



Institutional Review Board for the Protection of Human Participants

Purpose & Function

The purpose of the Institutional Review Board for the Protection of Human Participants (IRB) is the safeguarding of the rights and welfare of individuals participating in research. The Board reviews and has authority to approve, require modifications in (to secure approval), disapprove, and monitor all research involving human participants conducted at Marywood University or elsewhere under Marywood University sponsorship. The Board may establish policies that allow research posing minimal risk to subjects to be exempt from full review and may delegate some reviews to the department, school, or college level.

The Board is a decision-making group to approve applications for research involving human participants based on established policies and federal regulations. It serves as the liaison between the University and federal agencies regarding the protection of human participants.

Membership

Members represent the interests of the University and the community. There are at least nine primary members with various backgrounds and fields of expertise, including, at least:

- one member from outside the University who is not otherwise affiliated with the institution and who is not part of the immediate family of a person who is affiliated with the institution
- one physician, physician's assistant or medical professional
- up to two representatives from each college
- the Director of Human Participants Protection and Research Compliance
- one prisoner or prisoner representative (reviews prisoner research only)



Three alternates may serve as representatives for primary members from their respective colleges (one per each college).

Federal regulations require inclusion of at least one member whose primary concerns are in scientific areas and at least one member whose primary concerns are in nonscientific areas.

The Director of Human Participants Protection and Research Compliance staffs the committee.

Faculty members will self-nominate for college representative and alternate positions. The Provost appoints members, with a view to ensuring cultural, professional and academic diversity. Membership is contingent on year-round availability. When the Board reviews research that involves a vulnerable category, such as children, prisoners, pregnant women, or persons with mental disabilities, consideration is given to the inclusion of one or more individuals who are experienced or knowledgeable about working with these participants.

The Provost appoints the Chair, who must be an experienced member of the IRB. When at all possible, the Chair must be affiliated with Marywood University. If not possible, an unaffiliated member may be appointed.

Term

An appointed member's term is three years, with possibility of reappointment for one additional term. Eligibility is effective again after a hiatus of one year. If someone fills an incomplete term, they are eligible for two additional three (3) year terms. In order to ensure the availability of a physician, physician's assistant, medical professional, prisoner or prisoner representative to the IRB, the terms of the physician, physician's assistant or medical professional member and the prisoner or prisoner representative member is not limited to two three-year



terms. If no member affiliated with Marywood University agrees to serve as Chair, an unaffiliated member may be appointed for a term of one year.

Meetings: Except when an expedited review procedure is used, the IRB may review proposed research at convened meetings at which a majority of the members of the IRB are present, including at least one member whose primary concerns are in nonscientific areas. Alternates are not counted in the total number of IRB members used to calculate a quorum. Each alternate member may only vote in place of a primary member from the same college. If both the primary member and his/her college's alternate are present at a meeting, only one may vote for any individual agenda item. In order for the research to be approved, it shall receive the approval of a majority of those members present at the meeting and eligible to vote.

The Board meets once a month in a formal session. In exceptional cases, business may be conducted via telephone conference call. Times of monthly meetings are announced on the Institutional Review Board's website.

Documentation Requirements for this University Standing Committee

The Director of Human Participants Protection & Research Compliance, in collaboration with the Office of the Secretary of the University and General Counsel, must provide the following documentation at the end of each Academic Year:

Annual Report: **Yes** **No**

Minutes of Meetings: **Yes** **No**

Reports To

Provost



History

11-20-1987 Committee on Human Subjects approved by the President as recommended by College Committee on Policy.

1-12-1993 Board established by the President as recommended by College Committee on Policy.

11-8-2002 Revision approved by the Vice President for Academic Affairs.

4-21-2002 Terminology changed from "human subjects" to "human participants."

5-6-2008 Title change to Provost and Vice President for Academic Affairs.

5-6-2008 Title change to Assistant Vice President for Academic Affairs for Research and Community Collaboration.

5-4-2010 Revision approved by the Provost and Vice President for Academic Affairs.

2-18-2011 Title change to Assistant Vice President for Research and Sponsored Programs.

7-1-2011 Title change to Vice President for Academic Affairs.

9-4-2012 Membership revision approved by the Vice President for Academic Affairs to include physician or physician's assistant.

10-12-2016 The revision to the Description to better align with the Federal regulatory language was approved by the President of the University as recommended by the Policy Committee of the University.

7-1-2017 Membership and Description revisions were necessary due to recommendations by the SRA Report: Final 29 November 2016 and the Academic Restructuring, and were approved by the President of the University.

5-11-2018 The President of the University approved the revisions as recommended by the Policy Committee of the University.

12-20-2021 Clarification of number of representatives from each College; addition of the Documentation Requirements Section approved by the Director of Human Participants Protection & Research Compliance, Associate Provost, and the Provost.