From: OC GCP Questions
To: [redacted]
Subject: Question - Sub-I support of PI responsibilities for a limited time
Date: Monday, May 05, 2014 3:22:05 PM

Good afternoon --

FDA's guidance on the Form FDA 1572 found at http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM214282.pdf . Section VII of the document should provide you with guidance on who should be listed as a subinvestigator on the 1572. In particular, the guidance says:

31. Who should be listed as a subinvestigator in Section #6?
FDA's regulation at 21 CFR 312.3(b) states: "In the event an investigation is conducted by a team of individuals, the investigator is the responsible leader of the team. 'Subinvestigator' includes any other individual member of that team." 21 CFR 312.53(c)(1)(viii) requires the investigator to provide "a list of the names of the subinvestigators (e.g., research fellows, residents) who will be assisting the investigator in the conduct of the investigation(s)."

The purpose of Section #6 is to capture information about individuals who, as part of an investigative team, will assist the investigator and make a direct and significant contribution to the data. The decision to list an individual in Section #6 depends on his/her level of responsibility (i.e., whether he/she is performing significant clinical investigation-related duties). In general, if an individual is directly involved in the performance of procedures required by the protocol, and the collection of data, that person should be listed on the 1572. For example, if the protocol notes that each subject needs to visit a specified internist who will perform a full physical to qualify subjects for the clinical investigation, that internist should be listed in Section #6.

In the scenario that you describe, since the sub-investigator is now acting in place of the clinical investigator and is not part of the study team but is not the responsible leader, we advise that a new 1572 be signed by the replacing investigator. FDA encourages each study site to have their own CI, who signs a 1572, for the conduct of the study at the specific site. Sub-investigators are intended to assist the CI conduct the study at a specific site and not to substitute for the CI. The intention of FDA regulations are for the CI to conduct and/or supervise all aspects of a clinical study for which he/she agrees to conduct, according the investigational plan and applicable regulations, when he/she signs the 1572.

Additionally, many individuals do not realize that one of the main purposes of the 1572 is to provide the sponsor with advance information about the clinical site(s) where the research will take place, the investigator's qualifications, and information about other facilities that will be performing protocol required tests. Providing this information to the sponsor allows the sponsor to establish and document that the investigator and site are qualified to conduct the study. The other main purpose of completing the 1572 is to obtain the investigator's commitment to comply with FDA's regulations for conducting the clinical investigation. Although it is not required, many sponsors commonly submit a copy of the 1572 to FDA for IND studies as the information it contains is required for an IND application. The 1572 is meant to supply site-specific information to the sponsor.

I cannot comment on investigator agreements. You would need to contact the Center for Devices (CDRH) directly at DICE@fda.hhs.gov.

I hope this information is helpful. Please contact us again at gcp.questions@fda.hhs.gov should you have additional questions.

Kind regards,

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From: [Redacted]
Sent: Monday, May 05, 2014 9:31 AM
To: OC GCP Questions
Subject: Question - Sub-I support of PI responsibilities for a limited time

Hello,

On one of our studies, there is an investigator site where the PI will be out for ~3 months, during which time a sub-I will assume (and has been delegated) PI responsibilities.

The IRB is OK with leaving the 1572 and contract and process "as is", with documentation on the delegation of authority log. Is this an acceptable way to document this temporary leave? Do we need to have a new Form FDA 1572 signed and other forms as well (Investigator agreement) etc?

Thanks!