

Board Authority and Composition

Purpose

The purpose is to describe the authority, composition and administration of the Institutional Review Board (IRB).

Definitions

A **nonscientist** is an IRB member whose training, background, and occupation would incline him/her to view scientific activities from the standpoint of someone outside of a behavioral or biomedical research discipline. It is an individual with little or no scientific or medical training or experience.

An **unaffiliated** individual is an IRB member 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.

Policy

In order to safeguard the rights and welfare of individuals participating in research, the IRB has regulatory authority to review, approve, require modifications in (to secure approval), disapprove, monitor, suspend or terminate all research activities which fall within its jurisdiction [45 CFR 46.109 (a) and 46.113]. It also has the authority to observe or have a third party observe the consent process and the research [45 CFR 46.109 (g)].

Composition

Marywood University's [IRB Standing Committee](#) web page describes the IRB's overall composition and member terms for primary, alternate, scientist/non-scientist and unaffiliated members. In addition, the IRB may, at its discretion, invite individuals with competence in special areas to assist in the review of issues which require expertise beyond or in addition to that available on

the IRB. Such individuals will act as consultants and may not have voting privileges.

Functions and Operations

In order to meet Federal requirements, the IRB secures space for monthly meetings and maintains sufficient staff to support IRB review and record keeping duties.

All IRB members and staff receive human subject protection education related to federal regulations and guidance, institutional policies and procedures, and review processes. Training continues via meeting materials and presentations, email announcements, and webinars.

The IRB office maintains a current list of the IRB members identified by name, earned degrees, representative capacity, indications of experience such as board certifications or licenses sufficient to describe each member's chief anticipated contributions to IRB deliberations, and any employment or affiliation of each member and the institution.

The IRB maintains and follows written procedures for (a) initial and continuing review, (b) reporting of findings and actions to the investigator and institution, (c) determining which projects require more than annual review or verification from sources other than the investigators that no material changes have occurred since previous IRB review, (d) prompt reporting of research changes and ensuring that investigators will conduct the research activity in accordance with the terms of the IRB approval until any proposed changes have been reviewed and approved by the IRB (except with immediate hazards to the subjects), (e) prompt reporting to the IRB, institutional officials, and appropriate Federal agencies of any unanticipated problems involving risks to subjects or others or any serious or continuing noncompliance with Federal regulations or the requirements or determinations of the IRB, and (f) prompt reporting of any suspension or termination of IRB approval.

No IRB member may provide initial or continuing review of any project in which the member has a conflicting interest, except to provide information requested by the IRB.

Meetings

Except when an expedited review procedure is used, the IRB reviews proposed research at convened meetings at which a majority of IRB members are present, including at least one member whose primary concerns are in nonscientific areas. In order for the research to be approved, it shall receive the approval of a majority of those members present at the meeting who are eligible to vote.

The Board meets once a month in formal session. In exceptional cases, business may be conducted via telephone or web-based conference call, with members accessing meeting materials online ahead of the meeting. Times of monthly meetings are announced on the Institutional Review Board's website.

History

10/20/2017: Updated to align with Institutional policy for the IRB Standing Committee, last revised 07/01/2017

06/25/2019: Updated as a result of the Revised Common Rule and to eliminate redundancy