You may revise a previously submitted document (use this option when you want to add or create a new version of an existing project document):
At the bottom of the "Designer" page, first download the document by clicking on the Document Type or the paper icon to the right.

Make necessary changes and save the revised document to your computer file or desktop.

Click on the "pencil" icon of the document. Click "Browse" to look for the document in your computer file or desktop.

Click on the document and click "open" so the file is moved into the "file" field. Make appropriate changes in the Document Type and Description Fields.

Click the "Update" button. When you click Update, the revised document will appear in the "New and Revised Documents in the Package" Section of the Designer Page.

All versions of the document may be viewed by clicking on the stack of paper icons (Revision History)

5. You may share this project with your research team. Click the "Share this Project" button on the left bar, click the blue "Share" link to grant access to this project.

Select "Alvernia University, Reading, PA" from the organization box. Click "Select organization" and search for registered users with whom you'd like to share this project (e.g., co-investigators, research assistants, faculty advisor, collaborative researcher from another institution, etc.)

#### 6. Click 'Save"

\*Note: To "Share" your project with someone, they must be registered with IRBNet.

- 7. There are required signatures before the package is submitted. The principal investigator, co-investigators, and advisors MUST sign the package before the IRB will accept your submission. Click the "Sign This Package" button on the left menu. Choose your project role from the drop-down menu by clicking the arrow on the box. The click the "Sign" button.
- 8. Click "Submit This Package" button on the left bar. Select 'Alvernia University, Reading, PA" or type all or part of University name in the "Search for Organization" box. Select "Alvernia University, Reading, PA". Then click the "Continue" button. In the Submission Type drop down menu, select "New Project" and click "Submit".

# Section IX Locating Committee Decision Letters and Documents

- 1. Log-in to <a href="www.irbnet.org">www.irbnet.org</a>. This will take you to the "My Projects" page
- 2. Click on the **Title** of the project for which you would like to retrieve the decision letter or documents.
- 3. Click on "**Project History**" and then click the Package Type of the specific submission.
- 4. Click on "Review Details" at the top right of the screen. The decision letters or documents are located in the "Board Documents" section at the bottom of the page.
- 5. Click on the Document Type or the paper icon to open and read/save.

## Section X Helpful Tips!

- Your project is submitted ONLY after you click the "Submit" button
- The My Projects screen can be found by clicking on "My Projects" on the left bar. This will show the list of studies to which you have access.
- Projects which have not been "Submitted" to the IRB are labeled "Work in Progress" in the status column.
- Clicking the title of any project will take you to the "Project Overview" for the selected project which contains project details. On the Project Overview page, you may click on "Review Details" to see more about the status of your project, including Board Decision Documents. (See Section IX).
- An automatic email message will be sent to everyone with full access to the project when someone has signed the submission or a board decision letter has been published.
- To un-share a project with a user, follow the same steps in "Share this Project" and click on "No Access"
- You may click "Send Project Mail" on the left bar to send communications to your Project
  Team or Committee Contacts for any submitted package. Your messages will also be
  automatically posted to "Messages and Alerts". Messages sent from this page become part of
  the project record and can be viewed by the project team, other users granted access, board
  members and administrators.
- Make sure to "Mark Revisions Complete" using the Designer Page and re-lock the project once you are done with your revisions.
- When submissions are incomplete you will receive an IRBNet project mail message directing you to the request for information letter, which list what is missing or changes that need to be made. Please follow the instructions to complete your submission.
- Keep handy all INSTRUCTIONAL documents, which can me found in the IRBNet document library.

Did you submit an incomplete package?

The project package is <u>locked</u> upon submission. If you need access to this package for additions or revisions prior to review, please contact IRB:

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