From: OC GCP Questions
To: [redacted]
Subject: Sponsor Submission of Updated Investigator Information
Date: Monday, August 03, 2015 7:31:09 AM

Good morning –

The guidance (link below) on the 1572 Form has the answers to your questions.

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

3. When must this form be completed and signed by an investigator?

Whenever a sponsor selects a new investigator to participate in a clinical investigation that is being conducted under an investigational new drug application (IND), the sponsor must obtain a completed and signed 1572 ***before permitting the investigator to begin participation*** *in the clinical investigation (21 CFR 312.53(c)). The investigator should sign the form only after being given enough information to be informed about the clinical investigation and to understand the commitments described in Section #9 of the 1572. Having enough information about the study typically means that the investigator has received copies of, has read, and understands the protocol and investigator's brochure (if required2), and is familiar with the regulations governing the conduct of clinical studies. The investigator's signature on this form constitutes the investigator's affirmation that he or she is qualified to conduct the clinical investigation and constitutes the investigator's written commitment to abide by FDA regulations in the conduct of the clinical investigation.*

6. Does the 1572 need to be submitted to FDA?

No. Although the sponsor is required to collect the 1572 from the investigator, FDA does not require the form to be submitted to the agency. Many sponsors submit the 1572 to FDA, however, because it collects, in one place, information that must be submitted to FDA under 21 CFR 312.23(a)(6)(iii)(b).

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.

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.

From: [redacted]
Sent: Friday, July 31, 2015 10:57 AM
To: OC GCP Questions
Subject: Sponsor Submission of Updated Investigator Information

Hello,

I just wanted to start with some background stating I've read the "Frequently Asked Questions – Statement of Investigator (Form FDA 1572)" document and 21 CFR 312.53(c). After reading these and getting conflicting opinions from other industry folks I was hoping to get some clarification to the questions below.

Must updated investigator information be submitted to the sponsor IND?

Is it sufficient to submit the original 1572 and CV to the sponsor IND within 30 days of the investigator being added, and just keep a record of changes such as IRB address change, addition of sub investigators, or addition of clinical research labs?

If changes such as IRB address change, addition of sub investigators, or addition of clinical research labs must be submitted to the sponsor IND is the preferred format to replace the existing 1572 in the application every time a change is made? Should these changes be submitted to the sponsor IND within 30 days?

Best regards,
[redacted]