Student Research

Purpose

The purpose is to outline the policies and procedures for human research performed by students.

Definitions

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

An *agent* is an individual who: (1) acts on behalf of the institution; (2) exercises institutional authority or responsibility; or (3) performs institutionally designated activities. Agents can include employees such as faculty or staff, or students, contractors, and volunteers, among others, regardless of whether the individual receives compensation.

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). 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 employees or agents of Marywood University, including students, who will conduct research with human subjects at Marywood University, or under its purview at another location, must comply with applicable policies, procedures and guidelines for the protection of human subjects.

All research involving human subjects 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 and approval to the Marywood Exempt Review Committee (ERC).

Classroom Research Activities

Class assignments or exercises involving human subjects may require IRB or ERC review if they meet the definition of research or if they:

- Pose more than minimal risk to human subjects
- Involve populations vulnerable to coercion or undue influence (children, prisoners, individuals with impaired decision-making capacity, the economically or educationally disadvantaged, etc.)
- Obtain, use, study, analyze, or generate identifiable information
- Will be presented or published outside of the classroom
- Involve recruitment via large campus list-serves (e.g. students, commuters, residents)

IRB and ERC review cannot be provided retroactively. Students who anticipate interesting results need to seek IRB or ERC approval prior to the start of research activities if they believe that they will use data for publication or presentation beyond the classroom.

Research course instructors are asked to review the <u>Guidelines for Classroom</u> <u>Research</u>. The Director of Human Participants Protection and Research Compliance, or his/her designee, will assist with any questions regarding classroom projects.

Research Advisors

All Marywood University students conducting human research must identify a Marywood University research advisor (see Research Advisors policy). Advisors must be appropriately qualified by education, training and experience to assume responsibility for the proper conduct of 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 the advisor.

All student investigators and research advisors must complete required online training. In addition, student investigators must apply their electronic signatures to all submissions via IRBNet, while advisors must apply electronic signatures to initial and annual, continuing review (not check in) submissions.

In addition to identifying an advisor, any student planning to conduct medical procedures (i.e. medical screening, medical chart determination, blood draws, echocardiography, ultrasound, etc.) must obtain medical supervision. The student must describe who will be conducting such procedures and what their qualifications are to perform such procedures.

Because the IRB and ERC are charged solely with the protection of human subjects who participate in research, research advisors are responsible for ensuring that

student investigators do not put themselves in dangerous situations while conducting research.

Thesis or Dissertation Activities

Because they are typically designed to develop or contribute to generalizable knowledge, all thesis, honors thesis, or dissertation activities involving human subjects must be submitted for review by the IRB or ERC. Projects labeled as professional contributions must also be submitted if they meet the definition of research and involve human subjects.

Timing

Students wishing to graduate in a given semester need to apply to the IRB or ERC by the end of the semester prior to the one in which they plan to graduate, for example, by the end of the fall semester for a planned spring graduation. This allows ample time for initial review, submission and review of modifications, approval, implementation and analysis. The only exception is research courses spanning two semesters, which have course deadlines of the end of the fall semester (SSW 701/702) or by February 1 (PSY 421/422) of each year.

Students conducting a research project as part of a course which requires review should be mindful of a semester's timeline. Students should apply as early in the semester as possible to allow the entire research process to be completed by the semester's end.

Procedures

- 1. The Principal Investigator (PI) obtains an advisor and identifies the advisor on the application form.
- 2. The advisor registers with CITI (<u>www.citiprogram.org</u>) and completes necessary training.
- 3. The advisor registers with IRBNet (<u>www.irbnet.org</u>) and confirms the registration via an emailed link.
- 4. The PI shares the project with the advisor in IRBNet.

- 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
- Research Advisors
- Responsibilities of Investigators and Advisors

History

06/16/2016: Updated sponsor employment status

05/25/2018: Added definitions, information about advisors and reference to Research Advisor policy

01/25/2022: Added definitions and clarifications