From: OC GCP Questions
To: [redacted]
Subject: RE: IRB Quorum question
Date: Tuesday, August 23, 2016 10:28:00 AM

Dear [redacted] -

Thank you for your question. FDA has a **Draft** guidance titled, "*Minutes of Institutional Review Board (IRB) Meetings: Guidance for Institutions and IRBs*" that may be helpful to you. I think you may be referring to this Draft guidance in your question, but you inadvertently refer to it as regulations, so I wanted to mention that it is guidance, not regulation. A good way to think about the difference between regulations and guidance is to remember that FDA regulations establish legally enforceable responsibilities and must be followed. Regulations are found in the Code of Federal Regulations (the CFR). When you read regulations, you will usually see the use of the word "shall" or "must". This means something is required. However, FDA's guidance documents do not establish legally enforceable responsibilities. Instead, guidance describes FDA's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in FDA guidance means that something is recommended or suggested, but not required. Guidance does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations.

Although the **Draft** guidance mentioned above is still in draft format at this time, as you alluded to in your question, section III.A.2. (called Quorum) provides examples of calculating quorum:

> 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, plus 1 equals 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, and 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).

If you have 13 IRB members (as indicated in your question), using this guidance to calculate quorum, you are correct that majority is 7 (half of 13 is 6.5, and rounding up to the next whole number is 7). You will also want to make sure that the other "conditions of quorum" are met (see page 3 of the draft guidance) and copied here for reference:

> Minutes of IRB meetings must be in sufficient detail to show attendance at the convened meeting of the IRB (45 CFR 46.115(a)(2); 21 CFR 56.115(a)(2)). In addition, except when an expedited review procedure is used, the IRB must 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. [emphasis added]** In order for the research to be approved, it must receive the approval of a majority of those members present at the meeting (45 CFR 46.108(b); 21 CFR 56.108(c)).

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,

Janet

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From: [redacted]
Sent: Monday, August 22, 2016 11:35 AM
To: OC GCP Questions; [redacted]
Subject: IRB Quorum question

I am a former CCRC acting as interim IRB Coordinator at our hospital. We have had 14 IRB members consistently with Quorum being 8. Very recently, one of our IRB members needed to resign immediately for personal reasons and we are now left with 13 IRB members for the next meeting.

I have read the FDA regulations re: Quorum determination using the 1/2 + 1 technique / formula.

However, since we now have an "odd number" of 13 members, I want to be certain that I have correctly calculated a quorum for our next meeting.

According to Federal Regulations 45 CFR 46.108(b) and 21 CFR 56.108(c) :
"... 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, and 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)."

QUESTION:

- If we have 13 members (an odd number), am I correct to calculate a quorum to be "7" (1/2 of 13 = 6.5 rounded up to 7 for majority/quorum?)
- -OR- do we still need to add 1 for a Quorum of 8?

Thank you... [redacted]