From: OC GCP Questions
To: [redacted]
Subject: RE: ELECTRONIC SIGNATURES VS NO SIGNATURES
Date: Tuesday, March 04, 2014 12:52:00 PM

Dear [Redacted]-

I hope all is well with you too. Thank you for your question. I'm pretty sure that "the official audit report" you are referring to in your question is the final report an auditor prepares as the result of a specific audit, so I will respond with that understanding.

As you likely know, FDA's regulations do not specifically address audits. When the regulations are silent, sponsors, CROs, clinical investigators, sites, 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 and can be accessed at http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm073122.pdf) addresses audits in section 5.19. Specifically, section 5.19.3(a) says:

> 5.19.3 Auditing Procedures
>
> (a) The sponsor should ensure that the auditing of clinical trials/systems is conducted in accordance with the sponsor's written procedures on what to audit, how to audit, the frequency of audits, and the form and content of audit reports.

The guidance recommends that sponsors have written procedures on audits that include information on the form and content of audit reports. Such a written procedure should include a sponsor's determination of whether or not they require an audit report to be signed or not. If you have concerns about a sponsor's process, I suggest you talk to them about it.

Also, just wanted to mention to you that the office I'm in (the Office of Good Clinical Practice or OGCP) has a public mailbox where we accept questions from the public. The public mailbox is monitored daily Monday through Friday and we try to respond to GCP questions in a timely manner. I recommend that you send your GCP questions to that public mailbox just in case I am out of the office so you would not have to wait for me to return to the office to respond to your question. You can email your GCP questions to gcp.questions@fda.hhs.gov.

Also, in case you are not aware, OGCP makes available to the public a compilation of the GCP inquiries and FDA responses to such GCP inquiries. This compilation is searchable and may be a helpful resource for you. This information is available at http://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/RepliestoInquiriestoFDAonGoodClinicalPractice/default.htm .

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

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Office of Special Medical Programs, Food and Drug Administration

From: [Redacted]
Sent: Monday, March 03, 2014 11:03 AM
To: Donnelly, Janet; [Redacted]
Subject: ELECTRONIC SIGNATURES VS NO SIGNATURES

Hello Janet

Hope all is well.

I have a question regarding auditors signatures on the official audit report.
I reviewed 21 CFR 11.70 and it links the electronic signature to the document but what if the auditor does not sign the audit report at all; what is the FDA's view on this issue? I can't find any Guidances that explain this problem.

There are a few CROs and Pharma companies which don't require the auditor to sign the audit report.

Thanks

Warm Regards

[Redacted]