From: OC GCP Questions
To: [redacted]
Bcc: CDER DRUG INFO
Subject: RE: delegation of authority/responsibility logs - appended together
Date: Thursday, May 22, 2014 7:22:00 AM

Dear [redacted],

Your inquiry was forwarded to us for response.

FDA's regulations do not require a delegation of authority log. This log, however, is among the documents listed in the ICH E6 Good Clinical Practice (GCP) document which is official FDA guidance. FDA investigators inspecting a clinical site will not always review the delegation of authority log as it is not a regulatory requirement. If the study is clearly in good control and data verification - whether against data submitted by the sponsor or a check of source versus case report form data - indicates no problems, there is no need to verify that personnel delegated study responsibilities are qualified to do so, which is the main purpose for reviewing a delegation log.

FDA's main concern in the situation you describe is that both the study sponsor and FDA are informed that the clinical investigator (CI) responsible at the study site has changed and that the new CI has signed a Form FDA 1572 for a drug study or an investigator agreement for a device study indicating agreement to follow the protocol and applicable regulations. Under FDA regulations, the CI is held responsible for the conduct of the study at the site. If the new research manager has established procedures requiring that a delegation log is refreshed and maintained in a specific manner, that will not affect how an FDA investigator reviews this document should review be warranted. As noted above, an FDA investigator will usually only review a delegation log if there are problems with the study that may be due to delegation of a responsibility to an unqualified study staff member. As long as it is clear who was respons ble for what at a given time in the study, that is all that is needed for the delegation log to be an acceptable tool to facilitate an FDA inspection.

Hope this information is useful. If you need further information and/or have additional questions, please feel free to contact us once again 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.

Sincerely yours,

Jean Toth-Allen, Ph.D.

Office of Good Clinical Practice

Office of the Commissioner, US 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: Wednesday, May 14, 2014 9:03 AM

To: CDER DRUG INFO

Subject: RE: Clinical Research Question

Hi [redacted]-

It is the former, creating a new delegation of authority/responsibility log and then copying over delegation of authority/responsibilities currently in place over to the new log.

Please advise.

Thanks!

-------- Original message --------

From: CDER DRUG INFO

Date:05/14/2014 8:22 AM (GMT-05:00)

To: [redacted]

Subject: RE: Clinical Research Question

creating a new delegation of authority/responsibility log and then copying over delegation of authority/responsibilities currently in place over to the new logl

Dear [redacted]

Thank you for contacting the Division of Drug Information, in the FDA's Center for Drug Evaluation and Research (CDER).

To ensure we understand your situation, the does the new research manager propose

or is the new log for new changes only? We appreciate the additional information.

Best regards,

HY

Pharmacist

Division of Drug Information, Center for Drug Evaluation and Research

Food and Drug Administration

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This communication is consistent with 21CFR10.85(k) and constitutes an informal communication that represents our best judgment at this time but does not constitute an advisory opinion, does not necessarily represent the formal position of the FDA, and does not bind or otherwise obligate or commit the agency to the views expressed.

From: [redacted]

Sent: Monday, May 12, 2014 3:47 PM

To: CDER DRUG INFO

Subject: Clinical Research Question

Hi -

I'm hoping you can help, or forward to someone who can.

I am a CRA, and one of my sites changed their PI.

A new research manager has joined the organization, and is insisting that a new delegation of authority/responsibility log be completed.

They would staple the entirely new log to the original log.

I fail to see why this is necessary, but would this be detrimental?

The study is the same, the staff is the same (aside from the change of PIs) - nothing else changes.

What would the FDA say about this (having two separate logs) during an audit?

Can you please let me know how to advise my site?

Thanks!

[redacted]