From: Toth-Allen, Jean
Sent: Wednesday, August 09, 2006 10:46 AM
To: [purged]
Subject: Site SOPs and CI training

Dear [purged]:

Your inquiry was forwarded to us for a response.

There is no FDA regulation that requires SOPs regarding the conduct of studies at clinical sites, neither for pharmaceutical nor device studies. However, many sites find written SOPs useful as a guide for ensuring quality and consistency in the clinical studies undertaken at the site. To that end, several of the professional societies as well as for-profit organizations offer courses in writing such SOPs. See, for example, information from the Association for Clinical Research Professionals (ACRP) at http://www.acrpnet.org, the Society for Clinical Research Associates (SoCRA) at http://www.socra.org, and the Drug Information Association (DIA) at http://www.diahome.org/DIAHome/Home.aspx.

Sponsors are required to choose clinical investigators qualified by training and experience to conduct both pharmaceutical clinical studies (Title 21, Code of Federal Regulations - 21 CFR - 312.53(a)) and device studies (21 CFR 812.43(a)). In addition, clinical investigators are responsible for ensuring compliance with FDA regulations protecting the rights, safety, and welfare of study subjects (21 CFR 312.60 and 812.100). To ensure compliance requires knowledge of the requirements. While the regulations do not specify how a clinical investigator is to obtain such knowledge, training which could include official courses is obviously a possible route.

Hope this information is useful.

If you need further information and/or have additional questions, please submit them once again to the official GCP mailbox, gcpquestions@oc.fda.gov, in lieu of responding to my personal e-mail address.

Sincerely yours,

Jean Toth-Allen, Ph.D.
Good Clinical Practices Program
OSHC, Office of the Commissioner, US FDA

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.

-----Original Message-----
From: MYousof@kai-research.com [mailto:MYousof@kai-research.com]
Sent: Tuesday, August 01, 2006 1:20 PM
To: CDER DRUG INFO
Subject: DrugInfo Comment Form FDA/CDER Site

Name: [purged]

E-Mail: [purged]

Comments: hi,
I have two questions:
1. Is it mandatory that the PIs required having Standards operation procedures (SOPs) in their offices describing how to conduct clinical trials?
2. is mandatory for the PIs and his team to receive official training in PROTECTION OF HUMAN SUBJECTS?

Best regards,
[purged]