Submission Process for IRB and ERC

Submit all materials electronically through our online submission system at www.irbnet.org. If you submit to the wrong board, we will withdraw and forward it for you.



Review Type	Submit Electronically To
Exempt	Exempt Review Committee
Expedited	Institutional Review Board
Full	Institutional Review Board

Step 1: How to Prepare

- 1. Read Marywood's IRB policies and procedures, which explain review types, requirements and definitions.
- 2. **Complete online training.** All principal investigators, co-investigators, research advisors and assistants must register at the CITI website and complete the **human research course** (Social/Behavioral or Biomedical group, based on activities). Additional courses may be required. Find details on our Mandatory Training page, including CITI registration and completion report retrieval instructions.
- 3. Register on IRBNet at www.irbnet.org. All principal investigators, co-investigators and research advisors must register. Registration is optional for research assistants. Click on the New User Registration link at the top right of IRBNet's home page and enter requested information. When asked for institutional affiliation, search for and select Marywood University. After clicking the register button, you will be emailed a confirmation message. Click the confirmation link in the email message to finalize registration.
- 4. **Decide the review type based on activities, population and risk.** See our <u>policies</u>, consult with your research advisor or our office, or check OHRP's <u>decision charts</u> (2018 requirements on the right).
- 5. Review our checklist of what to submit.
- 6. **Download forms and templates to create your documents.** Find IRB forms and templates on IRBNet.Org. **DO NOT submit class, theses or dissertation proposal documents. DO NOT convert document types** (e.g., if original is .DOC format, do not convert to .PDF).
- 7. **Proofread and run a spell check in your word processing software.** Check for errors prior to submission. Editorial services should not be sought from the board and slow down review for everyone.
- 8. **Review the meeting schedule and submission deadlines.** Follow <u>deadlines</u> and allow adequate review time. Student investigators must apply during the semester *prior* to the one in which they plan to graduate, unless taking a course with an alternate deadline (e.g., end of fall semester for SSW 701, February 1 for PSYCH 422 or other research courses).

Step 2: How to Submit at IRBNet

- Print and carefully review our step-by-step <u>IRBNet Instructions</u>. If you need extra help, view our <u>tutorial videos</u>. Contact <u>irbhelp@marywood.edu</u> for the videos' password. Create a new project and upload all necessary materials.
- 2 **Sign your package.** E-signatures are required of the Principal Investigator (PI), the research advisor, and any co-investigators.
- 3. **Submit your package**. The upload to IRBNet itself does not transmit it to a board. Click the submit button in IRBNet's left menu, choose the board and submission type, and click submit. Once submitted, you'll arrive at a confirmation page, and the package's status will change from Work in Progress to Pending Review.

Step 3: How to Respond

- Monitor your e-mail account registered with IRBNet. IRBNet will email you when a decision letter has been uploaded to <u>IRBNet</u> (Reviews button on left, then under Board Documents table at the bottom). Office staff will also send instructions on next steps.
- 2. Create a package of requested modifications.
 - 1. **Track your changes.** See <u>How to Track Changes</u> for assistance with enabling tracking to show insertions or deletions.
 - 2. **Do not create a new project or ask for the initial package to be unlocked!** The original package must remain locked to maintain a history. Create a follow-up package within your *existing* project (i.e., IRBNet# 12345-1, 12345-2, etc.). Review our written IRBNet Instructions for exact steps.
 - 3. Upload your documents.
 - 4. **Sign your package:** The Principal Investigator must e-sign every package.
 - 5. **Submit your package.** The upload to IRBNet itself does not transmit it to a board. Click the submit button in IRBNet's left menu, choose the board and submission type, and click submit. You'll arrive at a confirmation page.
- 3. **Monitor your e-mail account.** You'll receive an email, prompting you to log in at IRBNet to retrieve your approval letter and stamped materials. Stamped versions of materials must be used unless otherwise noted in your letter. A check-in report or expiration due date and reporting requirements will be indicated in the letter.

Step 4: What to Report after Approval

- 1. Closure Report Form, Check-In Form or Continuing Review Application: A closure report form must be submitted when you complete your research or separate from MU, unless others from MU will still be engaged in activities. If activities will continue beyond one year, you must submit either a check-in report form annually (ERC and most Expedited IRB approved after 1/21/19) or apply for continuing, annual review, budgeting ample time so that there is no lapse in approval. All research activities must cease as of any expiration dates, until the board approves a renewal. Projects may not be closed until both data collection and analysis have been completed, unless all data are completely de-identified. See the appropriate forms on IRBNet.org.
- 2. **Deviations, Unanticipated Problems or Serious Adverse Events (All studies)**: Report these immediately. Please see our *Mandatory Reporting* policies and procedures, as well as the *Deviation* and *Adverse Event/Unanticipated Problem* forms on IRBNet.org.
- 3. **Revisions to Approved Research (All studies):** Researcher initiated changes after approval, however minor, must be reviewed and approved prior to implementation. See our *Revisions to IRB Approved Research Request* form on IRBNet.org.

Helpful Tools and Guidance



IRBNet Written Instructions
Step-by-step
instructions for IRBNet



IRBNet Tutorial Videos Instructs
on how to use IRBNet and the
tracking feature in MS Word
Contact irbhelp@marywood.edu for password.



Checklist of What to Submit

- <u>Decision Charts What Review Type</u> (2018 Requirements)
- Guidance on Common Errors
- Guidance on Data Collection via Online Survey
 NEW
- Guidance for Research Advisors
- Guidelines for Classroom Projects
- MU Permission Chart Contacts for recruitment or data permission on campus
- Instruction: Scanning
- Instruction: Tracking Changes
- REDCap Survey Information and Tutorials
- Readability Tips

Keyboard Photo by <u>Sergi Kabrera</u> on <u>Unsplash</u>