Sheet 19: CRITERIA FOR SELECTION AND USE OF ALTERNATE MEMBERS ON NIH INSTITUTIONAL REVIEW BOARDS

The DHHS and FDA regulations on the Protection of Human Subjects (45 CFR 46 and 21 CFR 56) do not address the use of alternate members on Institutional Review Boards (IRBs). The FDA "Guidance for Institutional Review Boards and Clinical Investigators" (1998) does, however, provide the following information:

> "The use of formally appointed alternate IRB members is acceptable to the FDA, provided that the IRB's written procedures describe the appointment and function of alternate members. The IRB roster should identify the primary member(s) for whom each alternate member may substitute. To ensure maintaining an appropriate quorum, the alternate's qualifications should be comparable to the primary member to be replaced. The IRB minutes should document when an alternate member replaces a primary member. When alternates substitute for a primary member, the alternate member should have received and reviewed the same material that the primary member received or would have received."

The Office of Human Subjects Research does not encourage the use of alternate members on NIH's IRBs and there is no NIH policy that requires Institutes to appoint them. However, if Scientific and Clinical Directors, in consultation with their IRB Chairs, believe that the use of one or more alternate members will be of value to their Institute's IRBs, the following criteria apply:

1. The appointment process for alternate members is the same as for regular members. The IC Clinical Director, in consultation with the Scientific Director, recommends the appointment to the Deputy Director for Intramural Research, who is the appointing official.

2. The alternate member must have expertise similar to that of the regular member whom she/he replaces. The alternate member acts as alternate, i.e., reviews and votes on protocols at a convened meeting, only in the absence of the regular member. The alternate member may not vote on behalf of any other regular member.

3. The alternate member must be appointed to a specified term (1 to 3 years).

4. The alternate member must be trained and oriented for IRB service in the same way as regular members, i.e., at a minimum, completion of the two OHSR computer-based training courses and orientation with an OHSR staff member.

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5. The alternate member must receive agenda packages for all IRB meetings and should be encouraged to attend as many meetings as possible even when not required to be present to act as a formal alternate.

6. The alternate member's service on the IRB may not exceed 3 meetings per year for Boards that meet monthly and 6 meetings per year for Boards that meet bi-weekly.

7. An IRB's quorum requirement is unaffected by the appointment of alternate members. The quorum requirement is still based on the number of regular members. When an alternate member is substituting for a regular member, his/her vote counts towards the quorum in the same way as the regular member's vote.

8. An IRB meeting may not be conducted when alternates constitute the majority of the members present.

9. The IRB minutes must document when the alternate member serves in place of the regular member.

10. When an IRB uses alternate members, its written standard operating procedures must be amended to include the criteria above and the name(s) of the alternate member(s) must be included in the IRB's membership roster.