From: OC GCP Questions
To: [redacted]
Subject: 1572 questions for Box 3
Date: Thursday, February 21, 2019 12:49:12 PM
Attachments: [redacted]

Good afternoon –

I think your question refers to Section #1. I assume the CI address is where the study files are kept. If an FDA inspection should occur, the FDA investigator would schedule a visit for that site and review the study data/records there. I don't think this address needs to be repeated in section # 3.

Please see FDA's 1572 Form guidance.
https://www.fda.gov/downloads/regulatoryinformation/guidances/ucm214282.pdf. See below.

20. What address should be entered into Section #1?
The address where the investigator can be reached by mail or in person should be entered in Section #1 of the 1572. Usually, this corresponds to the investigator's work or business address.

25. What address(es) should be entered in Section #3?

The address(es) of the location(s) where the investigation will be conducted and to where the test articles will be shipped, if different from the investigator's address of record, should be entered in Section #3.

I hope this information is helpful. Please contact us again 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: Fer[redacted]
Sent: Thursday, February 21, 2019 9:29 AM
To: OC GCP Questions <gcpquestions@fda.hhs.gov>
Subject: 1572 questions for Box 3

Hello,

Should a site address where study data will be kept qualifies for box 3? The address is not where IP or

patients being seen just the study regulatory binder and where study monitors.

Thank you in advance for guidance for this simple question.

Kind regards,

[redacted]