From: OC GCP Questions
To: [redacted]
Subject: ICF - Possibility that the FDA may inspect the Records
Date: Monday, May 02, 2016 6:37:56 AM
[redacted]

Good morning –

The regulations at 21 CFR 50.25(a)(5) state, "In seeking informed consent, the following information shall be provided to each subject: ...(5) A statement...that notes the possibility that the Food and Drug Administration may inspect the records.

For all FDA-regulated studies under IND/IDE, I believe the consent form for the study should specifically mention FDA by name.

I hope this information is helpful. Please contact us again at gcp.question@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

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: Friday, April 29, 2016 4:19 PM
To: OC GCP Questions
Subject: ICF - Possibility that the FDA may inspect the Records

Dear FDA Representative,

In past discussions with headquarters FDA, it was always the FDA's position that the informed consent form statement must specifically note that "the Food and Drug Administration" may inspect the records and may not simply state that "regulatory authorities" may inspect the records (i.e., 21 CFR 50.25(a)(5)). The rationale was that an individual may not recognize that the FDA is one of the possible regulatory authorities who may review their records, and they may not want the FDA to inspect their records. The bottom line is that the regulation clearly stipulates that the form must state the "Food and Drug Administration."

With so many global studies, many sponsors and sites use a generic informed consent form (ICF) template and substitute the wording "regulatory authorities" for ICFs and do not specify that the "Food and Drug Administration" may inspect their records. The IRBs typically, but not always, approve this language that omits the FDA in the statement.

Can you please confirm the FDA's current position regarding this statement for U.S. sites? Do you have a different opinion if the sites are OUS but part of the IND or IDE study that will ultimately be submitted for drug or device approval?

Thank you,

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