

**From:** [OC GCP Questions](#)  
**To:** [REDACTED]  
**Subject:** Question Regarding Training Documentation in Clinical Research  
**Date:** Monday, March 02, 2020 2:08:33 PM  
**Attachments:** [REDACTED]

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Good afternoon –

Thank you for your email. Neither FDA's regulations nor guidance provide guidelines on how often GCP training should be completed and by whom and who can perform the training. FDA does not require or provide certification. This would be up to the sponsor and the sponsor would also be involved in the documentation of training, if needed. The regulations require that sponsors choose investigators qualified by training and experience (see 21 CFR 312.53(a)). The regulations also require that investigators commit themselves to personally conduct or supervise the investigation (see 21 CFR 312.53(c)(1)(vi)(c)). FDA's guidance on Investigator Responsibilities - Protecting the Rights, Safety, and Welfare of Study Subjects (available at <https://www.fda.gov/media/77765/download>) states that, "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."

FDA regulations regarding qualifications for those involved with the conduct of clinical studies are very broad. Both Title 21, Code of Federal Regulations (21 CFR) Part 312 (for drugs and biologics) and 812 (for medical devices) simply state that sponsors are required to choose clinical investigators and study staff that are qualified by training and experience. Logically, clinical investigators and study staff need to be knowledgeable about applicable regulations as well as specific areas essential to the conduct of the particular study.

The expectation is that investigators, sub-investigators and study staff will be knowledgeable about good clinical practice, including human subject protection, data integrity, recordkeeping, etc. As noted, the sponsors have discretion in determining what qualifications will be needed to conduct a study and may identify in the protocol a required frequency of GCP training, in which case the investigator and sub-investigators would be expected to meet that frequency of training in order to comply with the sponsors requirements. Every effort should be made to train the investigational sites. This is the sponsor's responsibility.

Additionally what training is needed and how it is documented depends to some degree on the nature of the study. Some protocols need extensive training and others may need minimal, also dependent upon the background and experience of study staff.

Lastly, there is no FDA requirement for CIs (PIs) signatures/Initials to be added to the training log documents if the sponsor does not require it.

Kind regards,

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Office of Clinical Policy and Programs  
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This communication does not constitute a written advisory opinion under 21 CFR 10.85, but rather is

an informal communication under 21 CFR 10.85(k) which represents the best judgment of the employee providing it. This information does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the views expressed.

**From:** [REDACTED]

**Sent:** Friday, February 28, 2020 12:16 PM

**To:** OC GCP Questions <gcpquestions@fda.hhs.gov>

**Subject:** Question Regarding Training Documentation in Clinical Research

Dear Sir or Madam,

I am inquiring as to the FDA standards and/or guidance regarding research staff training documentation in investigational new drug and device trials.

Our research site conducts IND clinical trials on dementia and other neurodegenerative diseases. In general, to document training on study protocols, investigator's brochures, pharmacy manuals, etc., we utilize a training log that specifies who is the PI and where site staff members can print their name, specify study role, sign and date to confirm they have completed training. Recently, a CRA assigned to our site complained that our training log, in her opinion, did not show adequate PI oversight as it lacked a place for the PI to initial and date next to each staff member. However, this training log template has been reviewed by many different Sponsor and CRO monitors assigned to our site and this has never been an issue before.

Could you provide guidance on this matter? Does the FDA have any specific expectations regarding research site training documentation with regards to PI signature or initials?

Thank you for your assistance and clarification with this matter.

Kind regards,

[REDACTED]