From: OC GCP Questions
To: [redacted]
Subject: Question regarding SOPs
Date: Monday, January 30, 2017 9:35:00 AM
Attachments: [redacted]

Good morning –

SOPs can be considered working guidelines. However SOPs are not specifically mentioned in FDA regulations. When FDA regulations are silent, institutions are free to develop their own standard operating procedures (SOPs) or policies to address specific situations. While not mandatory, SOPs provide a standard working tool that can be used to document routine quality system management and technical activities. SOPs provide consistency when a process is being performed. They reduce the chance of errors and provide guidelines for employees to follow.

For example, sponsors should have monitoring SOPs and at least referenced in the specific study protocol(s) for which they will be applied. They would need to cover all aspects of monitoring as described in the monitoring SOPs. Whether or not a copy is left with the study site should be specified in the SOPs as well.

You can perform a web search and find a lot of information on writing SOPs as they related to clinical research and good clinical practice. While we cannot endorse/recommend non-government entities, you may also find courses on SOPs provided by a number of the professional societies to be useful. These include: the Association of Clinical Research Professionals (ACRP) (www.acrpnet.org/), the Society of Clinical Research Associates (SoCRA) (www.socra.org/), the Regulatory Affairs Professionals Society (RAPS) (www.raps.org/personifyebusiness/), the Drug Information Association (DIA) (www.diahome.org/DIAHome/Home.aspx), and the Society of Quality Assurance (SQA) (www.sqa.org/).

Additionally ICH-E6 Guidance
http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM073122.pdf addresses quality assurance in Section 5.1 ("Quality Assurance and Quality Control"). That section speaks to writing SOPs for the conduct of studies as well as obtaining agreements aimed at ensuring the quality and integrity of data resulting from such studies.

I hope this information is helpful. Please contact us again at gcp.questions@fda.hhs.gov should you have additional questions.

Kind regards,

Doreen M. Kezer, MSN
Senior Health Policy Analyst
Office of Good Clinical Practice
Office of the Commissioner, FDA

U.S. FOOD & DRUG ADMINISTRATION

From: [redacted]
Sent: Friday, January 27, 2017 9:49 AM
To: OC GCP Questions

Subject: Question regarding SOPs

Hello,

I have a general question about standard operating procedures. I am a clinical research nurse working in Bone marrow transplant research. I have been with my current employer for a year. I have conducted clinical trials for over 15years, with past experience in a multi-specialty outpatient SMO and a large private practice.

My question; in writing SOPs for a research department are there guidelines that the FDA offers in the actual writing, content to include, maintaining, updating, etc.?

If I have contacted the wrong division/department, if you wouldn't mind to advise me who to contact that would be most helpful.

All the best, and thank for all you do!!

[redacted]