

From: OC GCP Questions
To: [REDACTED]
Subject: RE: Engaged in Research question
Date: Thursday, May 28, 2015 7:43:00 AM

Good morning,

The term “engaged” is not mentioned in FDA regulations. That term is typically discussed in terms of its applicability to 45 CFR part 46 (i.e., the Common Rule) which involves research activities receiving Federal funding and which is overseen by the HHS/Office for Human Research Protections.

Listing the pharmacy on the Form FDA 1572 may be appropriate since it may be a location to where a test article may be shipped and/or stored during a clinical investigation. I would refer you to FDA’s [Information Sheet Guidance for Sponsors, Clinical Investigators, and IRBs Frequently Asked Questions – Statement of Investigator \(Form FDA 1572\)](#). Questions 25 and 26 of the Information Sheet describe identifying the locations of where research will be conducted.

I hope this information is helpful. Please contact us again at gcp.questions@fda.hhs.gov should you have additional questions.

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This communication does not constitute a written advisory opinion under 21 CFR 10.85, but rather is an informal communication under 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: Wednesday, May 27, 2015 4:22 PM
To: OC GCP Questions
Subject: Engaged in Research question

Good Afternoon,

My question is in regards to research sites and when a site is considered to be participating or “engaged” in a clinical research trial. We are working with a partner who would like to use one of our research pharmacies to store and perform accountability of the investigational product.

Would the FDA consider the research pharmacy to be “engaged” in research if the pharmacist is performing that function and the pharmacy is listed on the Form FDA 1572?

Kind regards,

