

**From:** [OC GCP Questions](#)  
**To:** [REDACTED]  
**Subject:** IRB question  
**Date:** Thursday, May 12, 2016 6:32:21 AM

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Good morning [REDACTED] --

Alternates are required to only be used for the same regular member.

While the regulations do not speak to alternate members, FDA has long considered use of alternates an appropriate way for an IRB to function. Long-standing guidance, [Guidances > Institutional Review Boards Frequently Asked Questions - Information Sheet](#) found in the Q&A section of the FDA Information Sheets, [www.fda.gov/RegulatoryInformation/Guidances/ucm126420.htm](http://www.fda.gov/RegulatoryInformation/Guidances/ucm126420.htm), advises that an alternate should be an appropriate substitute for the person he/she is acting instead of. See the information in Q&A 15 at the same link provided in the previous e-mail and as copied below.

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.

It is not a requirement that the alternate be the same gender. I hope this information is helpful.

Kind regards,

Doreen M. Kezer, MSN  
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Office of the Commissioner, FDA

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.

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**From:** [REDACTED]  
**Sent:** Wednesday, May 11, 2016 2:59 PM  
**To:** OC GCP Questions  
**Subject:** IRB question

Good Day,

I am a supervisor with the Atlanta district and a question was raised regarding use of alternates used during an IRB meeting. I need to confirm whether alternates are required to only be used for the same regular member? or Can they be used for different members who are not present?

Thanks,

[REDACTED]

[REDACTED]