From: OC GCP Questions
To: [redacted]
Subject: Discrepancy of self-report vs. source documents
Date: Friday, May 09, 2014 2:56:49 PM
Importance: High

Good afternoon --

FDA's regulations require investigators to "...prepare and maintain adequate and accurate case histories that record all observations and other data pertinent to the investigation on each individual administered the investigational drug or employed as a control in the investigation. Case histories include the case report forms and supporting data including, for example, signed and dated consent forms and medical records including, for example, progress notes of the physician, the individual's hospital chart(s), and the nurses' notes..." See 21 CFR 312.62(b).
http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=312.62 Because the regulations do not specifically address data discrepancies, it is left to the sponsor's and/or clinical investigator's discretion to create their own procedures for the individual study sites. When, the regulations are not specific, sponsors/sites have the flexibility to develop procedures that make the most sense to them.

Typically, it is the investigator or a member of his/her staff who would be responsible for entering information into the subjects' charts, medical histories, and case report forms (CRFs). If during the course of monitoring a study, the sponsor's monitor discovers a discrepancy between information in the source documentation (i.e., a subject's medical records) and what was reported on a CRF, the sponsor's monitor may bring it to the attention of the clinical investigator. Any change to a CRF should be endorsed by the investigator, per the advice in FDA's official guidance and well documented, the ICH E6 "Good Clinical Practice: Consolidated Guidance:" [
http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm073122.pdf
]. If data is changed to address a discrepancy and the change is complex, a note to file would also be appropriate.
Additionally, you may also be interested in reviewing information found within the FDA guidance on Investigator Responsibilities:
http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM187772.pdf
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I hope this information is helpful. Please contact us again at gcp.questions@fda.hhs.gov should you have additional information.

Kind regards,

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

From: [redacted]
Sent: Thursday, May 08, 2014 3:54 PM
To: OC GCP Questions
Cc: [redacted]
Subject: Discrepancy of self-report vs. source documents
Importance: High

Good Afternoon,

What would be the correct procedure to document information that is reported by a patient vs. information that documented by a physician in a patient's medical records? For example, if a patient reported to a study coordinator that he or she stopped smoking in 1985, however the medical records signed and dated by the physician is a different year than what is reported by the patient. How would I handle the discrepancy of information reported?

Kind Regards,