

From: OC GCP Questions
To: [REDACTED]
Subject: Clinical Trial Lab Results Question
Date: Friday, February 10, 2017 12:11:00 PM
Attachments: [REDACTED]

Good afternoon --

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. It appears from your email that additional documentation would be helpful.

Kind regards,

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From: [REDACTED]
Sent: Thursday, February 09, 2017 4:49 PM
To: OC GCP Questions
Subject: Clinical Trial Lab Results Question

Good day. What impact does it have on a PI when they have not signed/dated lab results from a clinical trial (that they are participating in); however, they noted that they reviewed them? Their is no documentation in the source that notes that the PI had reviewed the results.

I understand the responsibility of PI oversight (GCP) and the ALCOA-C principles; however, there is no signature/date on lab results for example a month, three months,

six months or longer after they received the results?

