From: OC GCP Questions
To: [redacted]
Subject: Measurements on PROs
Date: Wednesday, January 21, 2015 2:36:31 PM

Good afternoon –

FDA regulations pertaining to recordkeeping practices for clinical trial records are fairly general. The FDA regulations do not specifically address subject diaries or subject questionnaires.
Because the regulations and guidance do not specifically address the design and use of subject diaries and questionnaires, sponsor/CRO's have flexibility in how they will design and use such documents in a clinical study, which includes whether or not subjects will be required to initial/date diary entries and/or sign and date diaries. Keep in mind, it is expected that source documents be attributable to the person who provides the information.

Additionally, the regulations do not specifically address signing or dating of documents by the clinical investigator. That being said, it is always good to be able to ascribe a report to someone as these will likely be important study data. When FDA regulations on silent on a specific topic, we suggest developing standard operating procedures. These procedures will assist you in determining how to maintain records and, for those that could depend on the opinion/expertise of a particular person, how best to ensure they will always know who made the diagnosis/decision. Sites therefore have flexibility in how they handle documents at their sites because FDA's regulations do not specify how this must be done.

However, if a site were to have a bioresearch monitoring (BIMO) inspection, the FDA investigator would look for the site's procedures for validating e-signatures if they are used and determine if they were followed since there are no specific procedures identified in the regulations.

If you develop and SOP regarding how the subject questionnaires will be completed, you should document training of your study staff so that there will be consistency in reporting across all research staff.

Lastly, you may also find FDA's guidance titled, "Patient-Reported Outcome Measures: Use in Medical Product Development to Support Labeling Claims" to be of interest. You can access this guidance document at http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM193282.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

From: [redacted]
Sent: Tuesday, January 20, 2015 1:00 PM
To: OC GCP Questions

Subject: Measurements on PROs

Hello,
Is there something in GCP regarding the site staff writing on patient reported outcome questionnaires?

We have one where the subject makes a mark on a line denoting with zero on one end and 100 on the opposite end of this scale. The study coordinator then must use a ruler and determine a value associated with the pen mark from the patient, and that goes into a database.

Is it allowable for the study coordinator to write the value on the questionnaire and initial and date each entry (each scale is on a separate page)?
Should it be written somewhere else? Or not written at all, just entered into the database.

Thank you in advance,
[redacted]