From: OC GCP Questions
To: [redacted]
Subject: Monitoring Questions
Date: Thursday, July 13, 2017 7:18:00 AM
Attachments: [redacted]

Good morning –

FDA's regulations do not require the signature of the clinical investigator on the consent form (assuming that consent is obtained by someone else). It's really up to the IRB, however, to determine the acceptability of the process to be used for obtaining informed consent, as long as that process is consistent with the regulations. Having said that, if the IRB's procedure is to require the investigator to sign the form (for example, if there is a space on the consent form for him to do so), then we assume the IRB requires that signature and we may note that as a violation of the regulations if the signature is missing. As I've said, however, there is no specific requirement in our regulations for the investigator to sign the form, so the IRB can always modify the process, particularly if requiring the clinical investigator's signature on the form is too burdensome.

If there are SOPs in place at the site, these SOPs should be followed. Sites should update their SOPs if they find that they are inconsistent with what is really happening at the site.

I hope this information is helpful. Please contact us again at gcp.questions@fda.hhs.gov

Kind regards,

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U.S. FOOD & DRUG ADMINISTRATION

From: [redacted]
Sent: Tuesday, July 11, 2017 3:33 PM
To: OC GCP Questions
Subject: Monitoring Questions

Good day. In review of a subjects ICF, I see that the PI signed off on the ICF form (reviewed the ICF with the subject and signed/dated the ICF after the subject agreed to participate in the clinical trial).

The following questions were checked off as being done by the PI on the ICF checklist; however, the SC signed and dated the form.
-Subject meets all eligibility requirements
-Discussed, explained and reviewed the consent form with subject
-All of the subjects questions were answered.
-Subject was given time to review the consent form and to discuss participation in this study with family members.

-The subject agreed to participate in the study and signed/dated the ICF.
-A copy of the signed and dated consent form was given to the subject.

My question is, should the PI have been the one to sign off on the ICF checklist? Or is it okay that the subject signed off on the ICF checklist?

Second Questsion
In review of the sites SOP process, I noticed that the site has an SOP for capturing data in EDC; however, nothing in their SOP mentions capturing data on paper CRF's. Is it a requirement that the site update their current SOP to note their process on capturing data on paper CRF's if they are participating on a clinical trial that utilizes paper CRF's?

Third Question
If the verbiage in a sites SOP (Safety Equipment) contradicts information noted on the sites Safety Equipment log (log attached to the Safety Equipment SOP), is it a requirement that the site update the SOP and the log so that the verbiage is the same?

Thanks,