From: OC GCP Questions
To: [redacted]
Subject: FDA 1572 and Delegation of Duties
Date: Tuesday, May 21, 2019 12:04:13 PM

Good morning -

Please see the 1572 guidance

https://www.fda.gov/media/78830/download question 32 states – (see question 31 also)

32. Should research nurses, other nurses, residents, fellows, office staff, or other hospital staff be listed in Section #6?

Hospital staff, including nurses, residents, or fellows and office staff who provide ancillary or intermittent care but who do not make a direct and significant contribution to the clinical data, do not need to be listed individually. It is not necessary to include in this section a person with only an occasional role in the conduct of the research, e.g., an on-call physician who temporarily dealt with a possible adverse effect or a temporary substitute for any research staff (see ICH E3, Section 6) (http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm073113.pdf). I think this would include lab techs at many facilities.

You will have to decide with the auditor that all research lab staff need to be included on the 1572. However, given the limited information below, I would think not. Remember the 1572 form is a sponsor form. The sponsor should assist is resolving this issue.

Also, the sponsor and the CI will have to discuss the DOA log listing as FDA regulations do not address DOA logs. I don't think all the lab techs would not need to be listed here either. But again work with the sponsor.

Hope this information is helpful.

Kind regards,

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-----Original Message-----
From: [redacted]
Sent: Sunday, May 19, 2019 2:43 PM
To: OC GCP Questions <gcpquestions@fda.hhs.gov>
Subject: FDA 1572 and Delegation of Duties

Hello again FDA!

Let me preface this by saying I know the FDA does not mention Delegation Logs. No problem.

I have an auditor who is insisting that all of the Research Laboratory staff need to be included on the FDA 1572 and Delegation Log. They insist its required by the FDA and GCPs. I don't see this anywhere. I told them I'm going right to the FDA with this question as they are so adamant.

Now they are focusing on our Investigator: Sponsor studies (our investigator initiated trials or IIT). There are multiple correlative research labs done for the protocol. But I have heard this from sponsors too.

All research laboratory testing is done by Institutional employed Research Lab staff. They are hired only to do research sample processing and running out results. They're a lot of these staff and all are working on our multiple protocols. While I agree they do the processing of the samples that are used for study evaluation - they're only doing it as a part of their routine job description. Some of these Laboratories do testing for all different clinical areas (oncology, CV, GI, GU, Derm, etc.). Are these poor slobs supposed to be put on every study that they ever do anything with in the institution?

I think this Delegation Log is a slippery slope. I actually wish the FDA would set a regulation regarding it so we can all stop this silliness of sponsors wanting every parking lot attendant who parks a research subject's car and custodian who cleans the research office on the DOA (ok, an exaggeration but this is really sticking in my craw particularly when they insist and quote the FDA like they're Dr. Scott Gottlieb himself!).

I know the PI needs to oversee everyone involved in the study and assure they have education and experience. However, does this include these technicians running these labs as part of their routine job duties? We cannot put every research lab technician on the 1572 and DOA; nor can we have the PI responsible for every person who may process a research lab. the PI relies on the institution doing the proper vetting of these ancillary staff. I bet most of these techs don't even have a CV.

So I need the answer for------

1. do we need these research laboratory technicians on these DOA. I know this is not an FDA issue. I

AND

2. if you cant answer that - can you discuss the PI requirement to be able to oversee all of the research lab technicians and document this oversight? Where does it stop? This may help in the answering of this question regarding the DOA.

Many thanks