From: OC GCP Questions
To: [redacted]
Subject: Delegation of authority for prescribing/ordering investigational product
Date: Wednesday, April 01, 2015 12:35:12 PM

Good afternoon --

FDA's regulations do not require a delegation of authority log. This log, however, is among the documents listed in the ICH E6 Good Clinical Practice (GCP) document which is official FDA guidance. FDA investigators inspecting a clinical site will not always review the delegation of authority log as it is not a regulatory requirement.

http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM073122.pdf

That said FDA does expect an investigator to be in compliance with any state or local laws or requirements as part of being qualified. Therefore, an investigator (or a member of the investigator's staff) would need to maintain a medical license or other certification that is necessary to perform the study (for example, to diagnose or treat a patient or prescribing or ordering investigational product). If the license is subject to renewal, then a current license would be needed in order to be in compliance with the local requirements. So, although not specified in FDA's regulations, in order to be qualified, an investigator or subinvestigator would need to maintain any required state or local licenses or certifications needed to perform the clinical tasks necessary to conduct the study.

To answer your question, since the delegation of authority log is not an FDA requirement, there is nothing in the FDA regulations that prevents individuals that dispense or prescribe investigational product to be listed on these logs.

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: Wednesday, April 01, 2015 10:40 AM
To: OC GCP Questions
Subject: Delegation of authority for prescribing/ordering investigational product

Good Morning,

Templates for delegation of authority logs, while typically listing functions related to maintaining drug accountability, drug preparation and drug administration, do not typically list “prescribing” or “ordering” investigational product. While in most cases there is an “other” category under which prescribing or ordering could be entered, the prescribing/ordering function is not usually delegated. Is it good clinical practice for individuals who are authorized to prescribe/order investigational product to be listed on the delegation log?

Thank you for your consideration of this question.

[redacted]