From: Hommel, Carolyn - OC on behalf of OC GCP Questions
Sent: Tuesday, April 18, 2006 9:05 AM
To: [purged]
Subject: RE: Question

Dear Ms. [purged]:

Your question was forwarded to me for a response. I apologize for the delay in getting back to you.

There is nothing in FDA's regulations that specifically precludes an individual serving as a sub-investigator for 2 different clinical investigators.

Your e-mail, however, raises another interesting question. If Dr. [purged] place of business is listed as a site where the study will take place, how will investigators [purged] and [purged] supervise Subinvestigator [purged] when he is at his own place of business? Which investigator ([purged]?) is really responsible for overseeing Dr. [purged] conduct? The scenario you have described has the potential to generate confusion as to who is responsible for the study, and a lot of finger-pointing if something goes wrong.

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 having Dr. [purged] sign his own 1572 if he is going to conduct the investigation at his own place of business.

I hope this is helpful.

Sincerely,
Carolyn Hommel
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Good Clinical Practice Program
Office of Science and Health Coordination
Office of the Commissioner
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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, March 29, 2006 10:47 AM
To: OC GCP Questions
Subject: Question

To whom it may concern: (I sent this yesterday but was notified that it was not deliverable so I'm sending it again)

Would you please give me your thoughts on the following as I have never come across this before and while I can not find anything in the regulations/guidelines that prevent this, I am interested in your thoughts.

Can a person be a subinvestigator for 2 different principle investigators conducting the same protocol at 2 different sites? For example, Dr. [purged} and Dr. [purged] both are conducting Protocol 123 as principle investigators (not affiliated with each other) in Boston, MA. Each of their 1572s list Dr. [purged] listed as a subinvestigator and Dr. [purged] address as an additional place where the trial will be conducted. Is there anything wrong with this situation?

Thank you.

[purged]