From: OC GCP Questions
To: [redacted]
Subject: FDA 1572 / Question on the process
Date: Thursday, July 25, 2019 9:30:58 AM
Attachments: [redacted]

Hi [redacted] –

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word should in Agency guidances means that something is suggested or recommended, but not required.

So if the CRO chooses to use a different approach to collect changes to the clinical investigation (updating the 1572 form frequently) I am not sure what else you can do as the CRO is contracted by the sponsor.

Sorry I can't be more helpful.

Kind regards,

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

U.S. FOOD & DRUG ADMINISTRATION

From: [redacted]

[redacted]
Sent: Wednesday, July 24, 2019 4:05 PM
To: OC GCP Questions <gcpquestions@fda.hhs.gov>
Subject: RE: FDA 1572 / Question on the process

Dear Doreen,

Thank you for your prompt response. I completely appreciate the statement in the guidelines and that what we used in the discussion with the CRO.
However, they say they use 1572 as a part of their internal documentation and insist on updating the form for their needs in case of minor changes. Their reply is below:

I reached out to our Quality Management department and they advised that whilst the FDA does not require the 1572 to be updated in the event of a minor change (eg. New Sub-I), the [CRO] uses a

standardized approach to notifying the Sponsor of such changes. That process is to update the 1572 and it is to ensure consistency in our approach.

May I please ask you to comment on the following approach? It seems to be quite contradicting to the guidelines for FDA1572 completion.

Thank you.

[redacted]

From: OC GCP Questions [mailto:gcpquestions@fda.hhs.gov]
Sent: Thursday, 25 July 2019 5:07 a.m.
To: [redacted]
Subject: FDA 1572 / Question on the process

Good afternoon –

The guidance states that the sub-investigator change can be submitted in an information amendment or a protocol amendment. See below.

https://www.fda.gov/media/78830/download

7. When must a 1572 be updated or a new 1572 completed and signed by an investigator to reflect new or changed information?

There are two instances when it is necessary for an investigator to complete and sign a new 1572: when an investigator is participating in a new protocol that has been added to the IND and when a new investigator is added to the study (21 CFR 312.53(c)).

If there are other changes to information contained on a signed and dated 1572 (e.g., an IRB address change, the addition of new subinvestigators, the addition of a clinical research lab), the investigator should document the changes in the clinical study records and inform the sponsor of these changes, so that the sponsor can appropriately update the IND. The 1572 itself does not need to be revised and a new 1572 need not be completed and signed by the investigator. The sponsor can accumulate certain

changes and submit this information to the IND in, for example, an information amendment or a protocol amendment.

Kind regards,

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

From: [redacted]
Sent: Tuesday, July 23, 2019 4:20 PM
To: OC GCP Questions <gcpquestions@fda.hhs.gov>
Subject: FDA 1572 / Question on the process

Dear FDA team,

May I please ask you to comment on the following situation around FDA1572 form use?

Even though the guidelines outline that minor changes e.g. Sub-Investigator change do not trigger completion of the new form, a CRO wants the site to update FDA1572 each time a Sub-Investigator changes form stating it is the CRO's standardized approach to track updates in the site team, even though in accordance to the FDA1572 FAQ and completion guidelines it is a Sponsor responsibility to update the study portfolio, not the Investigator's one.

Is it an appropriate use of the FDA1572 form?

Thank you.

Kind regards,

[redacted]