From: Brown, Sheila (OGCP)
To: [redacted]
Subject: RE: Question Regarding 1572 Box 3 Site Name
Date: Friday, October 27, 2017 9:31:26 AM
Attachments: [redacted]

Dear [redacted],
According to FDA's guidance, Frequently Asked Questions – Statement of the Investigator (Form FDA 1572), the site at which the investigation will be conducted should be entered in section #3. The following questions and answers from the guidance are copied here for your convenience:

> **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.
>
> **26. What qualifies as a research facility for Section #3?**
> Section #3 is intended to identify facilities where study activities will be conducted and clinical data will be generated or collected. This includes facilities where subjects will be seen and study procedures performed. For example, this might include locations such as health care facilities where the test article will be administered, or where physical exams will be performed. Facilities where other important clinical investigation functions are performed may also be identified in Section #3. For example, a research laboratory where the test article is prepared, a special storage facility where the test article will be kept, or a location where tissue specimens are co llected should be listed in this section.
>
> **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.

The guidance may be found at https://www.fda.gov/ucm/groups/fdagov-public/@fdagov-afda-gen/documents/document/ucm214282.pdf

I'm not sure what you're referring to regarding location on the informed consent document. FDA's draft information sheet guidance provides the following information regarding contacts for questions about the research, subjects' rights, and whom to contact in the event of a research-related injury (21 CFR 50.25(a)(7). This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration on this topic.:

> The consent process must provide information on how to contact an appropriate

individual for pertinent questions about the clinical investigation and the subjects' rights, and whom to contact in the event that a research-related injury to the subject occurs. (21 CFR 50.25(a)(7).) This information should include contact names (or offices) and their telephone numbers. FDA recommends that the individual or office named for questions about subjects' rights not be part of the investigational team. Subjects may be hesitant to report specific concerns or identify possible problems to someone who is part of the investigational team. In addition, the consent process should include information on whom to contact and what to do in the event of an emergency, including 24-hour contact information, if appropriate.[22]

If contact information changes during the clinical investigation, then the new contact information must be provided to the subject. (21 CFR 50.25(a)(7).) This may be done through a variety of ways, for example, a card providing the relevant contact information for the clinical investigation.

The draft informed consent information sheet guidance can be found at https://www.fda.gov/RegulatoryInformation/Guidances/ucm404975.htm

I hope this information is helpful to you. If you need further assistance, please feel free to contact the GCP mailbox at gcp.questions@fda.hhs.gov .

Best regards,

Sheila

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This communication does not constitute a written advisory opinion under Title 21 CFR 10.85, but rather is an informal communication under Title 21 CFR 10.85(k), which represents the best judgment of the employee providing it. This information does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the views expressed.

From: [redacted]
Sent: Thursday, October 26, 2017 2:41 PM
To: OC GCP Questions
Subject: Question Regarding 1572 Box 3 Site Name

Dear Sir or Madam:

A question at our site was posed if, in Box 3 of the 1572, where it states “Name of Medical School, Hospital, or Other Research Facility,” it is correct to put the name of the site where the clinical investigation will be conducted or to put the name of the company that will conduct the clinical investigation?

Likewise, on the Informed Consent Document, is it required that the name of the site be included in the address provided, or does the company name suffice in identifying the location?

Thank you very sincerely for your time and assistance!

[redacted]