From: OC GCP Questions
To: [redacted]
Subject: RE: Temporary change in PI on 1572
Date: Tuesday, September 20, 2016 9:31:00 AM

Dear [redacted] -

Thank you for your questions. The FDA Form 1572 is a form the sponsor is responsible for obtaining (refer to 21 CFR 312.53(c)) and is meant to supply the study sponsor with pertinent information about a site who is conducting a particular study. The 1572 also serves as an agreement by the investigator, once signed, to comply with the investigational plan/protocol and pertinent regulations. For studies being conducted under an IND, the sponsor is required to submit information on investigators participating in a study to their IND (refer to 21 CFR 312.23(a)(6)(iii)(b) and 312.30(c)). Since the information required to be submitted to the IND is the same information collected on the 1572, sponsors usually submit copies of 1572s to FDA to fulfill this requirement because it provides a convenient means of supplying the required information.

FDA has guidance titled, "*Information Sheet Guidance for Sponsors, Clinical Investigators, and IRBs Frequently Asked Questions – Statement of Investigator (Form FDA 1572)*" that can be found at http://www.fda.gov/downloads/regulatoryinformation/guidances/ucm214282.pdf. FAQ#7 in section I states:

> ***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 guidance does not address your specific question about when a PI is **temporarily** out for sick leave/maternity leave/etc. and a sub-investigator on the study is appointed to oversee the study until the PI returns.

Since the 1572 is a form the sponsor is responsible for, I recommend that you discuss your questions and share your institution's policy with any sponsor you are working with on any study where such a temporary substitution occurs. Sponsors likely have their own policies and expectations regarding how they want to handle and document a temporary substitution, considering things such as the nature of the study, the expertise needed to lead the study, the status of the study, how long the substitution will last, etc. If the sponsor has questions about the need for an updated 1572 for a temporary substitution, they can always contact the FDA review division that they are working with on the study to discuss.

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

From: [redacted]
Sent: Wednesday, September 14, 2016 4:29 PM
To: OC GCP Questions
Subject: Temporary change in PI on 1572

Hi GCP Team,

When a principal investigator is out of the office temporarily for sick leave/maternity leave/etc. our IRB states they can appoint a sub-Investigator to oversee the study until they return (if out for 3 or more months an official amendment would need to be submitted to change the PI). We must notify the IRB of this, but a formal amendment is not put in place and the consent forms and subjects are not update with this information. Can you confirm if the 1572 would need to be updated indicating the Sub-I temporarily overseeing the study and then update the 1572 when the PI returns? If so would the study PI then be listed as a sub-I on the 1572 since the Sub-I temporarily overseeing the study may contact the PI for information related to the study.

Thank You,

[redacted]