Marywood University - Institutional Review Board

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http://www.irbnet.org

IRBNET INSTRUCTIONS FOR RESEARCHERS

Use of IRBNet to transmit documents is mandatory. Emailed or mailed documents will not be accepted. Please thoroughly review this document for proper submission.

I. HOW TO REGISTER WITH IRBNET

Please do not register for more than one IRBNet account, as it causes administrative issues.

1. Visit irbnet.org. At the upper right portion of the screen, click the *New User Registration* link.
2. Enter your name, create a username and password, and click *Continue*.
3. Review the terms of use and click *Accept*.
4. For organization, enter *Marywood*, click *Search*, and click on *Marywood University*. Click *Continue*.
5. Enter your telephone number and email address. We recommend your MU email account, Yahoo or Gmail. Click *Continue*.
6. Review your information and click *Register*.
7. Sign into the email account you had provided. Click the link in the message that IRBNet will email to you. This will activate your registration.
8. **If you do not receive an activation email, check your spam filter/junk box.** You may need to add nobody@irbnet.org to the contacts section of your email account. If you still do not receive an activation email, log into IRBNet and click *USER PROFILE* at the upper right. At the bottom of the next screen, where you see *Affiliations*, click *Edit*. Change your email address if it is incorrect. Enter a new or different fax number, and hit *Save*. This will trigger a new activation email. If not resolved, send a request to irbhelp@marywood.edu and we will notify IRBNet on your behalf.
9. **If you forget your password**, click on the *Forgot Your Password* link in the upper right corner of IRBNet's home page and follow the prompts to reset it. MU staff members do not have password access.

II. HOW TO UPLOAD A TRAINING REPORT

All principal investigators, co-investigators, research assistants, research advisors (of students) and live interpreters must complete at least one online training course in human research through CITI at citiprogram.org. Other courses or specific modules may be required, depending on circumstances. Please review our Mandatory Training policy or view our tutorial videos (password is training) at http://www.screencast.com/t/dtP7ForA.

1. **Visit citiprogram.org and download your *REPORT* (not certificate), which shows transcripts (modules and grades).** After logging in, choose *View Courses* next to Marywood University or your institution. Under Completed Courses, click the gold *View-Print-Share Record* button to the right of the appropriate course. On the next screen's left side and under Completion Reports, click the blue *View/Print* button and save it as a .pdf to your computer or flash drive.

2. **Upload your training report(s) into IRBNet through only *ONE* of the following methods:**

   a. Into your own IRBNet user profile (suggested method) - Report will be accessible across all projects, so you only have to upload it once until it expires.

DO NOT upload others' reports into *your* IRBNet profile. All users need to add reports into their *own* IRBNet user profiles.

OR

b. With your other project materials (see section III, below) - Report will be accessible in that project only, so you will need to upload it every time you are involved with a new project, since it will not automatically carry over to other projects.

To upload and submit training reports into an IRBNet user profile:

1. Log in at irbnet.org. At the upper right, click *USER PROFILE*.
2. **DO NOT click the *Add an External Account* link under External Accounts in the middle of the page!** MU does not subscribe to this auto-transfer service, so it will not function. Instead, scroll to the bottom of the page under *Training and Credentials* and click *Add New Record*.
3. For *Document Type*, click the drop down menu and scroll to *Marywood University* IRB or ERC in bold. Then, select the appropriate training label underneath it.
4. For *Effective Date*, enter the date of completion.
5. For *Expiration Date*, enter the date if one applies (e.g., the human course expires 3 years from the last completion date).
6. Click *Browse* and locate the file on your computer. Click the document and click *Open*.
7. Click *Attach*. You will return to the *User Profile* page.
8. Scroll to the bottom where your training document appears and in the same row, click *Submit* on the right side (blue link).
9. Type *Marywood* and click *Search*. Click on the appropriate board's name and click *Continue*.
10. Click *Submit*. Repeat with additional documents, or to send to additional boards, if applicable.

IMPORTANT: It is not necessary to link training reports to individual projects in IRBNet, so we do not offer instructions on this feature.

III. HOW TO BUILD A NEW PROJECT

IRBNet allows you to build a new project and any follow-up packages at your leisure. While building any package, the status will show "Work in Progress" and **the package *will not* automatically be transmitted to a board for review.** To transmit your package, follow the steps under section VI on p.3, below.

1. Log in at irbnet.org. Find and download forms on the left menu under *Other Tools* by clicking the *Forms and Templates* button and selecting the appropriate library (ERC, IRB, etc.). Some forms will change based on the library selected. Refer to our Checklist of What to Submit.

2. On the left menu, click the *Create New Project* button. Use this only if creating a brand new project. For subsequent packages within existing projects, see the steps under section VIII on p.4, below.

