

From: [OC GCP Questions](#)
To: [REDACTED]
Subject: CITI HSP Certification
Date: Friday, September 18, 2020 10:46:00 AM
Attachments: [REDACTED]

Good morning –

Thank you for your inquiry. 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. However, the sponsor and your internal SOPs should address this issue.

We cannot comment on CITI training. You will have to contact CITI directly.

Kind regards,

Doreen M. Kezer, MSN
Senior Health Policy Analyst
Office of Clinical Policy and Programs
Office of Good Clinical Practice (OGCP)
U.S. Food and Drug Administration



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: Thursday, September 17, 2020 3:54 PM
To: OC GCP Questions <gcpquestions@fda.hhs.gov>
Cc: [REDACTED]
Subject: CITI HSP Certification

Good afternoon,

My name is [REDACTED] and I am the project manager for [REDACTED]
[REDACTED]

Typically, CITI GCP and HSP certification expires every three years; however, one of the sites selected to participate in the [REDACTED] trial has CITI HSP certifications that state the certification does not expire.

Can you please confirm if a CITI HSP certification without an expiration date is valid?

Thank you in advance for your assistance!



