From: OC GCP Questions
To: [redacted]
Subject: RE: Regulations Pertaining to IRB Signatures
Date: Monday, November 23, 2015 2:56:00 PM

Dear [redacted] -

Thank you for your question. With regard to IRB approval, the FDA regulations at 21 CFR 56.109(a) state:

> **Sec. 56.109 IRB review of research.**
>
> (a) An IRB shall review and have authority to approve, require modifications in (to secure approval), or disapprove all research activities covered by these regulations.

The regulations at 21 CFR 56.109(e) state:

> **Sec. 56.109 IRB review of research.**
>
> (e) An IRB shall notify investigators and the institution in writing of its decision to approve or disapprove the proposed research activity or of modifications required to secure IRB approval of the research activity. If the IRB decides to disapprove a research activity, it shall include in its written notification a statement of the reasons for its decision and give the investigator an opportunity to respond in person or in writing. For investigations involving an exception to informed consent under 50.24 of this chapter, an IRB shall promptly notify in writing the investigator and the sponsor of the research when an IRB determines that it cannot approve the research because it does not meet the criteria in the exception provided under 50.24(a) of this chapter or because of other relevant ethical concerns. The written notification shall include a statement of the reasons for the IRB's determination.

The FDA regulations do not address any specific requirement for the IRB to sign the written notification. When the regulations are silent, IRBs and institutions are free to develop their own procedures and practices as long as applicable regulatory requirements are met.

The ICH GCP E6 Good Clinical Practice: Consolidated Guidance, (which is recognized as official FDA guidance) mentions IRB/IEC approval in a few sections (you can access this guidance at http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm073122.pdf. The ICH GCP E6 document provides some guidance on what should be included in the IRB written notification with regard to referencing what the IRB reviewed and the IRB's action (e.g., clearly identifying the trial, the documents reviewed, the IRB's decision, and the date of that decision). However, this guidance does not specify that the IRB must sign the written notification.

FDA also has Information Sheet Guidance for IRBs – Frequently Asked Questions that can be found at http://www.fda.gov/RegulatoryInformation/Guidances/ucm126420.htm. Question #29 under section III addresses signing IRB written notification of approval. This guidance states:

III. IRB Procedures

> **29. Does FDA expect the IRB chair to sign the approval letters?**
>
> FDA does not specify the procedure that IRBs must use regarding signature of the IRB approval letter. The written operating procedures for the IRB should outline the procedure that is followed.

So, as you can see, the FDA does not specify the procedure IRBs must use for written notification of approval, but instead provides IRBs and institutions flexibility. I suggest you consult your IRB and the appropriate institutional officials at your institution to discuss your question and consider outlining the process in your written procedures.

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, November 19, 2015 4:30 PM
To: OC GCP Questions
Subject: Regulations Pertaining to IRB Signatures
Importance: High

Good Afternoon:
My name is [redacted] and I had a question regarding regulations with respect to who can sign off on IRB approvals of administrative changes made to clinical trials. Currently our IRB Research Director signs off after the IRB Chair approves the changes. We wanted to know if regulations state that the Director has to sign off or an IRB Administrator can sign and approve the administrative changes/.
Thank you in advance for your assistance.

[redacted]