

Both HHS and FDA regulations address requirements for IRB membership and approval of proposed research at convened meetings. The University of Michigan Human Research Protection Program (or HRPP)'s Operations Manual outlines and expands on these requirements for University of Michigan IRBs.

Every IRB must consist of at least five members, with varying backgrounds to promote adequate review of common research. The IRB must be qualified through both the expertise and the diversity of its members.

Since the IRB must determine the acceptability of proposed research in terms of institutional commitments and policies, applicable laws and regulations, and standards of professional conduct and practice, the IRB must also include members knowledgeable in these areas.

Every IRB must include at least one member whose primary concerns are in scientific areas and at least one member whose primary concerns are in nonscientific areas. According to OHRP guidance, "members whose training, background, and occupation would incline them to view scientific activities from the standpoint of someone within a behavioral or biomedical research discipline should be considered a scientist, while members whose training, background, and occupation would incline them to view research activities from a standpoint outside of any biomedical or behavioral scientific discipline should be considered a nonscientist. In addition, the IRB must have members with sufficient knowledge of the specific scientific discipline(s) relevant to the research that it reviews."

When reviewing FDA-regulated studies, the IRB must include at least one physician.

If an IRB regularly reviews research involving vulnerable categories of subjects—such as children, prisoners, pregnant women, or handicapped or mentally disabled persons—consideration must be given to the inclusion of one or more individuals who are knowledgeable about and experienced in working with these subjects.

Every nondiscriminatory effort must be made to ensure that no IRB consists entirely of men or entirely of women. No selection may be made, however, solely on the basis of gender.

No IRB may consist entirely of members of one profession.

Every IRB must include at least one 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. OHRP considers the following individuals affiliated: part-time employees, current students, members of any governing panel or board of the University, paid and unpaid consultants of the University, healthcare providers with medical staff membership or other credentials to practice at University clinical sites, and volunteers working at the University on business unrelated to the University.

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IRB Membership Requirements and Quorum

To approve any proposed research, a convened IRB meeting must meet quorum. Quorum is the minimum number of voting members required for a valid IRB vote. To meet quorum, a majority of voting IRB members—or, if a regular voter is absent, an alternate voter with comparable qualifications—must be present. For example, if a board consists of 14 members total, no fewer than eight voting members—half the total membership, plus one—must be present to cast votes in order to meet quorum.

Meeting quorum also involves ensuring the presence of all IRB member types required by federal regulations and institutional policy. For example, for all discussion and votes at a convened IRB meeting, at least one non-scientist member must be present in order to meet quorum.

Attendance of all present members is recorded in the meeting minutes. If, during the course of the meeting, a non-scientist is not present or quorum is lost, votes may not be taken until all required members are present and quorum has been restored.

Contact the IRB for more information about IRB membership requirements and quorum.

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