**Marywood University  
Research with Human Participants  
Advisor/Sponsor Guide**

Congratulations on being a faculty advisor! You fulfill a significant role in your students’ research experience at Marywood University. Part of your responsibility is to ensure the protection of human participants in your students’ projects, and the accurate submission of applications for review by one of Marywood University’s research committees. As such, we would like to inform you about some of the requirements of our Human Research Protection Program.

# Institutional Policy - Review of Research The Policy Committee of Marywood University had last updated its policy concerning [*Institutional Review of Research Involving Human Participants*](http://www.marywood.edu/policy/detail.html?id=163836&crumbTrail=Institutional%20Review%20of%20Research%20Involving%20Human%20Participants&pageTitle=Institutional%20Review%20of%20Research%20Involving%20Human%20Participants)in April of 2011*.* Research by faculty, staff, or students of Marywood University involving human participants, conducted at Marywood University or under its sponsorship at another location, must comply with applicable policies, procedures and guidelines for the protection of human subjects.

# All research that can be defined as "a systematic investigation designed to develop or contribute to generalizable knowledge" (45 CFR 46) must be reviewed and approved by the Institutional Review Board for the Protection of Human Participants (IRB) or submitted as an exemption request for review to the Exempt Review Committee (ERC).

# IRB/ERC review is also required of research conducted by individuals outside of Marywood University but which is performed on the premises of Marywood University (including recruitment via email), even if the research has already been approved by the IRB at the sponsoring institution or elsewhere. Researchers outside of Marywood University must identify a full-time faculty or administrative sponsor from Marywood University.

# All dissertation, thesis/professional contribution, or honor’s thesis projects involving human participants must undergo IRB/ERC review.

**Mandatory Online Training for All Research Personnel**

All research personnel - principal investigators, co-investigators, research assistants, and advisors - are required to complete two, online training courses, one in each of the following:

1. **Human Research Curriculum** (Social/Behavioral or Biomedical)
2. **Responsible Conduct of Research** **(RCR)** (Basic Course)

Both courses must be completed via the Collaborative Institutional Training Initiative (CITI) at [www.citiprogram.org](http://www.citiprogram.org). Research personnel should not complete the member and staff course, as that is for Committee members and office staff only. Please see our [research training policy](http://www.marywood.edu/irb/detail.html?id=256737&crumbTrail=Mandatory%20Training&pageTitle=IRB:%20Mandatory%20Training&title=Mandatory%20Training) for information. Questions about certificates earned through institutions other than Marywood University may be directed to Ms. Courene M. Loftus at 570-961-4782 or [cloftus@marywood.edu](mailto:cloftus@marywood.edu).

# Websites and Instructions

# Three research review boards exist on campus, but only two involve human research. Information about the two human research boards may be found on the following websites:

# Exempt Review Committee (ERC): For exempt review <http://www.marywood.edu/research-office/research-at-marywood/erc.html> Exempt studies involve no greater than minimal risk to participants. All research activities must fit into one or more of the federal exemption categories.

# Institutional Review Board (IRB): For expedited or full review [www.marywood.edu/irb](http://www.marywood.edu/irb) Expedited studies involve no greater than minimal risk to participants, but all activities do not fit the federal exemption categories (e.g., audio/ video taping). Full review studies usually involve greater than minimal risk to participants, unless research activities do not fit into the federal expedited categories.

# Both websites contain policies and procedures, instructions, and required forms and templates. The IRB’s site also contains a “helpful tools” section, which includes a submission checklist, consent form readability tips, brief IRBNet video tutorials, and instructions on how to track changes in recent versions of Microsoft Word. Please familiarize yourself with these pages and inform your students about the availability of these tools.

# Submission and Management System - IRBNet

# IRBNet, an online submission and management system, is utilized by all of Marywood University’s research review boards. IRBNet may be found at [www.irbnet.org](http://www.irbnet.org). All principal investigators (PIs), co-investigators, and advisors must create a user registration through IRBNet. The same individuals must apply an electronic signature to initial and renewal applications (Note: PIs must sign every package).

# Please note that the default setting during submission is the IRB. Make sure that your students use the proper forms and select the correct board during the submission process. If they wish to apply to the ERC, they must click on a drop down arrow on the submission screen to scroll and find the ERC. Many researchers miss this part. Errors in submission may cause delays in review.

**Application Requirement Reminders**

Following are several important points which we ask you to share with your students.

* **Materials are not accepted outside of IRBNet** (no email or snail mail).
* **Be sure to utilize current forms and templates, as they are updated often.** The most current versions are available on our websites and IRBNet. We’d suggest not saving actual copies in Moodle and instead posting links to the forms pages.
* **Use only IRB or ERC templates**. Do not create your own forms, as required information may be missed.
* **Do not submit thesis or dissertation chapters or proposals.** Instead, use our application forms, which include sections with specific questions to be addressed.
* **When describing the procedures, use active vs. passive voice.** For instance, instead of saying that “participants will be given a survey,” tell them, “The researcher will give participants a survey.” Not only is passive voice less readable, it often eliminates the reference  
  to the agent of the action. It must be clear who is engaged in research activities.
* **Thoroughly proofread and perform a computer spell check on all documents prior to submission.** This will aid in a more timely return of a board decision.
* **Uploading documents into a new project or package does not automatically send them to a board.** Researchers must click on “Submit this Package” once per package. If a package displays a status of “Work in Progress,” it has not yet been submitted.
* **Submit to the appropriate board.** The system default is IRB, so change to ERC if that’s where it’s going.
* **Electronically sign the submission in IRBNet.** Student projects will not be assigned for review if the advisor’s signature is missing.
* **The application process does not end at the moment of approval**. Following are other requirements:
  + **IRB Only: A status report is due six months** from the date of approval, or sooner if completed (same form for status and closures).
  + **IRB and ERC: Closure reports** are required at completion, but by or before the 1 year expiration.
* **If a study has not been completed by the expiration date (including data collection and analysis), it is the researcher’s responsibility to submit a continuing review application prior to the expiration.** IRBNet will send several automatic e-mail reminders to the researcher and sponsor (as long as the PI grants the sponsor “full” access when sharing the submission). **Lapses in research approval are not allowed.** If a study expires without review and approval of the IRB or ERC, all study activities must cease. We’d suggest applying for continuing review at least two months prior to the expiration date.
  + All changes, however minor, must be submitted for review and approval prior to implementation, according to policy.
  + Deviations or violations from the approved protocol, whether intentional or not, must be reported according to policy. Adverse events must also be reported according to policy.

|  |
| --- |
| Courene M. Loftus, MPA, CIP Director of Human Participants Protection and Research Compliance Phone: (570) 961-4782 e-mail: [cloftus@marywood.edu](mailto:irb@maryu.marywood.edu?subject=IRB%20Questions%20or%20Comments) |

**For questions about this guide, please contact:**