

Children's Hospital and Health System, Inc.
Administrative Policy and Procedure
Children's Research Institute

SUBJECT: Institutional Review Board (IRB) Voting

POLICY

I. Purpose:

To provide guidance to the IRB on proper voting procedures and ensure observation of federal regulations.

II. Policy:

- A. Voting on proposed research may only be conducted when a quorum (50% plus 1) of the IRB members are present and eligible to vote. In addition, in order for a vote to be conducted, one member whose primary concerns are in a non-scientific area must be present.
- B. In order for a IRB member to be eligible for voting, they must be independent of the investigator and sponsor of the proposed research. An IRB member will be ineligible to vote if:
 1. the IRB member is listed as a member of the research team;
 2. the investigator or sponsor is an immediate family member or relative;
 3. there is a financial conflict of interest; or
 4. there is a reporting relationship to the investigator or sponsor.
- C. Members with a conflicting interest in the project under review will abstain and may not participate in the discussion of the study except to provide information requested by the IRB. In addition, the conflicted member must physically leave the room during deliberations and voting.
- D. Meetings Convened via Conference Call
 1. Although physical presence at the meeting is usually required, participation via telephone conference call will be allowed under limited circumstances **as long as** the following two (2) conditions have been satisfied and clearly documented in the minutes:
 - a. the member participating via conference call has received all pertinent material prior to the meeting, and
 - b. the member can actively and equally participate in the discussion of all protocols.
 2. Members participating via conference call can vote and be counted for quorum.

- E. Any meeting during which quorum should fail (e.g., those with conflicts being excused, early departures, loss of a non-scientist, etc.) will be terminated for further voting unless and until quorum can be restored.
- F. Approval by a majority of the voting members' present is required for a research protocol to be implemented at Children's Hospital of Wisconsin.

PROCEDURE

- A. Upon review of the protocol by the committee, and any conflicted members have left the room, the Chair will call for the vote as follows: "Approved", "Denied", and "Abstain".
- B. The IRB Coordinator will record the number of votes for each along with the total number of votes. Names of those abstaining also will be recorded, as well as the reason for abstaining.

References:

- A. 21 CFR 56
- B. 45 CFR 46.108(b)

(signed copy on file)

Peggy Troy, President CHHS