From: Beers Block, Patricia on behalf of OC GCP Questions
Sent: Friday, August 19, 2005 7:35 AM
To: [purged]
Subject: RE: FDA 1572

Dear Ms. [purged],

Do I understand your inquiry correctly when I conclude that you have two questions; one concerning which sites the sponsor might approve and the other concerning the specific information that can/should be included on the 1572? If I have misunderstood your inquiry, please reply and I can better address your concerns.

The sponsor has ultimate control over and within its legal authority in deciding which investigative sites it selects for the conduct of a clinical trial. Your case in point; the sponsor is within its authority to limit the conduct of the study to a specific site.

Multiple sites can be listed on the 1572. Moreover, it is important to list all sites where clinical trials will take place be listed on the 1572 so that FDA is aware of all of these locations.

I hope this information is helpful to you.

Sincerely,

Patricia M. Beers Block
Special Assistant to the Director
Good Clinical Practice Programs
OSHC/Office of the Commissioner
301-827-3340
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: [purged]
Sent: Tuesday, August 16, 2005 3:06 PM
To: gcpquestions@oc.fda.gov

Subject: FDA 1572

I would like so guidance on whether a sponsor can dictate which facilities an investigator can enter in block #3 of the FDA 1572. The reason I ask is that we are an investigative site that has both an in-patient and out-patient facility. There may be a time when we might have a need to see a patient who is in an out-patient clinical trial at our in-patient facility for their study visit. As long as both facilities have been inspected by the sponsor and deemed acceptable I was under the impression that both facilities must be listed on the FDA 1572. If you could please clarify this for me I would greatly appreciate your help.
Thank you,
[purged]