



IRB MEMBERSHIP, VOTING, AND QUORUM

11/20/2023

Federal regulations (45CFR46.107 and 21CFR56.107) describe the requirements for membership of a duly constituted IRB, including some of the heterogeneous characteristics of the members. Requirement for members with varying backgrounds is intended to promote complete, adequate, and broad-based review of research activities conducted by the institution.

The DUHS IRB is multidisciplinary and reviews a wide range of biomedical research from all components within DUHS, and when asked, by components from elsewhere within Duke University. From time to time, the IRB may review protocols from other sites for which the IRB has agreed to serve as the site's IRB of record and appropriate agreements are in place.

Each convened board includes members of both genders and at least one member whose primary concerns are in scientific areas and at least one member whose primary concerns are in non-scientific areas. Each board includes at least one member who is not otherwise affiliated with the institution and who is not a part of the immediate family (first degree relative) of a person who is affiliated with Duke University. Members affiliated with the institution include faculty and staff from the various components within DUHS and are selected for their clinical, scientific, and/or research expertise. Members who represent the general perspective of research participants include unaffiliated members, non-scientific members, and members with experience as clinical investigators or study coordinators. The unaffiliated member, the member representing the perspective of research participants, and the non-scientific member may be the same person, or it may be represented by two or three different people. The unaffiliated member, as well as a member who represents the general perspective of research participants, will be present for at least 80% of all convened board meetings.

The IRB documents the attendance of all members. Annually a spreadsheet showing the number of meetings attended by members is produced and reviewed by IRB leadership.

A quorum is defined as a majority of the members of that board. At least one member whose primary concerns are in non-scientific areas must be present for quorum. No meeting of a board shall proceed without a quorum of its members being present. Should a member be unable to attend, an IRB member who is an alternate for that member may substitute for that member. Members from the same department or representation may serve as alternates for each other but not as alternates for other representation. For example, an IRB member from the

Department of Medicine can serve as an alternate for any other Medicine representative but may not serve as an alternate for a member from Surgery.

Chairs, Vice Chairs, and the IRB Directors may be counted either as Administrative members of the boards, or as members representing their clinical departments. For example, a Chair or Vice Chair whose affiliation is with the Department of Pediatrics may be counted as the Pediatrics representative in the absence of any other representative from that Department, when a protocol involving children is being reviewed.

The IRB's standard practice is to count a maximum of three IRB administrative staff persons and Chairs in the overall total vote count, except in special circumstances as determined by the Executive Director and the Director of Compliance.

Approval of an IRB submission or action at a convened board meeting requires that a super-majority (at least 75%) of the members present vote to approve the submission. The super-majority is calculated by the formula: $0.75 \times (\# \text{voting for} + \# \text{voting against} + \# \text{voting to abstain})$. The DUHS IRB considers an abstention as a "vote to abstain," and it is a vote counted toward quorum. Voting may be by show of hands of those in favor (for), against or abstaining, or if requested by a member present, by written ballot.

Board Specialists will maintain the quorum count and record the vote counts throughout the meeting, using the Voting and Attendance Log. If both a primary member and their alternate(s) are present at a meeting, only one will be voting for any individual agenda item. The attendance of all individuals (voting and non-voting) at a meeting will be recorded, and the Voting Log will indicate who voted on each agenda item, but not whether they voted for or against. The voting log will be retained as a part of the record of the convened meeting.

Member Conflict of Interest

Any member with a conflicting interest (see DUHS IRB Policy titled "Conflict of Interest Pertaining to DUHS IRB Members and Consultants") may not participate in the review of a protocol except to provide information requested by the IRB. In such cases, the member with the conflicting interest will absent themselves from the room during the deliberations related to the protocol and the vote, and the absence will be recorded in the minutes.

Consultants

On occasion, the IRB may invite an individual or individuals with competence in a special area to assist in the review of issues that require expertise beyond or in addition to the expertise available among the members of the IRB. IRB members

who provide expertise at meetings for which their department or representation is not included on the roster are considered consultants.

Consultants are asked to declare verbally or in writing that they have no conflicting interest with the protocol or a related or competing protocol (see DUHS IRB Policy titled "Conflict of Interest Pertaining to DUHS IRB Members and Consultants"). These individuals may not vote with the IRB, including consultants who are also IRB members.

Previous Version Date(s): 5/27/2008, 8/18/2011, 5/20/2016, 11/8/2019, 4/14/2021