From: OC GCP Questions
To: [redacted]
Subject: 1572 Submission to IRB
Date: Monday, February 23, 2015 12:28:40 PM

Good afternoon -

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.

Please see the guidance below regarding updating a 1572 form. It 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.

There is no requirement that the revised 1572 form has to be submitted to the IRB.

Please see link below for guidance on the 1572 form.

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

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

Kind regards,

Doreen M. Kezer, MSN
Senior Health Policy Analyst
Office of Good Clinical Practice
Office of the Commissioner, FDA

From: [redacted]
Sent: Monday, February 23, 2015 10:57 AM
To: OC GCP Questions
Subject: 1572 Submission to IRB

Hello,

This is a question regarding submission to the IRB.

Site submitted initial 1572 with primary site location in [redacted] and an additional research location in [redacted].

Site later changed the primary and additional site, with new primary location being [redacted] and additional site in [redacted].

Both addresses are on the Informed Consent Form, approved by the IRB.

IRB does not have guidance on submission of the new 1572 due to administrative changes.

Are there any guidance from the FDA on whether this revised 1572 must be submitted to the IRB?