**From:** OC GCP Questions
**To:** [redacted]
**Subject:** RE: Question on Good Clinical Practice regarding Record retention for DMF
**Date:** Thursday, March 13, 2014 10:09:00 AM

Good morning,

FDA's regulations do not address site personnel logs. These are tools used by investigators and/or study sponsors to help ensure and document the proper conduct of a clinical trial. Some FDA guidance documents mention such logs, however, I am not aware of any FDA guidance that discusses the study staff signing the this type of log.

In accordance with FDA's regulations, investigators are required to commit to personally conduct or supervise the investigation (for drug and biologic studies under 21 CFR 312.53(c)) or to supervise all testing (for medical device studies under 21 CFR 812.43(c)).

The FDA recognized "ICH E6 Good Clinical Practice: Consolidated Guidance" (available at http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM073122.pdf ) states, in section 4.1.5, that, "The investigator should maintain a list of appropriately qualified persons to whom the investigator has delegated significant trial-related duties." This guidance also mentions a signature sheet for documenting the signatures and initials of study staff who may sign or initial study documents.

Another FDA guidance document, "Investigator Responsibilities – Protecting the Rights, Safety, and Welfare of Study Subjects" (available at http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM187772.pdf ), discusses a clinical investigator's responsibilities when delegating study tasks. This guidance includes the following statements:

"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."

I hope this information is helpful. Please contact us again at gcp.questions@fda.hhs.gov should you have additional questions.

Patrick J. McNeilly, Ph.D., C.I.P.
Office of Good Clinical Practice
Food and Drug Administration



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**From:** [REDACTED]
**Sent:** Wednesday, March 12, 2014 4:08 PM
**To:** OC GCP Questions

**Subject:** RE: Question on Good Clinical Practice regarding Record retention for DMF

Dear FDA,

I would like to know in what section of the FDA Code of Federal Regulations would I find information regarding Delegation of Responsibility & Site Personnel Signature Log for Clinical trials. Is there any additionals information you can provide to me?

Kindly regards,

[REDACTED]