

Topic: Voting at IRB Meetings**Overview of the Topic**

The IRB is given the authority to approve, require modifications to approve, or disapprove research protocols presented for review. At convened meetings of the IRB, these actions are determined by a vote of the committee. To conduct business (e.g. approve or disapprove protocols) at an IRB meeting, a quorum must be present. As members may come and go at meetings, or be recused, the number of members at any point of the meeting may vary and it must be documented that a quorum is present at the time of a vote. The dictionary defines a quorum as “the minimum number of members required to be present at an assembly or meeting before it can validly proceed to transact business.” While the federal regulations do not define what a quorum of the IRB is, the generally accepted practice is a majority of members, or more than half of the rostered members. So if there are 15 rostered members a quorum would be 8. If the number of rostered members is even, a quorum would be one more than half; 12 rostered members, the quorum would be 7. The quorum is not only numerical, but the non-scientific member and any required member (e.g. prisoner representative) must be present. Then, in order for the research to be approved, it must receive the approval of a majority of those members present at the meeting (45CFR46.108(b)).

To vote at a meeting, a person must be a rostered member of the IRB. This may be a primary member, or an alternate member who replaces a primary member. Since the IRB Chair is a rostered member, he or she may vote. At some IRBs the Chair only votes in situations of a tie vote – this is a procedure described in Robert’s Rules of Order. However, since the IRB Chair is usually an experienced, knowledgeable and valuable member of the committee it is recommended that he or she does vote and utilize their knowledge and experience in the discussion and decision.

No IRB may have a member participate in the IRB's initial or continuing review of any project in which the member has a conflicting interest, except to provide information requested by the IRB (45CFR46108(e)). The Chair should ask at the beginning of the meeting if any member has a conflict of interest on any protocols under review at the meeting. Sometimes a member may realize they have a conflict when the protocol is being discussed – in this case the member should disclose the conflict immediately to the committee. The conflicted member may be asked to provide information on the research under review, and then the Chair must ask the member to leave for the final discussion and vote. A conflicted member should not remain in the room for final discussion and voting, should not vote and should not be counted toward quorum when the vote is taken. Note this is recusal, not an abstention.

Debates by IRB members, and even dissent from the majority opinions, is not a bad thing and in most cases should be encouraged. It is essential for the IRB to explore all questions and issues related the protocol under review and all points of view. In fact, it is a requirement that all controverted issues be brought up, discussed and resolved. The regulatory criteria for approval (45CFR46.111) must be “satisfied” and thus any issues related to the criteria must be discussed and resolved or the protocol cannot be approved.

At some point in the discussion of a protocol, a member should make a motion to approve, approve with conditions, disapprove, or table the protocol (based on what motions and wording your policies and procedures stipulate). The motion must be seconded to be considered. Continued discussion then occurs. Motions, particularly the final motion, should be recorded in the exact wording, including the exact wording of any conditions for approval. IRB members should clearly know the motion and its requirements that they are voting on.

Example: Motion to conditionally approve the protocol with the following minor modification – change the words “myocardial infarction” to “heart attack” in the consent form; moved by Dr. Jones. Seconded by Dr. Strange.

Once an adequate amount of discussion and debate has occurred, any IRB member may “call the question” for a vote on the motion. Another member must second the request for the motion to be voted on. If the “call the question” motion is contested, a vote should be taken to determine if the majority of IRB members are ready to end discussion and vote. Alternatively, sensing that adequate discussion has occurred, the Chair may ask if the committee is ready for a vote. These procedures are not regulatory, but again come from Robert’s Rules of Order, and are an efficient and fair way to end discussion and call for a vote.

Most IRBs make decisions when the Chair takes a count of members who approve, disapprove, or abstain from voting for the motion. When all members are physically present in the meeting room, a voice count may be taken, or a hand count if the Chair cannot discern the numbers. If some or all members are attending by phone, a roll call vote must be taken to ensure all attending members vote and are accounted for. Some IRBs which conduct web meetings take the vote using the polling function present in most web meeting platforms. There are some IRB committees which only approve research once a consensus of all members occurs. Questions are answered or modifications made or required until all member agree to approve. While this method of approval meets the requirements of the regulations, a consensus is not required for approval. As different points of view are held by different IRB members, it is not a bad thing that a split vote occurs. In fact, a split vote may indicate that the discussion was robust and differences of opinions resulted. Sometimes a difference of opinion on issues may only be satisfied by the final vote. Again, a motion is carried when a majority of members present at the meeting approve the motion.

Example: Chair says "All those in favor of the motion raise your hands...opposed...abstaining. Dr. Curtis on the phone, what is your vote...Dr. Tyson on the phone, what is your vote?"

Since a majority of members present need to approve a protocol, abstentions may have an effect of the outcome. For example, if 13 members are at an IRB meeting and the vote is 6 approve, 5 vote no, and 2 abstain, the motion did not carry because a majority of the members (7 in this case) did not approve the protocol. This situation does not occur frequently but it is something the IRB should be aware of.

It is required that details of the vote and related review issues be documented in the minutes. The regulations require that minutes of IRB meetings which shall be in sufficient detail to show attendance at the meetings; actions taken by the IRB; the vote on these actions including the number of members voting for, against, and abstaining; the basis for requiring changes in or disapproving research; and a written summary of the discussion of controverted issues and their resolution (45CFR46.115(2)).

Example: Motion to approve passes (10 for, 2 against, 1 abstaining, note Dr. Booth voted via phone by voice vote, Dr. Smith recused for conflict of interest).

Your policies and procedures should stipulate all the information about quorum, voting, and the types of motions used by your IRB. Certainly the IRB Chair and members and all IRB staff involved in meetings should be very aware of all of these requirements, which should result in efficient and consistent IRB meetings and decisions.

Questions for the IRB to Consider when Voting at a Meeting of the Convened IRB

1. Are you aware of your SOPs concerning quorum and voting at IRB meetings?
2. Do you have a conflict of interest on the protocol under review?
3. Did adequate discussion occur so the vote can be called for?
4. Is a quorum present for the vote, including any required members present?
5. Was the motion clearly stated including all conditions so you understand what you are voting for or against?
6. Did the majority of members vote to approve the motion?
7. Have all discussions, determinations, and voting details been included in the meeting minutes?

Case Studies

Case 1. Nine members are at an IRB meeting, which is the minimum number required for quorum. Dr. Jones is the PI for the protocol under review and leaves the room after answering a few questions. The motion to approve is passed with a vote of 5 for, 3 voting no, and no abstentions. If the protocol approved?

Case 2. Thirteen members are at an IRB meeting, which is 1 above the required number for quorum. Just before a vote is called for, one member goes into the hall to answer a phone call and another member is in the rest room. What should the IRB Chair do?

Case 3. In a robust discussion at an IRB meeting over approval of a protocol, two members state their unwavering opposition to approval. The discussion goes on and on without any resolution. What should the IRB members or IRB Chair do?

Prospective Thinking: Have a discussion about what issues with quorum and voting have occurred in the past at your IRB meetings. Were they resolved correctly? Are there SOPs you could put in place to avoid these issues in the future?