3. Project Information Page:

    a. Fill in required information – Full title, first and last name, sponsor (for funding source, not advisor), highest degree attained, etc.
    b. Internal Reference Number – Leave this blank.
    c. Click *Continue*.
    d. IRBNet will assign a project number to your study, available under the photo header and in brackets at the top of every page while viewing your study. It consists of a base number, which is the project number, and a suffix, which is the package number within the project (12345-1, 12345-2, etc.).

4. Designer Page (Step 1): If you still need documents, you may also find them here. You may need to expand the view by clicking the blue *Need Forms/Show Form Libraries* link. Contract it by clicking *Hide Form Libraries.*

    a. Select a Library – Choose the correct library name from the drop down menu.
    b. Select a document – Download forms or templates here by selecting then clicking *Download*.

5. Designer Page (Step 2): Upload All Project Documents

    a. On the main screen, click the *Attach New Document* button. Browse your computer or device for the document, select it, and then click open.

b. On the left under *Document Type*, (*please select* in red font), choose the appropriate document label from the drop down menu. If unknown, choose *Other*. The board can change labels if needed.

c. Repeat as necessary. If you need to delete a document, click the red X in the document's row.

IV. *HOW TO SHARE A PROJECT*

If you have co-investigators, you must share the project with them. If you are a student, you must share it with your research advisor. While sharing with research assistants is not required, you may find it helpful if they have added training reports into their IRBNet user profiles. Otherwise, you will need to upload their reports with other study materials.

1. Verify that the individual is registered at IRBNet. If not, ask them to register and confirm their registration.
2. On the left menu, click the *Share this Project* button.
3. On the main screen, click the word *Share*.
4. Click *Marywood University* (or search for it) and select it. If the individual is registered with another institution, search for its name. Then, click *Select Organization*.
5. Type the last name of the individual and click *Search*.
6. Under *Permission Access*, designate the level of access you are granting. Comments are optional.
   a. Grant advisors "full" access so that they will receive all system email notices.
   b. Grant co-investigators "read" access so that there are not multiple editors
7. Click the *Save* button.

Your *Share Project* page will now show the names of all individuals with access to your project. You may edit or remove someone from this list at any time by clicking on the individual's name, choosing *No Access*, and clicking *Save.*

V. *HOW TO SIGN A PACKAGE*

Principal Investigators must electronically sign *every* package within their projects. Co-investigators and research advisors must sign initial project packages and any continuing review (renewal) packages.

To add a signature:

1. After logging in, click on the project's title. On the left menu, click the *Sign this Package* button.
2. Click on the drop down menu and select your project role.
3. Click the *Sign* button. Log in again if it asks.

The *Sign Package* page will now show the names of all individuals who have signed the package. Ensure that co-investigators and advisors sign the package <u>before</u> you submit it.

Applying your e-signature means that you comply with Marywood University's policies, as well as Federal, state and local regulations governing research with human subjects.

VI. *HOW TO SUBMIT A PACKAGE*

1. On the left menu, click the **Submit this Package** button.
2. <u>**IMPORTANT:**</u> **Select the appropriate board. There are three available for MU. Selecting the wrong one may delay review.** The default selection is Institutional Review Board (IRB). If applying for exemption, change it to Exempt Review Committee by clicking the down arrow button on the right side of the *Select a Board* box and scrolling down to Exempt Review Committee (ERC). Click on it to highlight it, and then click *Continue*.
3. Click the *Submission Type* drop down menu arrow and choose the appropriate type:

New Application = "New Project"	*Check In (ERC or Most Expedited) = "Other"*
Board-Requested Change = "Amendment/Modif'	*Official Renewal = "Continuing Rev/Prog Report"*
Change after Approval = "Revision"	*Closing Study = "Closure/Final Report"*

4. Comments (Optional): While you may add text to the comment box, do not add crucial information. Important study-related information must appear within the package's documents instead.

5. Click *Submit.*
This will transmit your package for review. Once submitted, it may not be deleted from IRBNet. If you have forgotten an item, contact our office to request that your package be unlocked. **NOTE: Once you have submitted an individual package, you may not submit the same package to the same board again.** Each package may only be submitted one time to each board.

6. After submitting, you will see a confirmation page and the package's status will change from "Work in Progress" to "Pending Review." View the status by (1) clicking *My Projects* on the left menu and locating your submission in the table - the status will then appear in the appropriate row under *Submission Type*, (2) while viewing your project, clicking *Project Overview* on the left menu - the status will appear in the middle of the page in green text, or (3) clicking the *Project History* button on the left menu – this will show if anything is still a Work in Progress (Not Submitted); if it does not state this, it has been submitted.

