From: OC GCP Questions
To: [redacted]
Subject: RE: Question Regarding IRB Member Conflict of Interest
Date: Friday, February 19, 2016 7:54:00 AM

Dear [redacted],

The FDA regulations regarding IRB membership can be found at 21 CFR 56.107. In addition to describing the composition of the IRB membership, the regulations also state that no IRB may have a member participate in the IRB's initial or continuing review of any project in which the member has a conflicting interest, except to provide information requested by the IRB. The FDA regulations do not define what constitutes an IRB member conflict of interest, so many IRBs consider the current guidance on this issue and address this issue in their IRB written procedures.

The FDA regulations at 21 CFR 56.108(c) require that except when an expedited review procedure is used (see 21 CFR 56.110), the IRB shall 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.

In the scenarios you describe below, the IRB should determine whether this IRB member in the role of co-investigator for this study is conflicted based on his/her role as a co-investigator and their SOPs. The determination of COI, or not COI, should be the same in either scenario if the IRB member knows prior to IRB review of the study that he/she would be eventually performing these roles if the study is approved.

I recommend that you determine, in accordance with the IRB's written procedures, whether the co-investigator has a conflict of interest, keeping in mind that an IRB member who is determined to have a conflict of interest may not vote or count towards quorum on that project. This may require discussion with appropriate facility representatives, including legal counsel and/or a COI committee, as applicable. You may also wish to review the joint HHS/FDA guidance, *Financial Relationships and Interests in Research Involving Human Subjects: Guidance for Human Subject Protection*, for additional information on conflicts of interest. The guidance can be found at http://www.hhs.gov/ohrp/archive/humansubjects/finreltn/fguid.pdf .

Once you've established whether or not the co-investigator has a conflict of interest, I recommend that you determine whether or not you continue to have a majority of the members present (i.e., quorum) needed to take an IRB action on the project.

FDA recommends that IRB members with a conflicting interest in a project recuse themselves by leaving the meeting room when the IRB conducts review of that project, except when requested by the IRB to be present to provide information. Any IRB member recusal should be noted in the minutes of the IRB meeting when recording votes on that IRB action.

The FDA-recognized good clinical practice guidance, ICH E6 (available at www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM073122.pdf), addresses IRB member conflict of interest in section 3.2.1, regarding IRB composition, functions, and operations, and states ***"Only those IRB/IEC members who are independent of the investigator and the sponsor of the trial should vote/provide opinion on a trial-related matter."*** (emphasis added).

Also, FDA guidance (available at www.fda.gov/RegulatoryInformation/Guidances/ucm126420.htm, see question 12) suggests that when selecting IRB members, the potential for conflicts of interest should be considered. When members frequently have conflicts and must absent themselves from deliberation and abstain from voting, their contributions to the group review process may be diminished and could hinder the review procedure. Even greater disruptions may result if this person is

chairperson of the IRB.

I hope this information is helpful to you. If you need further assistance, please feel free to contact the GCP mailbox at gcp.questions@fda.hhs.gov .

Best regards,

Sheila

Sheila Brown, RN, MS
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Office of Special Medical Programs, Food and Drug Administration

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From: [redacted]
Sent: Tuesday, February 16, 2016 1:22 PM
To: OC GCP Questions
Subject: Question Regarding IRB Member Conflict of Interest

Hello,

I am from the Research Compliance Department at [redacted]. I have two questions regarding IRB member conflict of interest (COI) for an FDA-regulated study.

Say an IRB member was a **co-**investigator on [redacted] research and in this role as co-investigator had no input in the study design, protocol development, nor publishing or authorship rights and was not paid directly by the sponsor. However, he/she was involved in the consenting, recruiting, safety monitoring for the study, data collection, and provide oversight of the conduct of the study at the site by delegation from the PI. Would this IRB member have a COI, via their role (as described) as a co-investigator?

If the answer is "no", in the above scenario would the same IRB member in the same role of **co-**investigator for this type of study have a conflict of interest at initial review, before he/she had identified a prospective participant, enrolled a participant, or performed or directed research interventions or interactions with participants, even though he/she knew that they would be eventually performing these roles if the study is approved?

[redacted]