From: Lepay, David on behalf of OC GCP Questions
Sent: Thursday, November 20, 2003 4:50 PM
To: [redacted]
Subject: RE: SOP training

Dear [redacted]:
There are no explicit SOP training requirement specified in FDA regulations. The regulations more generally require that individuals be qualified by education, training, and experience to perform their assigned duties.

Regards, Dave Lepay

This communication does not constitute a written advisory opinion under 21 CFR 10.85, but rather is an informal conmmunication 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.

-----Original Message-----
From: [redacted]
Sent: Thursday, November 20, 2003 4:42 PM
To: GCPQuestions@OC.FDA.GOV
Subject: SOP training

Thanks. Now I have another question. I'm wondering what your guidelines are for SOP training requirements for the conduct of clinical trials.
[redacted]

>>> OC GCP Questions <GCPQuestions@OC.FDA.GOV> 11/20/03 04:23PM >>>
Dear [redacted]:

I may need some further clarification of your question.

There is no "delegation of responsibility form" addressed in the CFR. Indeed, it is not possible to delegate clinical investigator responsibilities under the regulations --- only tasks can be delegated, as appropriate, to individuals qualified by education, training, and experience. The clinical investigator remains responsible under the regulations for personally conducting or supervising all aspects of the study.

Where tasks are delegated, the approach of identifying these tasks (and the individual to whom they are delegated) in writing would seem appropriate and consistent with GCP.

I hope that I am addressing your question; but again, it may be that additional clarification is needed.

Sincerely,

David A. Lepay, MD PhD
Senior Advisor for Clinical Science and
Director, Good Clinical Practice Programs,
OSHC, Office of the Commissioner, US FDA

-----Original Message-----
From: [redacted]
Sent: Thursday, November 20, 2003 3:52 PM
To: gcpquestions@oc.fda.gov
Subject: delegation of responsibility

Can you answer a question?
At the initiation of a study, we use a delegation of responsibility form to assign clinical trial responsibilities to specific personnel. Is this required according to GCP or CFR?
[redacted]