From: Hommel, Carolyn - OC on behalf of OC GCP Questions
Sent: Tuesday, September 19, 2006 9:38 AM
To: [purged]
Subject: RE: clinical trials

Dear Ms. [purged]:

There are no specific regulations that address site staff volunteering to participate as study subjects in a clinical trial, and likewise, no regulatory prohibition against a CI or site staff doing so, 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 to ensure that the rights and welfare of the subjects are protected.

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 staff. 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 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 or persons' 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).

Another consideration would be the need for steps to ensure that recruitment of study staff to participate in the study does not introduce an element of coercion into the consent process (e.g, does the staff member feel compelled to join the study as a condition of employment? would a staff member feel free to drop out of a study at any time?).

So, while I don't personally think it's a good idea, my advice would be to discuss the matter thoroughly with the sponsor and, especially, the IRB to ensure that these issues are carefully considered and addressed.

I hope this is helpful.

Sincerely,
Carolyn Hommel
Consumer Safety Officer
Good Clinical Practice Program
Office of Science and Health Coordination
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From: [purged]
Sent: Wednesday, September 06, 2006 3:00 PM
To: OC GCP Questions
Subject: clinical trials

I have three questions:

1. Can the site personnel listed on Form FDA 1572 be also enrolled in the trials they are conducting?
2. Is there a regulation that addresses the involvement of site staff as volunteers in their running clinical trials?
3. What would be the implications if they joined the trial?

Thanks for your help

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