From: Lepay, David on behalf of OC GCP Questions
Sent: Friday, June 20, 2003 2:07 PM
To: [Redacted]
Subject: RE: Failure to obtain Informed Consent

Dear Ms. [Redacted]:
FDA regulations require that "A sponsor who discovers that an investigator is not complying with the signed agreement" (Form 1572 --- which includes the investigator's commitment to ensure that the requirements relating to obtaining informed consent are met)... "shall promptly either secure compliance or discontinue shipments of the investigational drug to the investigator and end the investigator's participation in the investigation. If the investigator's participation in the investigation is ended, the sponsor shall require that the investigator dispose of or return the investigational drug in accordance with the requirements of 21 CFR 312.59 and shall notify FDA." (This cite is from 21 CFR Part 312.56(b), which is accessible from our GCP website: www.fda.gov/oc/gcp through the link to Regulations).

In answer to your question,then, the sponsor's obligation is to promptly secure compliance. If this is not possible, then the sponsor's obligation is to discontinue the investigator's participation. FDA must be notified if the investigator is discontinued.

Sincerely,
David A. Lepay, MD PhD
Senior Advisor for Clinical Science and
Director, Good Clinical Practice Programs
OSHC, Office of the Commissioner, US 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: Thursday, June 19, 2003 1:34 PM
To: gcpquestions@oc.fda.gov
Subject: Failure to obtain Informed Consent

Does the Sponsor need to notify the FDA if an Investigator fails to obtain IC prior to study procedures being performed?

Thank You,
[Redacted]