From: OC GCP Questions
To: [redacted]
Subject: inclusion/exclusion
Date: Monday, March 02, 2015 11:03:54 AM

Good morning –

FDA regulations require very few signatures so a mandatory signature on a CRF is not required. When FDA regulations on silent on a specific topic, we suggest developing standard operating procedures to allow for consistency in reporting and documentation. These procedures will assist you in determining how to maintain records and, for those that could depend on the opinion/expertise of a particular person, how best to ensure they will always know who made the diagnosis/decision.

ICH E6 – Good Clinical Practice: Consolidated Guidance, which can be found at the following web link: http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM073122.pdf , describes good clinical practice (GCP) for pharmaceutical studies, and does suggest other signatures (refer to sections 4.5.1, 5.6.3, 7.5, and multiple locations in section 8). While an official FDA guidance document, it is just guidance.

However if the protocol/investigational plan require signatures on study documents, then we would expect to find them on the appropriate documents.

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: Sunday, March 01, 2015 7:04 PM
To: OC GCP Questions
Subject: inclusion/exclusion

Do the CFR stipulate that investigators actually have to sign the inclusion/exclusion criteria CRF on each subject prior to enrollment onto a clinical trial?