From: OC GCP Questions
To: [redacted]
Subject: [redacted] Clinical Trial related ICF question
Date: Wednesday, December 07, 2016 8:03:00 AM
Attachments: [redacted]

Good morning –

FDA regulations at 21 CFR 50.25(a)(1) states –

(1) A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, **a description of the procedures to be followed [Emphasis added],** and identification of any procedures which are experimental.

How you explain the procedures is up to the IRB and the nature of the particular study. You would want to be consistent and to give the subject as much information as possible to understand the procedures and the clinical study. For example if you are going to be detailed in the explanation as in the main body of the email than we suggest the additional PK blood drawls should be added to the consent.

The statement in your #2 below might also be acceptable.

I hope this information is helpful.

Kind regards,

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

This communication does not constitute a written advisory opinion under 21 CFR 10.85, but rather is an informal communication under 21 CFR 10.85(k) which represents the best judgment of the employee providing it. This information does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the views expressed.

From: [redacted]
Sent: Monday, December 05, 2016 3:23 PM
To: OC GCP Questions
Cc: [redacted]
Subject: [redacted] - Clinical Trial related ICF question

Hello – I am a clinical monitoring project lead at [redacted] the CRO working on this study. I am contacting you regarding a question I have about an Informed Consent Document that was amended for a study. The study includes non-safety related PK blood draws at 4 different time points. During the recent amendment, the 3 PK timepoints were increased to 4 time points as well as adding additional PKs at a subset of visits. The ICF template has the PK blood draws listed out in sentence format per time point. These 4 new time points were inadvertently missed when updating the ICF. Another

pertinent fact is that this study is done primarily in an adolescent population. The study drug is an orphan drug. The drug received conditional FDA approval for the drug 21Sep16. The amendment was written 16Jul16. There are conflicting opinions about what to do with this issue. Can you please provide me with your opinion on not updating the consent to add the PK time points and the idea of deleting all the detail of the PK blood draws?

1. I believe the ICF and Assent templates need to be revised to add these 4 new templates and the sites should be advised immediately about this error. We also need to of course report any of these time points that were drawn to IRBs as an issue.
2. Another opinion thinks it is unnecessary to do this, as they feel like these blood draws could be included under the routine language seen in consents that says "additional blood draws may be done as necessary". I have always thought these draws would be done in cases of specimens collected that were non-evaluable for some reason.
3. Another opinion indicates, they should not have included all of this detail in the ICF to being with. Therefore, their suggestion is to delete all of the verbiage related to the specific time points all together in the next revised ICF.

Please let me know your thoughts.

Kind regards,

[redacted]