From: Beers Block, Patricia
Sent: Tuesday, May 09, 2006 6:31 AM
To: **[Redacted]**'
Subject: RE: 1572 Question

Dear Mr. **[Redacted]**,

In answer to your question about whether each suite needs to be identified in the 1572, we generally can rely on the address of the building for locating the study site. However, study records will need to identify the specific suite and the specific activities that will take place at each of these study sites. It may be useful to have SOPs that describe the study activities that will be conducted at each study site/suite. You may want to make certain that the sponsor knows/agrees with the manner in which the study will be conducted (especially if certain procedures will be performed at specific sites/suites) since the sponsor will need to be make certain that the study is conducted in accordance with its protocol and any requirements prescribed in the sponsor's SOPs.

Even more important than your concern about properly filling out the 1572 is the question of whether the clinical investigator signing the 1572 will be able to personally supervise study activities that go on in each study site/suite. The regulations require that the investigator be able to "personally conduct or supervise the described investigation(s)." The background and experience of the investigator, the nature of the condition under study, the complexity of the protocol and other similar factors all bear on whether the investigator is able to meet this responsibility to personally conduct or supervise for a given number of protocols/studies and a given number of study subjects.

Under FDA's regulations for the conduct of clinical trials, the clinical investigator makes a commitment to "...personally conduct or supervise the described investigation(s)..." [See 21 CFR 312.53(c)()1)(vi)(a) and (c).] The clinical investigator may delegate duties to others on his staff, but the regulations are fairly general, and do not specify who should or should not perform specific trial related activities. If the investigator decides not to personally perform certain duties, but instead delegates the duties to other staff members, the investigator is still responsible for supervising those staff members as they carry out the trial related activities, to ensure that the activities are performed in accordance with the relevant, current protocol(s) and in compliance with FDA's regulations. As part of this, the clinical investigator should ensure that study functions requiring medical expertise are performed only by study staff who are appropriately qualified and trained, and, if required under state law, appropriately licensed to carry them out. The clinical investigator should also check the study protocol, in case the sponsor has specified who should perform specific trial related activities, in order to avoid any protocol violations.

There is no regulation in the CFR that permits the "delegation of responsibility" from the clinical investigator to personnel. Indeed, it is not possible to delegate clinical investigator responsibilities under the regulations --- only *tasks* can be delegated, as appropriate, to individuals qualified by education, training, and experience. The clinical investigator remains responsible under the regulations for personally conducting or supervising all aspects of the study. Where tasks are delegated, the approach of identifying these tasks (and the individual to whom they are delegated) in writing would seem appropriate and consistent with GCP.

Development of SOPs pertaining to the delegation of study related tasks would be consistent with good clinical practice and something that might prove useful for your current building accommodations.

I hope this information is helpful to you.

Patricia M. Beers Block
Good Clinical Practice Program (HF-34)
Office of the Commissioner/ FDA
Telephone: 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: **[Redacted]**
Sent: Monday, May 08, 2006 3:51 PM
To: OC GCP Questions
Subject: RE: 1572 Question

3rd Request.

If there is a new e-mail address please let me know as this is holding up our submission for a new study and I was hoping I could get some clarification from the FDA.

Thanks in Advance.

From: **[Redacted]**
Sent: Wednesday, May 03, 2006 12:50 PM
To: ' (GCPQuestions@OC.FDA.GOV)'
Subject: FW: 1572 Question

2nd Request, first request sent on 4/28/06 at 8:40AM PST.

Thanks in advance for your response.

From: **[Redacted]**
Sent: Friday, April 28, 2006 8:40 AM
To: ' (GCPQuestions@OC.FDA.GOV)'
Subject: 1572 Question

Our Clinical Research Facility is located in a Medical Tower. Unfortunately we are unable to acquire contiguous space and as such have 5 different office or suites located within the same building.

Typically we list every Suite on the 1572 in Box 3 as the location for where the Research is to be conducted. Recently a sponsor told us we only needed to list the building address and there was no reason to list the Suite numbers as the subjects were seen at that building address and it made no difference to them what suite or office the subjects came to.

In terms of the FDA and upcoming pending FDA audits, would we be in compliance by just listing the building address without the Suites listed on the 1572, or would that be considered a finding?

If you could get back to me I would really appreciate it.

Thanks

[Redacted]