

From: [OC GCP Questions](#)  
To: [REDACTED]  
Subject: IRB Quorum  
Date: Tuesday, January 27, 2015 1:57:21 PM

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Good morning --

IRB should have written procedures as to how an IRB member can be replaced if needed. This insures the integrity of the membership and maintaining a quorum to vote. Please consult your IRBs SOPs. As you state you cannot vote if a quorum is not maintained. I can offer you the following information.

[Search for FDA Guidance Documents > Institutional Review Boards Frequently Asked Questions - Information Sheet](#) It states --

*14. When IRB members cannot attend a convened meeting, may they send someone from their department to vote for them?*

*No. Alternates who are formally appointed and listed in the membership roster may substitute, but ad hoc substitutes are not permissible as members of an IRB. However, a member who is unable to be present at the convened meeting may participate by video-conference or conference telephone call, when the member has received a copy of the documents that are to be reviewed at the meeting. Such members may vote and be counted as part of the quorum. If allowed by IRB procedures, ad hoc substitutes may attend as consultants and gather information for the absent member, but they may not be counted toward the quorum or participate in either deliberation or voting with the board. The IRB may, of course, ask questions of this representative just as they could of any non-member consultant. Opinions of the absent members that are transmitted by mail, telephone, telefax or e-mail may be considered by the attending IRB members but may not be counted as votes or the quorum for convened meetings.*

*15. May the IRB use alternate members?*

*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.*

*16. Does a non-affiliated member need to attend every IRB meeting?*

*No. Although 21 CFR 56.108(c) does not specifically require the presence of a member not otherwise affiliated with the institution to constitute a quorum, FDA considers the presence of such members an important element of the IRB's diversity. Therefore, frequent absence of all non-affiliated members is not acceptable to FDA. Acknowledging their important role, many IRBs have appointed more than one member who is not otherwise affiliated with the institution. FDA encourages IRBs to appoint members in accordance with 21 CFR 56.107(a) who will be able to participate fully in the IRB process*

You also much consider how replacing the sick IRB member will affect the membership areas as stated in the regulation below. The FDA regulations regarding IRB membership at 21 CFR 56.107(c) and (d) state:

Sec. 56.107 IRB membership.

(c) Each IRB shall include at least one member whose primary concerns are in the scientific area [emphasis added] and at least one member whose primary concerns are in nonscientific areas [emphasis added].

(d) Each IRB shall include at least one member who is not otherwise affiliated with the institution [emphasis added] and who is not part of the immediate family of a person who is affiliated with the institution.

It is important to ensure that if the institution/IRB has written procedures that define how IRB members are appointed as “scientist” or “non-scientist”, that those written procedures are followed.

Lastly, you might want to review FDA’s compliance program on for IRB inspections. Quorum is addressed in this document.

<http://www.fda.gov/downloads/ICECI/EnforcementActions/BioresearchMonitoring/UCM133768.pdf>

I hope this information is helpful. Please contact us again at [gcp.questions@fda.hhs.gov](mailto:gcp.questions@fda.hhs.gov) should you have additional questions.

Kind regards,

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This communication does not constitute a written advisory opinion under 21 CFR 10.85, but rather is an informal communication under 21 CFR 10.85(k) which represents the best judgment of the employee providing it. This information does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the views expressed.

**From:** [REDACTED]  
**Sent:** Monday, January 26, 2015 1:54 PM  
**To:** OC GCP Questions  
**Subject:** IRB Quorum

Good Afternoon,

Our IRB has a member that had serious surgery and will not be able to attend meetings from 3-6 months. Our membership is appointed by the Medical Executive Committee of our institution. Can we temporarily suspend his membership due to serious illness without going through the entire process of reappointment when he is physically able to return? We do not want his absence to affect our quorum. Please advise. Thank you.