From: OC GCP Questions
To: [redacted]
Subject: Question Please
Date: Wednesday, February 15, 2017 9:05:00 AM

Good morning --

FDA regulations have very few requirements for signatures - notably a CI signature on the Form FDA 1572 (1572) or investigator agreement and a subject/legally authorized representative signature on the informed consent document. ICH E6 - which describes good clinical practice (GCP) for pharmaceutical studies - does suggest other signatures. While an official FDA guidance document, it is just guidance. http://www.fda.gov/downloads/Drugs/Guidances/ucm073122.pdf

However, if the protocol/investigational plan requires any or all of these signatures including signing and dating the lab results, then we would expect to find them. If an FDA bioresearch monitoring (BIMO) inspection was conducted at a site and protocol-required signatures were absent, it would be cited as a protocol deviation. In addition, FDA does expect the CI to appropriately supervise all studies and therefore review of pertinent study documents is expected, even if no signature confirming review is required. You will find a discussion in this regard in FDA's guidance on CI responsibilities, which is found at www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM187772.pdf.

Documentation is important during a clinical trial. Every effort should be made to document all activities related to the trial.

Kind regards,

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

From: [redacted]
Sent: Monday, February 13, 2017 3:55 PM
To: OC GCP Questions
Subject: Question Please

Hello,

I am trying to get clarification for the requirements for subject laboratory and test reports having to be signed or initialed and dated by the principal Investigator for each test performed.

For 20 years in research, I understood that clinical lab results or test results entered into the eCRF either on paper or more current electronically are considered signed off/reviewed by the PI under these circumstances:

1. Medical Progress notes electronically or hand written, which includes

exam/findings/medical plan of care and the test results and any results that register outside the normal range are addressed if significant.

2. For each visit the PI signs off on either paper CRFs, eCRF, or within institutional EMR systems. All visits, labs, test results are included with each visit and available within the EMR for monitoring purposes.

My question for you is, is it required in addition to the above mentioned a FDA requirement to also have a paper copy for PI signature/date and marked as reviewed and either clinically or not clinically significant???

This was brought up as an additional step we should be performing in our clinical trials reporting to the sponsors. The conversation about redundancy and unnecessary keeps coming up in addition to, if it is necessary, what is the rational?

With every hospital, clinical trials office, sponsor I have called to get an opinion everyone has a different one but no one I spoke to has the PI sign off the paper copy of the report scenario. So I am addressing this with you directly to obtain clarity on this gray subject.

I appreciate your attention and clarification in this matter.

Sincerely,

[redacted]