From: OC GCP Questions
To: [redacted]
Subject: PI responsibilities
Date: Wednesday, December 17, 2014 11:31:52 AM
Attachments: FDA Guidance.pdf

Good morning [redacted] –

I discussed your email with my OGCP colleagues this am. FDA regulations require very few signatures. As the guidance that you reference points out, we ask that the clinical investigator (PI) supervise and oversee the study but FDA does not specifically spell out how to do this. This is why internal SOPs are important. It seems that you have those in place.

That said, if the protocol specifically states that the PI needs to sign off on study documents as outlined in your email from the monitor then the clinical investigator should follow the protocol.

Additionally, you can always discuss the monitor's request directly with the sponsor or their representatives to make sure that all communication and documentation is consistent between all parties.

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: [redacted]
Sent: Monday, December 15, 2014 7:34 PM
To: OC GCP Questions
Cc: [redacted]
Subject: PI responsibilities

Good Evening,

We are very familiar with the attached Guidance document. We are a large teaching institution that does hundreds of clinical trials utilizing both approved and investigational drugs (mostly chemotherapeutic studies) . We have a very large oncology practice, and most of our oncology protocols have a PI and approximately 6-10 Sub-Is. The Sub-Is listed for any given study are the treating oncology physicians on our oncology protocols. Therefore, the subjects enrolled are largely managed, on a day to day basis, by the treating physician (Sub-I) unless the PI happens to be the treating MD. Our oncology practice has routinely scheduled

staff meetings, PI oversight, and constant communication amongst all coordinating departments.

We recently received the following directive (in blue, below) from a study monitor, and based on our understanding of FDA regulations, the attached guidance, our sites SOPs and the results of innumerable cooperative group audits at our site by the NCI, we are questioning the information being given by this monitor. Our site's SOPs, and standard practice, in terms of delegation of authority and thorough documentation of both study activities and staff credentials has never been called into question until now.

Here was the directive from a monitor (she instructed us that the PI needs to sign all eligibility criteria, study labs and all imaging reports done on all study subjects):
" Sub-Is are permitted to sign; however, for an auditor stand point the PI needs to co-sign to show they agree and have reviewed. This shows PI involvement and is required by the FDA and sponsor auditors. In addition the PI has to make the call if the subject eligible so only Dr. (PI) signature would be accepted on I/E criteria. If you have any additional questions please let me know. I have been in multiple FDA and Sponsor audits and the highest number of findings come from PI involvement. Since the PI is the one contracted with the FDA under 1572 they have to take full responsibility."

Per our site's delegation logs, our sub-PIs are actually delegated as being responsible for those exact study specific tasks (eligibility criteria, assessing labs, determining response, tumor measurements, etc).

Thank you in advance for reviewing this issue for us.

Reards,
[redacted]