From: Beers Block, Patricia on behalf of OC GCP Questions
Sent: Monday, January 30, 2006 7:10 AM
To: [purged]
Subject: RE: DrugInfo Comment Form FDA/CDER Site

Dear [purged],

Thank you for the clarifying message you sent last week. I believe the best guidance on study conduct and the development/use of standard operating procedures (SOPs) can be found in the FDA guidance entitled "Guidance for Industry E6 Good Clinical Practice: Consolidated Guidance" (see http://www.fda.gov/cder/guidance/959fnl.pdf). Specific regulatory requirements for the conduct of studies on investigational drugs are found at 21 CFR 312 (see http://www.fda.gov/oc/gcp/regulations.html).

The FDA guidance noted above provides a unified standard for the European Union (EU), Japan, and the United States to facilitate the mutual acceptance of clinical data by the regulatory authorities in these jurisdictions. It contains suggestions about ways in which interested parties (e.g.,sponsors, clinical investigators, IRBs) can satisfy the requirements of the applicable statute and regulations that govern good clinical practice. Of course, other approaches that satisfy these regulatory requirements may be used as this guidance (unlike regulations) is legally non-binding on FDA or the public and simply represents the agency's current thinking on good clinical practices.

As this guidance notes in Section 5.1 (Sponsor Quality Assurance and Quality Control):

"the sponsor is responsible for implementing and maintaining quality assurance and quality control systems with written SOPs to ensure that trials are conducted and data are generated, documented (recorded) and reported in compliance with the protocol, GCP and the applicable regulatory requirement(s)."

To meet these recommendations, the sponsor may, and often do, develop SOPs that are to be used by the clinical sites where the studies are conducted.

The regulations found at 21 CFR 312 do not specifically require the development of SOPs by sponsors or clinical investigators but, instead, require that studies be conducted in accordance with good clinical practice, and in accordance with the study protocol. Sponsors are required to select a monitor qualified by training and experience to monitor the progress of the investigation. Again, sponsors often develop SOPs that describe the controls/procedures it intends to use to monitor a study, as well as those it expects clinical sites to follow to ensure compliance with the regulations and the study protocol.

I hope this information is helpful to you. Please let me know if I can be of any further assistance.

Sincerely,

Patricia M. Beers Block
Good Clinical Practice Program (HF-34)
Office of Science and Health Coordination
Office of the Commissioner
5600 Fishers Lane, Rm. 9C24
Rockville, MD 20857
Telephone: 301-827-3340

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: [purged]
Sent: Wednesday, January 18, 2006 8:19 AM
To: CDER DRUGINFO
Subject: DrugInfo Comment Form FDA/CDER Site

Name: [purged]

E-Mail: [purged]

Comments: Dear Sir or Madam,

I would like to inquire about FDA/CDER policy regarding any requirements for institutions participating in industry sponsored clinical reserch trial of investiational drugs to have written Standard Operating Procedures in place.

thank you