From: Lee, Bonnie on behalf of OC GCP Questions
Sent: Tuesday, April 05, 2005 3:09 PM
To: [Redacted]
Subject: RE: Protocol procedure question

Dear [Redacted],

From your email below, it sounds as though this is a Phase 2 or 3 study and, as such, is subject to 21 CFR 312.23(a)(6)(ii) that requires in those phases "detailed protocols describing all aspects of the study." As such, a description of the videotaping should be included in the protocol and the consent form.

I hope this is helpful to you.

Sincerely,

Bonnie

Bonnie M. Lee
Associate Director for Human Subject Protection Policy
Good Clinical Practice Program, 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.

-----Original Message-----
From: [Redacted]
Sent: Monday, March 28, 2005 3:33 PM
To: gcpquestions@oc.fda.gov
Subject: Protocol procedure question
Importance: High

Due to a conflict of opinions between [Redacted] and a Sponsor company, I pose the following question.

The Sponsor would like the subjects to sign an IC addendum providing consent to participate in a videotaping of a [Redacted] procedure that they are having performed as part of the study. The purpose of the videotaping will be for training doctors and healthcare professionals in the administration procedure.

The videotaping procedure is not currently in the protocol and we believe it should be. Our client disagrees.

Please advise. Your prompt response is greatly appreciated.

[Redacted]