

Institutional Review of Research Involving Human Participants

Policy Statement

Ethical and policy issues in research involving human participants are grounded in Marywood University's self-imposed commitment to safeguard the rights and welfare of human participants in all research under its sponsorship and to serve as their protector on behalf of the community of persons of which the University is a part. The University seeks to comply with all federal regulations requiring the establishment and operation of an institutional review board for the protection of human participants (see University Standing Committee titled Institutional Review Board for the Protection of Human Participants).

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 Marywood Exempt Review Committee (ERC). Procedures for establishing a College or Department Exempt Review Committee are available from the Office of Research and Sponsored Programs (ORSP). Research activities that are intended only to teach research methods to students may not require IRB/ERC review. Research course instructors should obtain *Guidelines for Student Research Activities* by contacting the Office of Research and Sponsored Programs (ORSP). The Director of Research Compliance assists with any questions regarding student research activities.

IRB/ERC review is also required of research carried out under the sponsorship of an institution other than Marywood University but which is performed on the premises of Marywood University, even if the research has already been approved by the IRB at the sponsoring institution or elsewhere.

The IRB is to provide an independent determination concerning the safeguarding of the rights and welfare of individual research participants; whether the participants are placed at risk and, if risk is involved, whether

- the risks to the participant are so outweighed by the sum of the benefit to the participant and the importance of the knowledge to be gained as to warrant a decision to allow the participant to accept such risks;
- the rights and welfare of the participants are protected;
- informed consent will be obtained by adequate and appropriate means;
- the conduct of the activity will be reviewed at timely intervals.

Research covered by this policy, which has been approved by the IRB, may be subject to further review and approval or disapproval by officials of the institution. However, those officials may not approve the research if it has not been approved by the IRB or ERC.

Procedures

A booklet containing detailed definitions and procedures is available from the Marywood University Institutional Review Board for the Protection of Human Participants. Members of the faculty, administration, or staff of Marywood University who are considering becoming involved in such projects should obtain one from the Board. Students must seek the guidance of a faculty or staff sponsor familiar with the student and the proposed activity.

Related Policies and Committees

University Standing Committee - Institutional Review Board for the Protection of Human Participants

Policy - Educational Training in Human Subjects Protection for IRB Members and IRB Administrative Personnel

Policy - Educational Training in Human Subjects Protection for Investigators

History of the Policy

01/12/93 – Approved by the President as recommended by College Committee on Policy

04/23/03 – Revision approved by the Assistant to the Vice President for Academic Affairs for Community Collaboration and Research while the Vice President was on medical leave.

11/14/08 – Revision approved by the President of the University as recommended by the Assistant Vice President for Community Collaboration and Research and the Policy Committee of the University.

04/22/10 - Revision approved by the President of the University as recommended by the Assistant Vice President for Community Collaboration and Research and the Policy Committee of the University.

04/29/11 – Revision approved by the President of the University as recommended by the Policy Committee of the University.

MARYWOOD UNIVERSITY POLICIES AND PROCEDURES MANUAL

Mary T. Gardier Paterson, Esquire
Secretary of the University and General Counsel
Phone: 570-340-6018
Email: paterson@marywood.edu