From: OC GCP Questions
To: [redacted]
Subject: MCRF GCP questions
Date: Thursday, February 23, 2017 1:26:00 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

1572 Form Guidance -- https://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM214282.pdf Please see question #24 on page 11.

However, if the protocol/investigational plan or IRB requires any or all of these signatures including signing and dating the CV and each ICD page, 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

Kin regards,

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

FDA U.S. FOOD & DRUG ADMINISTRATION

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From: [redacted]
Sent: Thursday, February 23, 2017 12:54 PM
To: OC GCP Questions
Subject: MCRF GCP questions

Dear FDA
I have 2 quick question about GCP:

1. Is a CV required to be signed by investigators?
2. Is each page of an Informed Consent required to be initialed by the subject?

Thanks so much.

[redacted]