From: Hommel, Carolyn - OC on behalf of OC GCP Questions
Sent: Monday, May 22, 2006 4:14 PM
To: [purged]
Subject: RE: QA vraagje

Dear [purged]:

I apologize for taking so long to answer your question.

There is nothing in FDA's regulations that would preclude an investigator from simultaneously conducting a study at more than one site. However, the practice raises some important issues.

You did not say how far apart the hospitals are, but if they are geographically remote, it may prove difficult for an investigator to personally conduct or supervise the investigation at both sites. The other problem with a scenario like the one that you have described is that it has the potential to generate confusion as to who is responsible for the study and a lot of finger-pointing if anything goes wrong. Thus, you (or the ethics committee that is reviewing the study) may want to pursue this matter a little further with the investigator.

You might want to raise the following with the investigator to see what he/she has in mind:

--How will he/she ensure that the study is being conducted according to the study protocol and investigational plan if he is not at a particular site while the study is going on?
--How will he/she ensure that all observations related to the study are appropriately documented, and that all study staff are complying with the requirements for the conduct of such studies and for reporting adverse events, if he is not physically present?
--How will he/she keep study staff apprised of changes/important developments related to the study?

I would also like to point out that FDA's official guidance, the ICH E6, Good Clinical Practice: Consolidated Guidance, defines "Investigator," as "A person responsible for the conduct of the clinical trial at a trial site..." [See Section 1.34; emphasis added] Thus, in keeping with the ICH guidance, you might consider recommending that there be an investigator at each site.

I hope this is helpful, and again, apologize for the delay in responding to you.

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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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: Wednesday, April 12, 2006 4:13 AM
To: Hommel, Carolyn - OC
Subject: FW: QA vraagje

Dear,

What is your opinion on this?

Situation:
A study will be performed in two hospitals. The principal investigator in the first hospital is also the Head of the involved department in the other hospital. Is it allowed to have in the two hospitals the same principal investigator. Or even have this investigator in the first hospital principal and in the other one co-investigator?

My considerations:
Will this person have enough time to be responsible in the two hospitals? PI is responsible for the overall conduct of the trial.

What about possible bias? This would be practically the same as just having the trial done in one center?

Thanks for your feedback.

Kind regards
[purged]

From: [purged]
Sent: dinsdag 11 april 2006 16:21
To: [purged]
Subject: QA vraagje

Beste [purged],

Ik ben een studie aan het starten (UZA en paolaziekenhuis) waarbij de principal investigator van het UZA ook diensthoofd is in het paolaziekenhuis. Mijn vraag is nu of hij zowel in het Paolaziekenhuis als het UZA principal investigator mag zijn en dus beide EC submissies mag doen en alle andere documenten in beide ziekenhuizen aftekenen?

Alvast bedankt,
[purged]