

From: [OC GCP Questions](#)
To: [REDACTED]
Cc: [Clinicaltrialconduct-COVID19](#)
Subject: GCP training question in the time of COVID
Date: Friday, April 24, 2020 12:13:00 PM
Attachments: [REDACTED]

Good afternoon Leslie –

Thank you for your email. There are many sites and institutions that are conducting virtual training and internet instructions and courses during the COVID-19 pandemic. You may use these resources as needed. The training information for FDA-regulated clinical studies is outlined below and has not changed.

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 – (discussed and link provided above), 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.

Please see FDA guidance - Investigator Responsibilities — Protecting the Rights, Safety, and Welfare of Study Subjects - <https://www.fda.gov/media/77765/download>

Also, I wanted to provide you additional FDA information on COVID-19. See below.

[Coronavirus Disease 2019 \(COVID-19\) | FDA](#) You can subscribe to email updates at the top left of the page. When the FDA COVID-19 Guidance is updated with additional Q/As, if you subscribe, you will be notified by email.

FDA COVID-19 Guidance - <https://www.fda.gov/media/136238/download> Virtually clinical study alternatives are mentioned through this document. The same may be applied to training.

Coronavirus Disease 2019 (COVID-19) Resources for Patients
<https://www.fda.gov/patients/coronavirus-disease-2019-covid-19-resources-patients>

I hope this information is helpful.

Kind regards,

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From: [REDACTED]
Sent: Thursday, April 23, 2020 5:04 PM
To: OC GCP Questions <gcpquestions@fda.hhs.gov>
Subject: GCP training question in the time of COVID

Good afternoon,

How can I obtain a concise training on good clinical practice as a PI on a study sponsored by another institution (ie I am at a local hospital and the study is sponsored by the Mayo Clinic). Are there any changes in this policy related to COVID 19 therapies/studies?

Thank you,

