From: OC GCP Questions
To: [redacted]
Subject: Fraud
Date: Tuesday, January 17, 2017 1:41:00 PM

Good afternoon

I cannot confirm when the guidance will be finalized as my office is not involved with finalizing this guidance. I can offer you the following information however.

FDA's regulations do not specifically define "fraud" or "misconduct," FDA can (and does) initiate disqualification proceedings against clinical investigators who have "...submitted to FDA or to the sponsor false information in any required report..." (See 21 CFR 312.70 and 812.119.)

FDA can also debar--that is, prohibit--investigators and firms from participating in drug studies if they have been convicted of crimes related to FDA's regulation of drugs. FDA's disqualification and debarment actions were discussed in a press release, which also contains links to lists of disqualified and debarred individuals, and basic questions and answers about these types of actions. Here's the link to a 2009 press release:
www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm176040.htm .

Additional documents/links that may be of interest to you:

Clinical Investigator - Disqualification Proceedings - Clinical Investigators - Disqualification Proceedings

FDA's regulations related to the conduct of clinical trials:
www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/ucm155713.htm

Compliance and Enforcement links:
www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/ComplianceEnforcement/default.htm

Compliance Policy Guide - Sec. 120.100: Fraud, Untrue Statements of Material Facts, Bribery, and Illegal Gratuities (CPG 7150.09)
www.fda.gov/ICECI/ComplianceManuals/CompliancePolicyGuidanceManual/ucm073837.htm

Regulatory Procedures Manual - Chapter 5-9: Disqualification of Clinical Investigators stating on page 88 Regulatory Procedures Manual

Staff Manual Guide 7711 - Disqualification of a Clinical Investigator: The Hearing Process
http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/StaffManualGuides/UCM252821.pdf

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

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: Monday, January 16, 2017 10:48 AM
To: OC GCP Questions
Subject: Fraud

Hello,

Can you please confirm whether the 2010 draft guidance document regarding fraud/misconduct was ever finalized? What is the current FDA thinking on fraud/misconduct?

Kind regards,

[redacted]