From: OC GCP Questions
To: [redacted]
Subject: IRB membership
Date: Tuesday, September 09, 2014 12:28:25 PM

Good afternoon --

As you state the minimum number of members an IRB must have is 5.

The regulations at 21 CFR 56.108(c) require:

(c) Except when an expedited review procedure is used (see 56.110), review proposed research at convened meetings at which a majority of the members of the IRB are present, including at least one member whose primary concerns are in nonscientific areas. In order for the research to be approved, it shall receive the approval of a majority of those members present at the meeting [emphasis added].

Majority (often referred to as quorum) is the minimum number and type of IRB members that must be present for the IRB to conduct business. IRBs often calculate majority by using the "half-plus-one" technique. This technique works well for IRBs with an even number of IRB members. For example, if the total IRB membership is 10, then majority is 6 (half of 10 is 5 +1 = 6).

However, if the IRB has an odd number of members, then majority should be calculated by taking half of the total number of IRB members, then rounding up to the next whole number. For example, if the IRB membership is 15, then majority is 8 (half of 15 is 7.5, and rounding up to the next whole number is 8).

So to answer your question, if an IRB had 5 members then 3 members would be needed to meet the quorum requirement for the number of members needed to hold a convened meeting. Keep in mind that 1 of those 3 members present and participating in the convened meeting must have concerns in nonscientific areas.

One thing to keep in mind is the IRB regulations require an IRB to have a diverse membership. When an IRB has the minimum number of members (5) it may run into problems if during a meeting where only 3 members are present, if 1 of those 3 has a conflict of interest and must recuse themselves from del beration and voting on that research, then the IRB has lost it's quorum and can no longer conduct business at that meeting unless quorum is restored.

To meet the requirements of a divers membership some IRBs have more than the minimum number of IRB members and/or have alternate members who may replace a member who is absent at a given meeting so the IRB does not run into issues of meeting a quorum. FDA has guidance on IRB membership that you can find in the FDA Information Sheets – Institutional Review Boards Frequently Asked Questions that can be accessed at http://www.fda.gov/RegulatoryInformation/Guidances/ucm126420.htm (see section II).

I hope this information is useful. If you need further information and/or have additional questions, please feel free to contact us at the official GCP mailbox, gcp.questions@fda.hhs.gov. You may also find it useful to access the set of redacted GCP e-mails found at http://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/RepliestoInquiriestoFDAonGoodClinicalPractice/default.htm since we find that many questions and concerns are repeated over time.

Best Regards,

Doreen M. Kezer, MSN
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Office of Good Clinical Practice
Office of the Commissioner, FDA

From: [redacted]
Sent: Monday, September 08, 2014 4:01 PM
To: OC GCP Questions
Subject: IRB membership

Dear Office of Good Clinical Practice:

Good afternoon. I have a question about IRB membership, which comes from 21 CFR 56.107(a), that includes, "Each IRB shall have at least five members, with varying backgrounds to promote complete and adequate review of research activities

commonly conducted at the institution." Does the FDA interpret this to mean that in order for an IRB to review research activities, the convened IRB must have at least five members present at the meeting? Or does the FDA interpret this wording to mean that if a majority of the members of the IRB are present at the convened meeting, in this case only 3 members, review of research activities can be conducted?

Thank you for your time and help with this.

[redacted]