

From: [OC GCP Questions](#)
To: [REDACTED]
Subject: Please advise: Protocol training and re-training requirements and documentation
Date: Wednesday, April 08, 2020 3:39:00 PM

Good afternoon –

Thank you for your email. Please see the information below.

Training –

Neither FDA's regulations nor guidance provide guidelines on how often GCP training and/or retraining should be completed and by whom and who can perform the training. Also, 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 - <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. Whether to retrain the study staff would be 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. A "read receipt" for completed training is not against FDA regulations. However, the sponsor and your internal SOPs should address this issue.

Delegation Log –

A site delegation log is not required in FDA's regulations regarding the conduct of clinical trials (Title 21, Code of Federal Regulations - 21 CFR - Part 312 for drugs and biologics and Part 812 for medical

devices). However, it is a recommended document in the ICH E6(R2) guidance document (guidance on good clinical practice – GCP -- <https://www.fda.gov/media/93884/download> , which is official FDA guidance. (While the ICH document specifies it covers drug and biologics studies only, FDA considers areas related to the general conduct of a clinical trial to be applicable to all studies with FDA-regulated products.) However, this ICH document does not provide details as to who should be included. FDA therefore considers it important to document what study task was delegated to whom.

Who should be included on the delegation log - it would be anyone who has an essential role in the conduct of the study. Whether or not the examples you cite, need to be specifically included will depend on the specifics of the study. Those assigned to the study should therefore be listed. If blood draws are essential to either the timing, dosage, or follow-up of study subjects, the identity of the lab tech, for blood draws, or the medical assistant, for vitals, assigned to the study may also be important to capture. In most cases, this information would not receive major scrutiny if an FDA bioresearch monitoring (BIMO) inspection of the site were to occur.

Kind regards,

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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.

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Sent: Wednesday, April 08, 2020 3:00 PM

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

Subject: Please advise: Protocol training and re-training requirements and documentation

Good afternoon,

What is the FDA guidance around evidence of “adequate training” for staff on the DOA log. In addition, what is the FDA requirement around re-training when a protocol amendment occurs. And finally, is a “read” receipt email acceptable to reflect training was completed.

Thank you,

[REDACTED]

