From: Hommel, Carolyn - OC on behalf of OC GCP Questions
Sent: Friday, December 17, 2004 8:37 AM
To: [Redacted]
Subject: RE: Question regarding 21CFR Part 50.25(a)(5)

Dear Ms. [Redacted]:

Your letter to the GCP Questions e-mail account was forwarded to me for a response. I regret the delay in responding to you.

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."

Thus, I believe the consent form for the study should also specifically mention FDA by name.

I hope this is helpful.

Sincerely,

Carolyn Hommel
Consumer Safety Officer
Good Clinical Practice Program
Office of Science and Health Coordination
Office of the Commissioner
U.S. Food and Drug Administration (HF-34)
5600 Fishers Lane, Room 9C24
Rockville, MD 20857

Phone: 301/827-3340
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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.

-----Original Message-----
From: [Redacted]
Sent: Wednesday, November 17, 2004 1:05 PM
To: GCPQuestions@OC.FDA.GOV
Cc: [Redacted]
Subject: Question regarding 21CFR Part 50.25(a)(5)

Hi,

I have a question regarding the wording of an informed consent form to meet the requirements of 21CFR Part 50.25(a)(5). Would the following statement be acceptable to fulfill the requirement of noting "the possibility that the Food and Drug Administration may inspect the records."?

Representatives of the Sponsor (x) , the IRB (x), or domestic or foreign regulatory authorities may directly access your medical records at your doctor's site in order to determine the accuracy of the reported data. These representatives will observe professional secrecy and keep your identity confidential to the extent permitted by law.

I was not sure if this wording of the consent document would be acceptable since the FDA is a domestic regulatory authority. Your feedback is greatly appreciated.

Kind regards,
[Redacted]