From: Hommel, Carolyn - OC
Sent: Thursday, January 12, 2006 9:55 AM
To: [purged]
Subject: RE: GCPs

Hi, Claudette,

Thanks for reminding me--yesterday was pretty hectic and I didn't have time to get to it right away. This is what we said in the past to a similar inquiry.

There is no regulatory prohibition against a CI or site staff participating in a trial. 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.

As you note below, this particular institution (IRB) allows the enrollment of study staff in a clinical trial (unless they are "subordinates" whose job/evaluation could be affected in some way) and does not have a policy specifically directing enrollment of investigators in their own trials.

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 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 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 constitute the most significant shortcomings of study staff participating as subjects.

Finally, please note that if this is a study that is conducted under an IND, the sponsor IS still responsible for monitoring the study.

Claudette, I hope this helps you respond to the CI. Call or e-mail if you need anything else.

Carolyn

-----Original Message-----
From: [purged]
Sent: Wednesday, January 11, 2006 5:29 PM
To: Hommel, Carolyn - OC
Subject: GCPs

Carolyn,

I called about the Clinical Investigator's question of whether it is acceptable for him to participate in the clinical study that he is conducting. You indicated you may have some info on the subject. Were you successful in finding anything?

Thanks,

[purged]