From: OC GCP Questions
To: [redacted]
Subject: RE: Requiring names of all non-IRB members who attend IRB meetings to be listed in IRB minutes
Date: Monday, June 27, 2016 10:42:00 AM

Dear [redacted] -

Thank you for your question. As you mentioned, the November 2015 draft joint OHRP and FDA guidance on minutes of IRB meetings currently states on page 4:

> If the IRB permits non-members and guests to attend a convened meeting (e.g., IRB support staff, the investigator whose study is being reviewed, study coordinator), then the minutes must record the name(s) of all such attendees (45 CFR 46.115(a)(2); 21 CFR 56.115(a)(2)). The minutes should be clear that the non-member or guest did not participate in the deliberation and voting. The institution and the IRB may consider having a written policy covering the attendance of non-members and guests at a convened meeting. This policy may help to ensure that those who attend an IRB meeting understand the confidential nature of the information being reviewed and promote respect for the IRB's advice and counsel in safeguarding the rights and welfare of human subjects.

As noted, this is draft guidance at this time. Public comments submitted to the docket are currently under review and consideration.

We appreciate that having IRB support staff listen in on an IRB meeting to keep abreast of IRB matters or for training purposes is a great opportunity for staff to hear about the projects they are managing and to further their HSP training. We also recognize the important role the IRB support staff plays for the IRB in assisting to ensure the meeting is conducted in accordance with the applicable regulations.

As required by the regulations at 21 CFR 56.115(a)(2), the minutes of the meeting must be in sufficient detail to show attendance at the meeting. Recording the names of all who attend a meeting is particularly important to determine compliance with applicable regulations (e.g., ensuring whether a quorum was established and maintained) and would not vary by the type of IRB (e.g., local IRB or independent IRB). Recording all who attend an IRB meeting also provides insight into who else is present at the meeting (e.g., an investigator whose study is being reviewed may be present to provide information to the IRB, or a consultant the IRB has invited to assist in the review of a particular project, or IRB support staff who are able to provide regulatory knowledge and/or institutional memory on similar actions or studies the IRB previously reviewed).

In a worst case scenario, knowing who attends an IRB meeting, and in what capacity, might also assist in assessing a complaint from an IRB member(s) who may feel stifled or compromised by the mere presence of a particular non-member or guest. A complete record of attendance will reflect all who attended the meeting.

We don't anticipate that recording attendance is overly burdensome to most IRBs and encourage you to think of an innovative method for recording attendance by non-members and guests, including staff for education and training purposes. The draft guidance also suggests the IRB consider having a written policy covering the attendance of non-members and guests at a convened meeting.

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

Janet Donnelly, RAC, CIP
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Office of Special Medical Programs, Food and Drug Administration

From: [redacted]
Sent: Monday, June 20, 2016 5:04 PM
To: OC GCP Questions
Subject: Requiring names of all non-IRB members who attend IRB meetings to be listed in IRB minutes

We appreciate that regulations that adequate documentation of IRB activities include meeting minutes be in sufficient detail to describe what is occurring. 21 CFR 56.115(a). In recent joint OHRP-FDA draft guidance, states that "[i]f the IRB permits non-members and guests to attend a convened meting (e.g., IRB support staff, the investigator whose study is being reviewed, study coordinator, then the minutes must record the name(s) of all such attendees (45 CFR 46.115(a)(2); 21 CFR 56.115(a)(2))." Food and Drug Administration Minutes of Institutional Review Board (IRB) Meetings: Guidance for Institutions and IRBs Draft Guidance 2015-11-05, available at http://www.hhs.gov/ohrp/newsroom/rfc/draftguidirbminutes2015.html (last accessed 2016-02-11).

However, this seems to fit better in an institutional IRB office type environment. We have numerous IRB staff that we encourage to listen in to keep abreast of IRB matters or for training purposes. Due to the large volume of staff attending the IRB meetings, a questioned was posed as to whether all attendees need to be listed even though they are 1) not voting IRB members and 2) do not participate in the IRB meeting in any way.

We appreciate your time and consideration of this question.

[redacted]