From: OC GCP Questions
To: [redacted]
Subject: FDA Form 1572
Date: Monday, August 05, 2019 1:56:03 PM

Good afternoon –

Please see FDA's 1572 Form Guidance. https://www.fda.gov/media/78830/download It states

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.

27. If an investigator sees study subjects at more than one site, should the investigator list all sites on the 1572?

Yes. The names and addresses of each of the study sites should be identified in Section #3. However, if the protocol specifies that the investigative product can be administered at a subject's home (for example, the protocol allows for daily injections to be administered by a registered nurse in the subject's home), the subjects' home addresses do not have to be listed on the 1572. Study records should reflect that the test article was administered at subjects' homes per the protocol.

It appears that both sites should be listed on the 1572 form.

Kind regards,

Doreen M. Kezer, MSN

Senior Health Policy Analyst

Office of Good Clinical Practice

Office of the Commissioner, FDA

From: [redacted]
Sent: Thursday, August 01, 2019 1:57 PM
To: OC GCP Questions <gcpquestions@fda.hhs.gov>
Subject: FDA Form 1572

To Whom It May Concern:

If a site is seeing subjects at one location and, at a separate different location, houses the study regulatory documents and monitoring is conducted there, should BOTH locations be listed on the FDA Form 1572? Thank you.