From: Toth-Allen, Jean
Sent: Wednesday, August 09, 2006 1:04 PM
To: [Redacted]
Subject: SOPs

Dear [Redacted]:

Thank you for your inquiry regarding the adequacy of SOPs.

There are no requirements in FDA regulations that a CRO have SOPs, never mind details as to their contents. However, FDA ultimately holds sponsors responsible for the conduct of their clinical studies, even when they contract some or all of their responsibilities to a CRO. (Device regulations in Title 21, Code of Federal Regulations - 21 CFR - Part 812, Investigational Device Exemption, do not even speak to transfer of regulatory responsibility to contracted bodies.) Therefore, we usually recommend that sponsors ensure that the CRO's SOPs for whatever responsibility is being contracted meet the sponsor's requirements and are capable of ensuring compliance with the regulations. In addition, the ICH document on Good Clinical Practice, found at http://www.fda.gov/cder/guidance/959fnl.pdf and recognized as guidance by FDA, speaks of sponsor SOPs under section 5.1, Quality Assurance and Quality and Control. Section 5.2, which discusses CROs, states at 5.2.4 that "All references to a sponsor in this guideline also apply to a CRO to the extent that a CRO has assumed the trial-related duties and functions of a sponsor."

As a result of such guidance, courses on SOP writing for various aspects of clinical trials are presented by both professional organizations and for-profit companies. For example, see their websites for information with regard to such courses presented by the Association for Clinical Research Professionals (ACRP) (http://www.acrpnet.org), the Society for Clinical Research Associates (SoCRA) (http://www.socra.org), and the Drug Information Association (DIA) (http://www.diahome.org/DIAHome/Home.aspx).

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: [Redacted]
Sent: Saturday, August 05, 2006 5:43 AM
To: CDER DRUG INFO
Subject: DrugInfo Comment Form FDA/CDER Site

Name: [Redacted]

E-Mail: [Redacted]

Comments: I am working for a CRO and would like to have your comments as to how important it is to have detailed SOPs. I will site an example if an SOP on 'Writing, revising and storing of Standard Operating Procedures' has in the text portion for writing written 'Standard Operating Procedures will be written and updated by the personnel in the Laboratory, Quality Assurance, Clinic, Pharmacokinetics and Facility Management and will be reviewed by the department heads.'This is followed by the numbering system.

How far is this acceptable to FDA and what standard of documentation is acceptable for a CRO.