From: OC GCP Questions
To: [redacted]
Subject: Standard Operating Procedures
Date: Thursday, July 31, 2014 11:37:04 AM

Good morning –
.
We often say when FDA regulations are silent sponsors, sites, and institutions are free to develop their own standard operating procedures to address a specific issue or situation.
Companies are free to set-up their own internal infrastructures to ensure the integrity of a clinical trial.
Additionally, SOPs ensure consistency in a clinical trial.

FDA uses Compliance Program Guidance Manuals (CPGM) to direct its field personnel on the conduct of inspectional and investigational activities. The purpose of each program is to ensure the protection of research subjects and the integrity of data submitted to the agency in support of a marketing application. Please see the link below to the sponsor CPGM.

http://www.fda.gov/downloads/ICECI/EnforcementActions/BioresearchMonitoring/UCM133770.pdf

Please also see a few guidance documents that might be helpful for you to review.
Guidances > Sponsor - Investigator - IRB Interrelationship - Information Sheet

http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM187772.pdf

http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM269919.pdf

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

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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.

From: [redacted]
Sent: Wednesday, July 30, 2014 2:08 PM
To: OC GCP Questions
Subject: Standard Operating Procedures

Dear Sir/Madame,
Does the FDA expect (and look for during inspections) sponsors to have certain Standard Operating Procedures (SOPs) and if so what are those SOPs.

Thank you in advance for any information you can provide.