From: OC GCP Questions
To: [redacted]
Subject: 1572 question?
Date: Thursday, November 02, 2017 10:43:10 AM
Attachments: [redacted]

Good morning --

The 1572 has two purposes: 1) to provide the sponsor with information about the investigator's qualifications and the clinical site that will enable the sponsor to establish and document that the investigator is qualified and the site is an appropriate location at which to conduct the study, and; 2) to inform the investigator of his/her obligations and obtain the investigator's commitment to follow pertinent FDA regulations. A sponsor must obtain a completed and signed 1572 before permitting an investigator to begin participation in a clinical study (21 CFR 312.53(c)). The initial 1572 is signed at the beginning of the study and submitted to the sponsor.

While an FDA form, the 1572 is meant to supply the study sponsor with pertinent information regarding the conduct of a study at a site and serve as an agreement by the clinical investigator (CI), once signed, to comply with the investigational plan/protocol and pertinent regulations. Since the information the 1572 contains is information required to complete an IND application, sponsors usually submit copies of 1572s to FDA with their application, though they are not required to do so, as it provides a convenient means of supplying required information. Since the 1572 is a sponsor form, the original should stay with the sponsor.

It might be helpful to review FDA's 1572 guidance.
https://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM214282.pdf

Kind regards,

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Office of Good Clinical Practice
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From: [redacted]
Sent: Thursday, November 02, 2017 9:50 AM
To: OC GCP Questions <gcp.questions@fda.hhs.gov>
Subject: 1572 question?

Dear FDA GCP Team:

Could you please kindly advise if FDA has the requirement on the original wet-signature 1572s? Should these be in the Sponsor or the Site files?—I have not seen any definite requirement on the original 1572. If you could please advise that would be well appreciated. Thank you.

Thank you, and have a good day.

Kindest regards,

[redacted]