From: Hommel, Carolyn - OC on behalf of OC GCP Questions
Sent: Monday, February 28, 2005 10:15 AM
To: [purged]
Subject: RE: FDA Form 1572

Dear [purged],

I apologize for the delay in responding to your last e-mail. I think some of the confusion may be due to the various terms that are being used.

The prefix "co-" in "co-investigator" implies equality--that is, that each "co-investigator" would have equal (and full) reponsibility for the conduct of a study. However, the term "co-investigator" (and, for that matter "principal investigator") do not appear in FDA's regulations, although the term "principal investigator" does appear in FDA's official guidance (see below).

FDA regulations use the terms "investigator" and "sub-investigator":

> "Investigator means an individual(s) who actually conduct(s) a clinical investigation (i.e., under whose immediate direction the drug or biologic is administered or dispensed to a subject). In the event an investigation is conducted by a team of individuals, the investigator is the responsible leader of the team. "Subinvestigator" includes any other individual member of that team." (See 21 CFR 312.3.)

For IND studies, sponsors are required to obtain a 1572 from each investigator before permitting the investigator to begin participation in an investigation. On the 1572, the investigator is required to list, in block #6, the names of the "subinvestigators (e.g., research fellows, residents, associates) who will be assisting the investigator in the conduct of the investigation(s)." (See 21CFR 312.53(c)(1)(viii).)

The prefix "sub-" in "sub-investigator" implies that the "sub-investigator" is subordinate to (i.e., reports to) the investigator who is responsible for the conduct of the study. Indeed, it is not possible to delegate clinical investigator responsibilities under the regulations --- only tasks can be delegated, as appropriate, to individuals qualified to conduct them, based on their education, training, and experience; thus, the investigator remains responsible under the regulations for personally conducting or supervising all aspects of the study.

I think the larger question--who is assuming responsibility for the conduct of the study, and thus, who would need to sign a 1572--is critical.

FDA's official guidance, the ICH E-6 Good Clinical Practice: Consolidated Guideline, contains the following definition for "Investigator" in section 1.34:
"A person responsible for the conduct of the clinical trial at a trial site.
If a trial is conducted by a team of individuals at a trial site, the investigator is the responsible leader of the team and may be called the 'principal investigator'."

I think the ICH guideline implies that there should be a responsible individual at a trial site who is responsible for the conduct of the clinical trial at that site.

Does this help?

Carolyn
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 9C24
Rockville, MD 20857
Phone: 301/827-3340
Fax: 301/827-1169
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-----Original Message-----
From: [purged]
Sent: Monday, January 24, 2005 4:09 AM
To: GCPQuestions@OC.FDA.GOV
Subject: FW: FDA Form 1572

Dear Carolyn,

I hope you could help me with another issue in regards to Form 1572. As you

may know most IND studies would conduct not only by principal investigator but also some co-investigators. Colleagues of mine from other disciplines shared an experience with me of their local monitors. They requested only PIs to complete the Form 1572. The rationale from the monitors is that only the PIs are responsible for the study conduct and data quality. If something bad happened in regards to the study conduct and data quality which are done by the co-investigators, only the PIs would take all the responsibilities. Being co-investigators are not at risk of "disqualification". This is the spirit of signing the Form 1572. Is that true?

Regards,

[purged]