From: Lee, Bonnie on behalf of OC GCP Questions
Sent: Wednesday, March 02, 2005 8:44 AM
To: [Redacted]
Subject: RE: Question regarding quorum

Hi [Redacted],

FDA regulations do not define what constitutes a majority of members. Because, as you note, you cannot (or should not) cut one person in half, we would suggest that you take a simple majority, which in your case would be 6 members out of 11.

On a different topic, please note: FDA will be holding a public hearing in Rockville, Maryland, on March 21 to solicit views on the process by which IRBs obtain and review information on adverse events that occur during the conduct of clinical investigations. Registration to attend and/or speak at the hearing is required and can be done online at http://www.accessdata.fda.gov/scripts/oc/dockets/meetings/meetingdocket.cfm. We encourage registrants to participate as speakers. Information about the hearing is available at http://www.fda.gov/OHRMS/DOCKETS/98fr/oc04297.pdf. If you have questions or difficulty registering, we encourage you to contact Nancy L. Stanisic at 301-827-1660 or at stanisicn@cder.fda.gov.

Sincerely,

Bonnie

Bonnie M. Lee
Associate Director for Human Subject Protection Policy
Good Clinical Practice Program, 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.

-----Original Message-----
From: [Redacted]
Sent: Tuesday, March 01, 2005 5:20 PM
To: OC GCP Questions
Subject: RE: Question regarding quorum

Hello Bonnie,

Thanks for your reply, but I'm still a bit confused. I read that a majority is defined as 50% plus one. With 11 members, 50% would be 5 and a half, plus one would be 6 and a half. Since you can't have half a person, we wondered if 6 and a half should be rounded up to 7 or down to 6?

Thanks,
[Redacted]

-----Original Message-----

From: Lee, Bonnie [mailto:BLee@OC.FDA.GOV] On Behalf Of OC GCP Questions
Sent: Tuesday, March 01, 2005 1:55 PM
To: [Redacted]
Subject: RE: Question regarding quorum

Dear [Redacted],

It's a majority of members that is needed; thus, if the IRB has 11 members, you would need 6 (round up) to conduct a meeting.

Hope this is helpful.

Sincerely,

Bonnie

Bonnie M. Lee
Associate Director for Human Subject Protection Policy
Good Clinical Practice Program, 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.

-----Original Message-----
From: [Redacted]
Sent: Tuesday, March 01, 2005 3:57 PM
To: gcpquestions@oc.fda.gov
Subject: Question regarding quorum

Hello - If a board has 11 members and half is 5.5, is a quorum achieved with 6 or 7? Do you round down or up?

Thank you,
[Redacted]

DISCLAIMER:
This message is confidential, intended only for the named recipient(s) and may contain information that is privileged or exempt from disclosure under applicable law. If you are not the intended recipient(s), you are notified that the dissemination, distribution or copying of this information is strictly prohibited. If you received this message in error, please notify the sender then delete this message.

DISCLAIMER:
This message is confidential, intended only for the named recipient(s) and may contain information that is privileged or exempt from disclosure under applicable law. If you are not the intended recipient(s), you are notified that the dissemination, distribution or copying of this information is strictly

prohibited. If you received this message in error, please notify the sender then delete this message.