VII. HOW TO ACCESS A DECISION LETTER

Once a board renders a decision, IRBNet will send all individuals with full project access an automatic e-mail message about the action. It will look something like this:

Please note that Marywood University's IRB has taken the following action on IRBNet:

Submission: [37382-1] Title of the Study
Action: Modifications Required
Effective Date: 07/01/2023

Additional information is available in IRBNet. Should you have any questions, contact us.

Accessing the Board's Decision or Other Materials:

1. Log in at irbnet.org.
2. Locate your existing project (use search box, if necessary). Click the study's title.
3. On the left menu, click the *Reviews* button.
4. On the bottom of the main screen, locate the decision letter under *Board Documents.*
5. Click on the letter's name (in blue) to open it. Save it to your computer.

VIII. HOW TO SUBMIT FOLLOW UP MATERIALS (MODIFICATIONS, REVISIONS, REPORTS)

Follow-up materials may include anything beyond the initial submission, such as board-requested modifications, revisions you wish to request after approval, reports (check-in, closure, deviation, or adverse event), and official continuing review applications. **DO NOT CREATE A NEW PROJECT when submitting follow-up materials!** In addition, when submitting modifications or revisions, **MAKE SURE YOU ENABLE TRACK CHANGES IN YOUR WORD PROCESSING SOFTWARE** (see tracking instructions on website under tips at the bottom) so that the additions or deletions can be easily seen.

To submit follow-up materials:

1. Log in at irbnet.org and locate your **existing project**. **Click the study's title.**
2. While viewing your study, on the left menu, click "Create New Package."
3. Assemble your new package. You may download new forms or templates under the library (click blue link - Need forms?). Make sure the correct library is selected. IRBNet shows previously submitted documents at the bottom for reference only, but does not automatically add them to the new package. If you modify any documents while on the site, save the modified versions to your computer or device after completion, since IRBNet does not automatically save them.
4. On the main screen, click on the "Attach New Document" button. Browse for the file on your computer or device and open. Choose the document type in the drop down menu where it says "please select" (in red). Repeat as necessary.
5. On the left menu, click "Sign this Package." Log in if it asks. Select your role and click "Sign." The PI must sign every package.

6. **IMPORTANT: On the left menu, click "Submit this Package". If you miss these final steps, the board will not receive your package.**
   a. Select the correct board from the drop-down menu and click "Continue."
   b. Choose the Submission Type and **click "Submit."**

You will see a confirmation message. Your package's status will change from "Work in Progress" to "Pending" until the board makes its decision.

NOTE: All approved projects require some type of follow-up package (e.g. closure report form, check-in report form, etc.). Approval itself is not the end of communication with the board.

IX. ADDITIONAL IRBNET FEATURES

Accessing a Project's History: To view your entire project's history:

1. After logging in, click your project's title. On the left menu, click the *Project History* button.
2. Numbered packages will appear in reverse order, with the most recent package on top.
3. To select one, click its name under the Submission Type column.

Editing Your User Profile: To edit your password, contact information or affiliations, click on *USER PROFILE* in the upper right hand side of any screen after logging in.

1. To edit your account information or password, click *Edit.* Make the change and save.
2. To add affiliation with another institution, click on *Add an Additional Affiliation.* Follow the screens. If the organization is not listed, click the blue *add a new organization* link.

Locating a Project: IRBNet's search feature allows search by IRBNet number, project title, keyword (if used), etc. Make sure you have logged into the correct user account, not a duplicate account. Make sure that you have been granted project access if someone else had created it, or that you have not accidentally transferred oversight when trying to share access with others. Finally, if you still cannot locate your study, click the *My Projects* button on the left menu and search from there.

Removing Another User's Project Access: If you no longer wish for someone to have access to a project:
1. After logging in, click your project's title.
2. At the bottom under the Shared table, click the individual's name (in blue).
3. In the same row as their name and under the Access Type, click the circle next to *No Access.*
4. At the bottom of the page, click *Save.*
5. Submit to the ERC/IRB a revision request form to officially remove the individual. Include revised (and tracked) documents if their name appears on any advertisements or consent/parental/assent forms.

Sending Project Mail: To send a message to a project team member or board contact:

1. After logging in, click your project's title. On the left menu, click the *Send Project Mail* button.
2. Check the box for each individual to whom you would like to send a message.
3. Edit the subject, compose the message and then click *Send*. The message will be saved in the system.

Transferring a Project to Another User: Use this ONLY if you need to completely relinquish your access to the entire project and name another individual in your place. To transfer:

1. After logging in, click your project's title. On the left menu, click *Share this Project.*
2. On the main screen, click *Transfer.*
3. Type in the organization's name and click *Search.* Click the organization's name and then click *Select Organization.*
4. Select the user's name from the drop down menu. A message is optional. Click *Save.*

For assistance, contact us. We will respond during office hours.
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