From: OC GCP Questions
To: [redacted]
Subject: 1572 form question from [redacted]
Date: Wednesday, July 13, 2016 1:31:00 PM

Good afternoon –

As you state the 1572 guidance addresses your question.

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.

If a new protocol is in place or a new clinical investigator is overseeing the study, it is best to use the most current version of the 1572 form. The current CI does not need to sign a new 1572 form when the new revised form is released. The old signed form can stay in effect.

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

From: [redacted]
Sent: Wednesday, July 13, 2016 12:20 PM
To: OC GCP Questions
Subject: 1572 form question from [redacted]

Hello,

I have reviewed the FAQ Form 1572 and the document Guidance for Industry E6 GCP, regarding when to update a 1572 form.

Could you tell me when a new 1572 form is released, does the investigator need to complete and sign a new 1572 form on the new updated 1572 form template, if there are not changes to the original 1572 form template signed by the investigator?

When the investigator needs to update a 1572 form, does the investigator need to use the updated released form or can the 1572 form used at the beginning of the study (now expired) be updated?

Thanks,