From: Hommel, Carolyn - OC on behalf of OC GCP Questions
Sent: Monday, December 11, 2006 4:04 PM
To: [purged]
Subject: RE: Definition of Satelite site

Dear Ms. [purged]:

The term "satellite site" is not defined in FDA's regulations or guidance.

In general, an investigator should have a detailed plan for the supervision and oversight of a clinical trial. In FDA's experience, conducting a study from a remote ("satellite") location, particularly if that site is geographically distant (i.e., in another city, county, state, or country), is one factor that may compromise the ability of an individual investigator to provide adequate supervision of the conduct of an ongoing clinical trial.

FDA believes there should ordinarily be an individual (or subinvestigator) responsible for the conduct of the clinical trial at each trial site. Subinvestigators should report directly to the investigator (that is, the clinical investigator evaluates the individual's performance and has the authority to hire/fire the subinvestigator).

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)
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Rockville, MD 20857
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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: [purged]
Sent: Monday, December 11, 2006 3:22 AM
To: OC GCP Questions
Subject: Definition of Satelite site

Dear all,

could you kindly give me the FDA definition of what is a satelite site in a clinical trial.

Thank you very much

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