From: OC GCP Questions
To: [redacted]
Subject: Questions please?
Date: Wednesday, October 15, 2014 11:27:43 AM

Good morning –

Your email was forwarded to my office for a response. Delegation of authority logs are not addressed in the FDA regulations related to the conduct of clinical trials (21 CFR Part 312 for drugs and biologics and Part 812 for medical devices). Such a checklist is also not specified in the list of essential documents in the ICH good clinical practice (GCP) guidance document (ICH E6), though signature sheets are included.
http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM073122.pdf

Appropriate delegation of clinical trial responsibilities is addressed in the FDA guidance regarding clinical investigator responsibility (available at http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM187772.pdf).

The guidance document states:

It is common practice for investigators to delegate certain study-related tasks to employees, colleagues, or other third parties (individuals or entities not under the direct supervision of the investigator). When tasks are delegated by an investigator, the investigator is responsible for providing adequate supervision of those to whom tasks are delegated. The investigator is accountable for regulatory violations resulting from failure to adequately supervise the conduct of the clinical study. The investigator should ensure that any individual to whom a task is delegated is qualified by education, training, and experience (and state licensure where relevant) to perform the delegated task.

Though a delegation log or checklist is not required, it is commonly used at clinical sites to document who is assigned essential study tasks. While an FDA investigator would not routinely request to see such a log/checklist during a bioresearch monitoring (BIMO) inspection of a site, since it is not a regulatory requirement, he/she may request documentation of who performed which task during a study, particularly when regulatory noncompliance is observed. The clinical investigator is ultimately responsible for the conduct of the study. However, determining if an observed noncompliance resulted from improper delegation of a task is essential to correction of the problem, in the present study or in future studies if the study inspected is already complete. However a site chooses to document those assigned to essential study tasks, it should be updated whenever there is a change in personnel performing any of those tasks. The date on which the designation of the individual was made should be captured, but an ending date would not be necessary. Later addition of a different person for the same task would suffice. If the same study site personnel are assigned essential tasks throughout the life of the study, than no update would be required.

Please note when the regulations are silent sponsors, sites, and institutions are free to develop their own standard operating procedures to address a specific issue or situation as you describe in your email. Please also remember FDA guidance represents FDA's current thinking on a specific topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations.

I am not able to provide you legal advice regarding your question, as FDA is not in a position to provide legal counsel. I recommend you discuss your question with your institution's legal counsel.

It might be helpful for you to review our Good Clinical Practice website. (Link below) There are many links on this site related to FDA-regulated clinical trials.

Clinical Trials and Human Subject Protection

Please also see a few documents that discuss clinical investigator FDA inspections.

http://www.fda.gov/downloads/ICECI/EnforcementActions/BioresearchMonitoring/UCM133773.pdf

http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM126553.pdf

I hope this information is helpful. Please contact us again at gcp.questions@fda.hhs.gov should you have additional questions.

Kind regards,

Doreen M. Kezer, MSN
Senior Health Policy Analyst
Office of Good Clinical Practice
Office of the Commissioner, FDA

From: Walters, Dana L
Sent: Tuesday, October 14, 2014 1:51 PM
To: OC GCP Questions
Subject: FW: Questions please?

Hello,

Please see the original email below – is this a question that can be answered by OGCP?

Thanks.
Dana

From: Parker, Catherine
Sent: Tuesday, October 14, 2014 12:45 PM
To: Walters, Dana L
Subject: FW: Questions please?

Hi Dana,

Below is a CI question. It isn't a complaint, just someone looking for answers so I am not sure if you take care of this or there is someone else I should forward this to.

Thanks as always for your help!
Cp

From: Krefting, Ira
Sent: Tuesday, October 14, 2014 10:22 AM
To: Parker, Catherine

Subject: FW: Questions please?

Please help provide an informal response to this new investigator who is worried about the FDA inspection process. See email below. She asked my questions at the [redacted] meeting earlier in the year.
Thanks.
Ira

From: [redacted]
Sent: Wednesday, October 08, 2014 11:38 AM
To: Krefting, Ira
Subject: Questions please?

Dear Ira,
Hello again. To remind you – I met you at the [redacted], and reached out to you for questions that I had at that time. As you know, I have made this career move to a CRO and have yet more questions that I'd like to ask you – if you have the time? I have only been in this field 9 months, and because I came out of clinical practice, this world is somewhat surprisingly foreign.

My questions lie around the medical responsibilities as well as the legal responsibilities, and of course the FDA. As a PI, I sign a paper called a delegation or authority. (Not a form used in clinical practice.) This clearly states that I assume the responsibility of many persons that help run a study. Is this a requirement of the FDA? Are you familiar with this? If you think about it, when you open a practice, you have the reality that if your nurse (for example) does something, that you could get sued, but as a doctor, you don't sign a paper saying that you understand that everyone is your responsibility.

Instead of a legal suit, most everyone around here is "scared" of the FDA coming. I understand that there needs to be regulation. That's not it. I'm concerned that the FDA can come in, do an audit, and issue a 483 and that will stay on my "record" (help me to understand where that falls), and it is essentially uncontested? So, in some respects, the FDA can be judge and jury and I would not have any say? Plus, it might be issued because of action by any single individual that I have signed the delegation of authority? It seems like the form makes it easy for the CRO's and the FDA to point a finger at the PI? What is your understanding of that?

I would so appreciate your time and guidance with this, as I am a little perplexed with where my support is, should something terrible happen someday. Of course in the testing of drugs, anything could happen. But, as I mature in this career, I believe I have legitimate concerns involving the structure of what is expected of the PI.

Thank you ahead of time for your time.

Regards,
[redacted]