

# Research Advisors

## Purpose

The purpose is to outline the policies and procedures for research advisors.

## Definitions

An **advisee** is a student investigator of a human research project who is mentored by an advisor.

A **human subject (or participant)** is a living individual about whom an investigator (whether professional or student) conducting research: (1) obtains information or biospecimens through intervention or interaction with the individual, and uses studies or analyzes the information or biospecimens, or (2) obtains, uses, studies, analyzes or generates identifiable private information or identifiable biospecimens.

**Research** is a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Research projects are designed to test a hypothesis, permit conclusions to be drawn, and thereby develop or contribute to generalizable knowledge, which may be expressed in theories, principles, and statements of relationships.

A **research advisor (formerly sponsor)** is an individual who mentors a student investigator (advisee) during the planning and conduct of human research. This individual shares the responsibility for the ethical conduct of research, making adequate time for consultation with the advisee and monitoring research progress.

A **student** for the purposes of this policy is any individual studying at the undergraduate, graduate, or doctoral level or for personal enrichment, transfer credit, or other non-degree purposes.

## Policy

All Marywood University students conducting human research must identify a Marywood University research advisor. Advisors must be appropriately qualified by education, training and experience to assume responsibility for the proper conduct of the research. All students from other institutions who engage Marywood University in research (e.g., a Marywood employee studying at another institution) must identify a qualified advisor from the other institution, unless one is not required by that institution, in which case one must be identified from Marywood University. Doctoral student investigators usually select their dissertation chair as advisor.

The research advisor must complete mandatory human research training and register with IRBNet at [www.irbnet.org](http://www.irbnet.org). The advisor must electronically sign the advisee's initial project in IRBNet as well as any annual continuing reviews (usually full IRB research only).

A research advisor is expected to discuss the general principles of human research ethics and assist the student investigator through the research process. By agreeing to serve on a project, the advisor affirms that s/he has thoroughly read the application materials and that the investigator has not begun subject recruitment or collected any data prior to application. The advisor must also support the advisee in the conduct of the research project after attainment of Institutional Review Board (IRB) or Exempt Review Committee (ERC) approval and throughout the life of the project until its completion.

In collaboration with the advisee, a research advisor is responsible for the overall management of a research protocol. Management of the research encompasses the ethical, administrative, fiscal, and applied elements of a project. The research advisor:

- Serves as an active mentor to the student
- Shares responsibility for ethical conduct of the research

- Ensures that the project is appropriate to the student's training and experience
- Ensures a sound research design and methods
- Helps the student determine whether a project requires IRB or ERC review
- Ensures that all materials are in adequate condition prior to submission (includes proofreading)
- Guides the student through the application process
- Supports the student in the conduct of the project after approval is attained
- Ensures appropriate reporting, including submission of
  - adverse event, unanticipated problem or deviation report forms
  - revisions to approved research requests
  - check in or continuing annual review forms if activities will extend beyond one year
  - a closure report form once the project is complete
- Ensures that the student is not placed in dangerous situations while conducting research

An immediate family member of a student investigator may not serve as research advisor.

If an advisor separates from Marywood University during the life of a project, a new advisor must be identified and approved by the IRB or ERC via submission of a revision request (see Revisions to Approved Research policy).

## Procedures

1. The Principal Investigator (PI) obtains an advisor and identifies the advisor on the application form.
2. The advisor registers with CITI ([www.citiprogram.org](http://www.citiprogram.org)) and completes necessary training.
3. The advisor registers with IRBNet ([www.irbnet.org](http://www.irbnet.org)) and confirms the registration via an emailed link.
4. The PI shares the project with the advisor in IRBNet ([www.irbnet.org](http://www.irbnet.org)).
5. The advisor applies his/her e-signature to the initial submission package and any annual continuing reviews (usually full IRB research only).

6. If there are any changes to an advisor's status, the PI submits a revision request to the IRB or ERC via IRBNet and obtains approval prior to implementation.

## **Related Policies**

- Mandatory Training
  - Responsibilities of Investigators and Advisors
  - Student Research
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## **History**

05/25/2018 – Updated definitions, requirements and procedures

12/15/2021 – Updated advisor requirements; clarified advisor's role in protocol management

01/25/2022 – Added definitions and a policy bullet point