From: OC GCP Questions
To: [redacted]
Subject: RE: Meeting Minutes
Date: Friday, May 30, 2014 4:12:00 PM

Dear [Redacted]-

Thank you for your question. The FDA regulations regarding minutes of IRB meetings (found at 21 CFR 56.115(a)(2) – see http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=56.115) address the requirements for what must be included in IRB meeting minutes but do not address the process for preparation and maintenance of meeting minutes. The regulations provide institutions and IRBs flexibility in choosing how to prepare and maintain meeting minutes and do not include a requirement for signature of IRB meeting minutes. When the regulations are silent, IRBs and institutions are free to develop their own procedures and practices as long as the applicable regulatory requirements are met.

The ICH GCP E6 Good Clinical Practice: Consolidated Guidance, (which is recognized as official FDA guidance) mentions meeting minutes in section 3.2.2 (you can access this guidance at http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm073122.pdf). Section 3.2.2 states:

> 3.2.2 The IRB/IEC should perform its functions according to written operating procedures, should maintain written records of its activities and minutes of its meetings, and should comply with GCP and with the applicable regulatory requirement(s).

I recommend that you discuss your question internally at your institution and IRB and follow applicable institutional policies and IRB written procedures for the preparation and maintenance of IRB meeting minutes.

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

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From: [Redacted]
Sent: Thursday, May 29, 2014 2:00 PM
To: OC GCP Questions
Subject: Meeting Minutes

Our IRB creates meeting minutes electronically. These are then printed off, distributed to members and then the IRB Chair signs them after they have been approved. I wanted to know if it is a FDA requirement that IRB meeting minutes are signed by the member that chaired the meeting or is signature not required by anyone?

Thanks,

[Redacted]