From: OC GCP Questions
To: [redacted]
Subject: FDA question 1572. Site Address
Date: Friday, May 19, 2017 11:13:00 AM
Attachments: [redacted]

Good morning –

FDA's 1572 guidance (link below) states --
https://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM214282.pdf

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.

You don't need to add the address twice, only if it is different than the investigator's address.

Kind regards,

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

U.S. FOOD & DRUG ADMINISTRATION

From: [redacted]
Sent: Thursday, May 18, 2017 6:32 PM
To: OC GCP Questions
Subject: FDA question 1572. Site Address

Hello

I want to confirm if for Section Name and Address of any Medical School, Hospital or Other Research facility where the Clinical Investigation will be conducted.

Is it necessary to add again the site Address on this section?
IF the only place where the study will be done, is the address, where it has the PI Name and

Address of the Investigator.

Thanks for the Clarification

[redacted]

[redacted]

[redacted]