From: OC GCP Questions
To: [redacted]
Subject: RE: signing rating scales
Date: Friday, September 26, 2014 12:26:00 PM

Dear [Redacted]

Thank you for your question. FDA's regulations do not specifically address rating scales or the question you are asking about requirements for signature and date. As you know, the regulations at 21 CFR 312.62(b) require the following:

> *(b) Case histories. An investigator is required 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. The case history for each individual shall document that informed consent was obtained prior to participation in the study.*

I imagine that the various rating scales/tools/instruments used in the conduct of clinical trials may come in a variety of formats (e.g., paper vs. electronic) and some may require information such as subject name, name of the person executing the assessment and the date, whereas others may not.

The monitor may likely be suggesting that information such as signatures and dates on clinical trial documentation is a good documentation practice. FDA's guidance for industry titled, "Electronic Source Data in Clinical Investigations (see http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm328691.pdf) states:

> *The review of source data by both the FDA and sponsor is important to ensure adequate protection of the rights, welfare, and safety of human subjects and the quality and integrity of the clinical investigation data. Source data should be attributable, legible, contemporaneous, original, and accurate (ALCOA) and must meet the regulatory requirements for recordkeeping.*

As stated in FDA's guidance for industry titled, "Investigator Responsibilities — Protecting the Rights, Safety, and Welfare of Study Subjects" (see http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm187772.pdf):

> *It is common practice for investigators to delegate certain study-related tasks to employees, colleagues, or other third parties (individuals or entities not under the direct supervision of the investigator). When tasks are delegated by an investigator, the investigator is responsible for providing adequate supervision of those to whom tasks are delegated. The investigator is accountable for regulatory violations resulting from failure to adequately supervise the conduct of the clinical study.*

This guidance also says:

> *The investigator should ensure that any individual to whom a task is delegated is qualified by education, training, and experience (and state licensure where relevant) to perform the delegated task. Appropriate delegation is primarily an issue for tasks considered to be clinical or medical in nature, such as evaluating study subjects to assess clinical response to an investigational therapy (e.g., global assessment scales, vital signs) or providing medical care to subjects during the course of the study. Most clinical/medical tasks require formal medical training and may also have licensing or certification requirements. Licensing requirements may vary by jurisdiction (e.g., states, countries). Investigators should take such qualifications/licensing requirements into account when considering delegation of specific tasks. In all cases, a qualified physician (or dentist) should be responsible for all trial-related medical (or dental) decisions and care.*
>
> *During inspections of investigation sites, FDA has identified instances in which study tasks have been delegated to individuals lacking appropriate qualifications. Examples of tasks that have been inappropriately delegated include:*
> - *Screening evaluations, including obtaining medical histories and assessment of inclusion/exclusion criteria*
> - *Physical examinations*
> - *Evaluation of adverse events*
> - *Assessments of primary study endpoints*
> - *Obtaining informed consent*
>
> *The investigator is responsible for conducting studies in accordance with the protocol (see 21 CFR 312.60, Form FDA-1572, 21 CFR 812.43 and 812.100). In some cases a protocol may specify the qualifications of the individuals who are to perform*

certain protocol-required tasks (e.g., physician, registered nurse), in which case the protocol must be followed even if state law permits individuals with different qualifications to perform the task (see 21 CFR 312.23(a)(6) and 312.40(a)(1)). For example, if the state in which the study site is located permits a nurse practitioner or physician's assistant to perform physical examinations under the supervision of a physician, but the protocol specifies that physical examinations must be done by a physician, a physician must perform such exams.

The investigator should maintain a list of the appropriately qualified persons to whom significant trial-related duties have been delegated. This list should also describe the delegated tasks, identify the training that individuals have received that qualifies them to perform delegated tasks (e.g., can refer to an individual's CV on file), and identify the dates of involvement in the study. An investigator should maintain separate lists for each study conducted by the investigator.

Your question did not indicate any specific reason why the monitor believes that not signing and dating a rating scale would be problematic if audited, but if the concern is related determining who performed the assessment (i.e., is it attributable), there may be any number of ways that this could be addressed. The protocol and the sponsor will likely dictate "when" and "how" rating scales need to be completed during the conduct of a clinical trial. The sponsor is required to select qualified investigators and the investigator is responsible for conducting studies in accordance with the protocol. If there is any question about whether or not the protocol and sponsor require signatures and dates on clinical trial documentation such as rating scales, you should consult the sponsor.

I hope this information is useful. If you need further information and/or have additional questions, please feel free to contact us at the official GCP mailbox, gcp.questions@fda.hhs.gov. You may also find it useful to access the set of redacted GCP e-mails found at http://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/RepliestoInquiriestoFDAonGoodClinicalPractice/default.htm since we find that many questions and concerns are repeated over time.

Best Regards,

Janet

Janet Donnelly, RAC, CIP
Policy Analyst, Office of Good Clinical Practice
Office of Special Medical Programs, Food and Drug Administration

---

From: [Redacted]
Sent: Wednesday, September 24, 2014 9:35 AM
To: OC GCP Questions
Subject: FW: signing rating scales

One of our clinical sites had a monitor who commented about the fact that our sponsors do not necessarily require rating scales to be signed and dated by their executor. These rater scales are associated alzheimers clinical trials. She was concerned that, although the sponsor doesn't require it, if we got audited it would be problematic. Do you know of any regulation that requires this? I know that we have not been signing/dating rating scales consistently – only when required by the sponsor. Please advise as I believe this is all sponsor driven.

[Redacted]