From: OC GCP Questions
To: [redacted]
Subject: CRF data with no source documentation
Date: Monday, September 29, 2014 1:23:13 PM

Good morning –

Please see the guidance documents below, especially the second one listed below. This one discusses eCRFs and source documents. For your specific question, it would be difficult to not have source documentation for an adverse event. Adverse events need to be documented, evaluated by the investigator, and reported to the sponsor and reviewing IRB when appropriate. It is possible to provide additional documentation in paper format as to how you found out about the AE and the details (start/stop dates, severity, adjudication, and resolution). It would be beneficial if an FDA inspection occurred at your site.

An electronic data capture system for FDA-regulated studies should be Part 11 compliant. FDA's regulations for electronic records and electronic signature can be found at 21 CFR Part 11 (http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=11). Part 11 applies to records in electronic form that are created, modified, maintained, archived, retrieved, or transmitted under any records requirements set forth in Agency regulations, as well as electronic records submitted to the Agency under the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act, even if such records are not specifically identified in Agency regulations.

I've listed below a few FDA guidance documents that you may find helpful:

FDA's Guidance for Industry – Computerized Systems Used in Clinical Investigations found at http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM070266.pdf

FDA's Draft Guidance for Industry – Electronic Source Data in Clinical Investigations found at http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM328691.pdf

FDA's Guidance for Industry -- Part 11, Electronic Records; Electronic Signatures --Scope and Application found at http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM126953.pdf

Additionally, please see the links below for additional safety reporting requirements.

http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM227351.pdf

http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM332846.pdf

Investigational New Drug (IND) Application > Final Rule: Investigational New Drug Safety Reporting Requirements for Human Drug and Biological Products and Safety Reporting Requirements for Bioavailability and Bioequivalence Studies in Humans

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

does not bind or otherwise obligate or commit the agency to the views expressed.

From: [redacted]
Sent: Thursday, September 25, 2014 5:09 PM
To: OC GCP Questions
Subject: CRF data with no source documentation

Hello,

Where can I find a regulation and/or guidance document for data reported in the eCRF requiring supporting source documentation. I have searched through 21 CFR 312 and 812 but was unable to find anything regarding this.

For example, if there is an adverse event reported in the eCRF with no source documentation for specific data points, i.e., start/stop date, severity, relationship to investigational product etc. would this be considered a deviation from federal regulations?

Thank you for your help,
[redacted]