From: OC GCP Questions
To: [redacted]
Subject: Use of addendum to report locations of research
Date: Thursday, November 05, 2015 6:44:15 AM

Good morning ---

FDA's1572 guidance (link below) states the following --

http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM214282.pdf

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.

So you can document the informational changes to the research in the study records, inform the sponsor, and the sponsor should notify FDA of the changes in the IND in an information amendment or a protocol amendment.

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

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.

-----Original Message-----
From: [redacted]
Sent: Wednesday, November 04, 2015 4:57 PM
To: OC GCP Questions
Subject: Use of addendum to report locations of research

Hello,

Is there any guidance as to the use of a non-FDA issued addendum form to communicate additional locations for where study related procedures would be conducted?

For example, when a site completes an initial 1572, and then later wants to add a location for where research is being conducted, can they use their own site/SMO created form, as long as it has the correct information, or must this information eventually be transcribed onto the FDA-issued 1572 continuation form/original full 1572?

The clinician in question would be an ophthalmologist, and site/SMO is calling that entity a vendor.

If site/SMO declines to use FDA form, what is sponsor's obligation/requirement?

Kind regards,

[redacted]