From: Hommel, Carolyn - OC on behalf of OC GCP Questions
Sent: Monday, October 02, 2006 8:52 AM
To: '**[Redacted]**'
Subject: RE: 1572

Dear Ms. **[Redacted]**:

In general, the address(es) of the locations where the investigation will be conducted and where the test articles will be shipped, if different from the investigator's address of record, should be entered in Block #3 of the 1572. This block is intended to identify facilities where study activities will be conducted and study data will be generated or collected. This should include all facilities where subjects will be seen and study procedures performed (for example, administration of the test article, physical exams). Facilities where other important study functions are performed may also be identified in Block #3 (for example, a research laboratory in which the test article is prepared or a special storage facility for the test article).

It is not clear from your e-mail why the consent is being "obtained at the hospital" when "all remaining procedures are performed at the PI's clinic." In my opinion, obtaining consent is an important study function, and therefore, the location where consent is being obtained deserves to be included on the 1572.

The way you phrased your question, however, suggests to me that your site has already submitted a 1572, and that you are asking if you need to update the 1572 to reflect new or changed information. If there are changes to information contained on the 1572 (e.g., an IRB address change, the addition of new subinvestigators, discontinuing the use of a clinical lab), the investigator should document the changes and inform the sponsor, so that the sponsor can appropriately update the IND. In such cases, the 1572 itself does not need to be revised and signed by the investigator. However, if you're filling out a brand new 1572, and know in advance that you will be recruiting and enrolling subjects at one location, and carrying out other study-related activities at another location, then you should list both locations on the 1572.

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 14-B17
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: [Redacted]
Sent: Friday, September 29, 2006 11:12 AM
To: OC GCP Questions
Cc: [Redacted]
Subject: 1572

Dear FDA,

I would appreciate your input on the following issue:

If only the consent is obtained at the hospital, and all remaining procedures are performed at the PI's clinic, does the hospital need to be added to the 1572?

I appreciate you assistance in this matter.

Best Regards,
[Redacted]