From: OC GCP Questions
To: [redacted]
Subject: ICF, EMR, CV and SOP GCP Questions
Date: Monday, October 30, 2017 10:11:31 AM
Attachments: [redacted]

Good morning –

ICF question – FDA regulations are not that specific to address your question. It is best to ask the reviewing IRB what their recommendation is to address the scenario you describe on correcting the ICD.

CV question – Please see FDA guidance on the 1572 form.
https://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM214282.pdf

22. What is the purpose of Section #2?

Section #2 requires the investigator to attach a curriculum vitae (CV) or other statement of qualifications, showing the education, training and experience that qualifies the investigator as an expert in the clinical investigation of the drug/biologic for the use under investigation. Information identified in this section and attached to the 1572 enables the sponsor to assess an investigator's qualifications.

23. Does the CV or other statement of qualifications need to be updated during a clinical study?

No. FDA regulations do not require a CV or other statement of qualifications to be updated during a clinical study.

24. Are CVs required to be signed and dated?

No. FDA regulations do not require a CV to be signed and dated. The investigator's dated signature on the 1572 is sufficient to attest to the accuracy of the CV or other statement of qualifications submitted with the 1572.

There is no FDA requirement to have the CI (PI) or sub CI note their position as participating in a clinical trial.

SOP question – SOPs should be updated as often as needed to ensure compliance with a clinical study and to protect the rights, health, and safety of clinical research subjects.

EMR question - The site should follow its internal procedures for updating the electronic medical records. Study records should be as accurate as possible.

The following guidance documents might be helpful to you.

Part 11 -Electronic Records -
https://www.fda.gov/downloads/regulatoryinformation/guidances/ucm125125.pdf

Computerized Systems Used in Clinical Investigations -
www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM070266.pdf

Electronic Source Data in Clinical Investigations -
www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM328691.pdf

Draft guidance on Electronic Records (2017) -
https://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm563785.pdf

Kind regards,

Doreen M. Kezer, MSN
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Office of Good Clinical Practice
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From: [redacted]
Sent: Wednesday, October 25, 2017 10:37 PM
To: OC GCP Questions
Subject: Re: ICF, EMR, CV and SOP GCP Questions

Good day. Can you provide GCP guidance on the following scenarios:

ICF question: The parent of the neonate signs the informed consent form (ICF) and is provided with a copy of the ICF prior to the neonate being delivered and prior to any study related procedure being conducted. Upon delivery of the neonate, the Study Coordinators added the neonates date of birth on the ICF (per the ICF requirements); however, did not add the neonates initials on the ICF (per the ICF requirements). There were no initials/date noted next to the neonates date of birth (that was added after consent was obtained) nor was there documentation that the parent was provided with a revised copy of the ICF and the reason why.

CV question: Is it a requirement that a PI or sub-investigator's note their position on their CV as a PI or Sub-Investigator if participating in a clinical trial?

SOP Question: How often should sites update their SOP's?

EMR Question: If a sites electronic medical records were updated since the onset of a clinical trial, is it necessary for that site to go back and update any new information that may be noted in the electronic medical records a subject enrolled/participating in a clinical trial? Here is an example of a scenario:

- The Electronic Medical Records (EMRs) were updated as of August 12, 2017. The SC's completed the subject specific Electronic Case Report Forms (eCRF's) based on the old version of the sites EMR from 2016. Upon review of selected subjects during this audit, the CRA's found that the parents medical history, and/or concomitant medications have not been updated in the eCRF's to reflect the current information that is now available in the updated EMR. In addition, transcription errors between the source and the EMR exist since the new update.

Thanks,

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