From: Hommel, Carolyn - OC on behalf of OC GCP Questions
Sent: Thursday, November 02, 2006 12:27 PM
To: [purged]
Subject: RE: GCP question

Dear [purged]:

There is no regulatory prohibition against a CI or site staff participating in a trial, provided that they meet the inclusion/exclusion criteria outlined in the study protocol. However, both the sponsor and the IRB have some responsibility over the recruitment of subjects so either/both can impose restrictions on whether a CI or site staff can participate in a trial. For example, the sponsor may include restrictions in the study protocol; and the IRB/institution may establish written policies in this area.

There are a number of potential difficulties with conducting studies that involve study staff that should be considered by the sponsor, the IRB and the study site. One of the most significant complications pertains to the CI's ability to successfully evaluate the conduct of a study while participating in the study as a subject. The regulations require that the Clinical Investigator identified in the Form FDA-1572 personally supervise the conduct of the study. With the CI participating in the study as a subject, the CI would not be able to personally conduct or supervise his/her participation (including the treatment and reporting of unanticipated and serious adverse events). As a result, a second Clinical Investigator would have to be selected by the sponsor to ensure that the study was properly conducted throughout the entire study. Sponsors may be reluctant to do this because this approach to the conduct of the study may unnecessary complicate the study. IRBs likewise may find it difficult for the CI to properly supervise the conduct of the study while enrolled as a subject in the study, and the IRB may impose specific conditions on the conduct of the study before it approves the study. Again, this is especially true if the CI has an unanticipated and/or serious adverse event experience as a result of the administration of the investigational product.

A second important complication when other study staff participate as subjects in the study is the need for appropriate (and possibly additional) staff to perform that person's job responsibilities while enrolled as a subject. Again, all of this would need to be considered by the sponsor (and potentially addressed in the study protocol), the IRB (and potentially addressed in written procedures/policies) and study staff (possibly in the form of a written procedure that describes who will be responsible for the duties of the staff member when he/she is enrolled as a subject).

There are additional complications that should be considered, such as the potential for introducing bias into the study because the CI or study staffer who enrolls as a subject may have access to information that other subjects do not typically have access to (e.g., the staffer has seen another subject experience an unanticipated adverse event and is now aware of an event about which other subjects are not aware). The items mentioned above are probably the most significant shortcomings of a CI or study staff member participating as subjects.

I would urge you to bring these issues to the attention of the sponsor, clinical investigator, and IRB to ensure that they are fully explored.

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
Phone: 301/827-3340
Fax: 301/827-1169
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: Thursday, November 02, 2006 8:51 AM
To: OC GCP Questions
Subject: GCP question

Hello, I have a question. I have reviewed the regulations for a while about this and can not find any specific requirements.

I would like to know the FDA's stand on employees of a practice participating in a clinical trial.

In a web based initation meeting the other day, one of the other sites asked if non-research related employees could participate in the study if otherwise qualified. The sponsor said that was ok with them, but it was based on the offices practices.

In the past we have not allowed any employees of the practice to particpate because we were not clear on the guidlelines. Employees have often asked us about participating after seeing flyers and things. We do have a study coming up soon, that I am sure we will get alot of questions about.

Please let me know what the guidelines say about this.

thanks

[purged]