Application Process and Deadlines

Purpose

The purpose is to outline the policies and procedures for the application process to the Institutional Review Board (IRB) or Exempt Review Committee (ERC) and appropriate deadlines for each.

Policies

All research involving human subjects (participants) must be submitted for review and approval via a web-based submission and management system, IRBNet, at www.irbnet.org. In the system, three boards exist, each with its own forms and templates.

- Institutional Review Board (full or expedited human research review)
- Exempt Review Committee (exempt human research review)
- Institutional Animal Care and Use Committee (animal research review)

Investigators must submit to the correct board. No hard copy or emailed materials will be accepted.

In determining the human research review type, investigators should first read our policies for exempt, expedited, and full review of research. If an investigator has difficulty in selecting the appropriate review level, the investigator should refer to the Office of Human Research Protections' Decision Charts. If there is still a question, the investigator may consult with the Director of Human Participants Protection and Research Compliance. The Director will make the final determination about review type, with consultation of the IRB chairperson, appropriate members of the IRB, or Assistant Provost, as needed.

Submission instructions and a checklist of what to submit for each board may be found on our IRB Forms and Instructions web page.

Student Research Projects

Student investigators must identify a research advisor from Marywood University, unless they are studying under the auspices of another institution for the project and have an advisor at their home institution. Students who plan to graduate in a given semester must apply during the semester *prior* to the one in which they plan to graduate, in order to allow ample time for the review process and study execution. The exception would be research courses which have a built in submission deadline of February 1st (e.g. PSY 421/422), or a deadline of the end of fall semester (e.g. SSW 701/702). Also see our Student Research policy.

Deadlines and Review Timing

Since all research projects are equally important, review takes place on a first-come, first-served basis. Deadlines and turnaround times are shown in the table below. Submissions must be complete at the time of receipt in order to meet a deadline. Submissions received after the close of business on the day of any deadline are subject to the next meeting or review cycle.

Review Type	Submission Deadline	Package Decision Usually Within	Recommend Applying Ahead by
Full	2 Weeks before Meeting	2-7 Business Days after Meeting	3 Months
Expedited	Every Monday by 5:00pm	2-3 Weeks from Deadline	2 Months

Exempt	N/A	1 Week after Receipt	1 Month

Certain types of research may require the IRB to consult with an expert in a particular field (e.g., medical specialist, pharmacist, Registrar, etc.). Research involving prisoners requires activation of our Prisoner Advocate, a voting IRB member. These situations often involve additional review time.

Modifications

Turnaround times for review of any requested modifications depend on the original type of review performed and decision rendered by the IRB or ERC. In most cases, a study which was granted a decision of "modifications required" will have a turnaround time of roughly one week or less, depending on completeness of the package and current submission volume. Turnaround times for studies with a decision of "deferred" take more time. For instance, a full study with a decision of "deferred" must have its modifications reviewed at another convened meeting of the IRB.

Investigators must submit any requested modifications within three (3) months, otherwise the IRB or ERC will administratively withdraw the idle project. If this happens, the project will not be reopened and must be resubmitted if the PI decides to move forward with the application process.

Revisions or Continuing Review in Approved Research

Turnaround times for revisions to approved research or annual continuing reviews are subject to the same schedule as an initial review. There are a few exceptions allowed in the regulations, such as where certain minor changes or renewals may be reviewed as expedited if the initial project had undergone full review. These instances will be determined by the Director.

Please see our meeting schedule and submission deadlines for specific deadlines.

Procedures

1. The investigator reviews policies concerning human research, a submission checklist, and instructions on how to submit, which are found on the IRB or ERC's websites, and/or views IRBNet Tutorial Videos (email irbhelp@marywood.edu for password).
2. The investigator completes a human research training course at www.citiprogram.org, and other courses if applicable. Advisors, co-investigators and/or research assistants also complete training.
3. The investigator registers at www.irbnet.org, affiliates with Marywood University, and confirms the registration via e-mail. If applicable, co-investigators or advisors do the same. Registration by research assistants is optional in many cases, but necessary when an RA will submit study materials on behalf of a faculty investigator, or when an RA has uploaded CITI training into their IRBNet user account.
4. The investigator downloads and completes necessary forms and templates, which are located on the IRB or ERC's websites or in IRBNet's forms library.
5. The investigator and advisor, where applicable, proofreads and runs a spellcheck on all completed documents.
6. Following the written and/or video instructions for IRBNet, the investigator creates a new project, shares it with research team members (if applicable), applies an e-signature, has the advisor and/or co-investigators sign, and then submits it to the IRB or ERC.
7. The investigator awaits an emailed notice, which informs of the decision letter's location for download by the investigator. The IRB or ERC's decision letter describes requested actions, if any.
8. If requested by the IRB or ERC, the investigator submits a follow-up package of modifications via IRBNet, making sure that all modifications are tracked.
9. Once approved, the IRB or ERC emails an approval notice, prompting the investigator to download the approval letter and all stamped materials (documents part of the consent process) from IRBNet. Stamped versions of documents must be used in the research unless the IRB or ERC states otherwise (e.g. online locations where a stamped version is impossible to use, such as the body of an email message or some survey platforms).

10. The investigator submits any requests for revisions after approval, deviations from the approved research, unanticipated problems or serious adverse events, via IRBNet, should they occur. See appropriate policies and procedures about these topics.
11. The investigator submits a completed closure report form upon study conclusion. If activities will continue beyond a study's one-year anniversary, the investigator submits either an annual check-in report form (all exempted and most expedited studies) or a continuing review/annual renewal form (full studies and some expedited). One form covers both conditions. See Mandatory Reporting policy for report requirements.

Related Policies

- Approval of Research
- Expedited Review of Research
- Exempt Review of Research
- Full Review of Research
- Mandatory Training
- Revisions to Approved Research

History

07/11/2014 - Updated to remove pregnant women exclusive IRB requirement and add statement about research involving children

06/12/2017 - Consolidated Submission and Application Procedures policy pages; adjusted format; pregnant women/children removed (already in other policies)

05/24/2018 - Updated checklist links

06/25/2019 - Updated as a result of the Revised Common Rule

10/01/2019 - Corrected checklist link and updated student deadline due to SSW's policy change

10/14/2021 - Corrected missing links and clarified procedures

12/02/2021 - Updated idle period length and added minor clarifications