From: OC GCP Questions
To: [redacted]
Subject: RE: Changes to a 1572
Date: Wednesday, December 31, 2014 2:18:00 PM

Dear [Redacted]-

Thank you for your question. FDA has Information Sheet guidance for sponsors, clinical investigators, and IRBs titled, "Frequently Asked Questions – Statement of Investigator (Form FDA 1572)" that can be found at the following web location: http://www.fda.gov/downloads/regulatoryinformation/guidances/ucm214282.pdf. This guidance applies to clinical investigations conducted under 21 CFR Part 312 (Investigational New Drug Applications or IND regulations). It describes how to complete the Statement of Investigator form (Form FDA 1572).

Question #7 in section I of the guidance addresses your question about updating a 1572 (I copied the passage here for your reference):

> 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.

The Statement of Investigator, Form FDA 1572 (1572), is an agreement signed by the investigator to provide certain information to the sponsor and assure that he/she will comply with FDA regulations related to the conduct of a clinical investigation of an investigational drug or biologic. Since the 1572 is a sponsor form, I suggest you also consult any sponsor that you work with since different sponsors may have certain expectations for how their sites fill out and/or document changes in information to the 1572.

I hope this information is useful. If you need further information and/or have additional questions, please feel free to contact us at the official GCP mailbox, gcp.questions@fda.hhs.gov. You may also find it useful to access the set of redacted GCP e-mails found at http://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/RepliestoInquiriestoFDAonGoodClinicalPractice/default.htm since we find that many questions and concerns are repeated over time.

Best Regards,

Janet

Janet Donnelly, RAC, CIP
Policy Analyst, Office of Good Clinical Practice
Office of Special Medical Programs, Food and Drug Administration

-----Original Message-----
From: [Redacted]
Sent: Monday, December 29, 2014 11:59 AM
To: OC GCP Questions
Subject: RE: Changes to a 1572

Hi-

I am a CRA working on human clinical trials and this question has come up with my colleagues. When a sub-investigator that was on the original 1572 leaves the site, is it required to generate a new 1572 showing this person is no longer associated with the trial? Or if a new sub-investigator joins the practice and comes in to work on the trial, is a new 1572 required?

Thank you very much and Happy New Year.

Sincerely,

[Redacted]