JOURNAL OF CLINICAL RESEARCH BEST PRACTICES
Vol. 14, No. 7, July 2019 "Happy Trials to You"

Good Clinical Practice Q&As

Should the delegation log at a site be signed by both the clinical investigator (to establish/acknowledge that he/she is delegating the specified tasks) and the site personnel (as importantly, to establish/ acknowledge that each understands that the specified tasks have been delegated to him/her)?

In an informal February 2010 response to this question, the FDA's Office of Good Clinical Practice responded that, "while the delegation log is a site document recommended in ICH E6, which is official FDA guidance, the delegation log is not required by regulation. FDA does expect personnel delegated study activities to be qualified for the task(s) assigned and overseen by the clinical investigator ... It is therefore prudent to document this information.

"While FDA regulations require few signatures, even on required documents, protocols/investigational plans and/or IRB directives often call for signatures as documentation of just what you discuss. Therefore, if the sponsor or IRB directs such signatures, they would be expected, and a site can be cited for lacking them as part of a bioresearch monitoring (BIMO) inspection — as a failure to follow the investigational plan or IRB requirements. Such documentation may also be required by site SOPs, if SOPs are employed by the site."

Source

"Good Clinical Practice: A Question & Answer Reference Guide," Barnett International. The Guide is available at http://www.barnettinternational.com in electronic and paper form.