



## **IRB MEMBERSHIP, VOTING, AND QUORUM**

5/27/2008

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.

Members are selected based on their experience and expertise and their standing in the community to ensure diversity of membership, including considerations of race, gender, and cultural backgrounds and sensitivity to community attitudes. The standing of the members promotes respect for the IRB's advice and counsel in safeguarding the rights and welfare of human research subjects. In addition to possessing the professional competence necessary to review specific research activities, the membership includes persons who are knowledgeable of, and who are able to ascertain the acceptability of, the proposed research in terms of institutional commitments and regulations, applicable law, and standards of professional conduct and practice. Since the IRB regularly reviews research that involves vulnerable subjects, such as children, prisoners, pregnant women, or persons with diminished capacity, the membership includes one or more individuals who are knowledgeable about and experienced in working with such subjects.

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. No member participates in the initial or continuing review of a protocol in which the member has a conflicting interest, except to provide information requested by the IRB. In such cases, the member with the conflicting interest will absent himself or herself from the room during the deliberations related to the protocol and the vote.

Each convened board includes at least 11 members, with a quorum being 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.

Chairs, Vice Chairs, and the IRB Directors may be counted as either 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.

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. These consultants are asked to declare in writing that they have no conflicting interest with the protocol or a related or competing protocol. These individuals may not vote with the IRB.

As designated by the Chancellor for Health Affairs, all members are appointed by the Dean of the Duke University School of Medicine or his/her designee. Their term of appointment is indefinite. Members from within DUHS are nominated for IRB membership by their respective Department chair or director, whether the Department is an academic Department or a clinical Department within Duke University Hospital. The nomination includes a statement of support from the nominator and a copy of the nominee's curriculum vitae. Members who are unaffiliated with DUHS or Duke University are nominated for IRB membership by current members of the Duke community or by community leaders who are knowledgeable of the qualifications of the nominee and the requirements of DUHS IRB service.

On each IRB submission Key Personnel are identified to ensure that each person involved in the performance of the research who has access to identifiable private research information also has appropriate ethics education. "Key Personnel" for a research study are research personnel who are directly involved in conducting the research with human subjects through an interaction or intervention for research purposes, or who are directly involved with recording or processing identifiable private information, including protected health information, related to those subjects for the purpose of conducting the research study.

In addition, the list of Key Personnel in the IRB submission identifies those who might have a conflict of interest in the protocol review process while acting in the role of IRB member or IRB consultant. DUHS IRB Policies and Procedures permit the IRB member/consultant to review the protocol or participate in the study's discussion and deliberations at a convened meeting if the person does not have a conflicting interest of any kind as defined in the DUHS IRB Policy

titled “Conflict of Interest Pertaining to DUHS IRB Members and Consultants”, and if the person’s study-related activities are limited to those defined in the same policy.

In such cases the minutes of the IRB meeting will reflect the basis for the determination that the member/consultant meets the requirements for being able to participate in the discussion/review of the protocol.

Please refer to the DUHS IRB Policy titled “Conflict of Interest Pertaining to DUHS IRB Members and Consultants” for further information.

Approval of an IRB submission or action (protocol, amendment, report or finding [such as a report of an unanticipated problem involving risks to subjects or others, a finding of serious or continuing noncompliance, or a suspension or termination of a research study]) at a convened board meeting requires that a super-majority (at least 75%) of the members present vote to approve the submission. 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. The DUHS IRB considers an abstention as a “vote to abstain,” and it is a vote counted toward quorum.

Board Specialists will maintain the quorum count and record the vote counts throughout the meeting, using the Voting and Attendance Log. The log will indicate who voted, but not of how anyone voted. The names of members who absent themselves from the room for a particular discussion and vote due to having a conflicting interest will be recorded in the minutes and so designated. On the rare occasion that there is more than one member present from the same Department or representative group, and the membership roster for that IRB lists only one person as a member from that entity, only one person from that entity is permitted to vote, and the minutes reflect who voted and who did not vote. The voting log will be retained as a part of the record of the convened meeting.