

From: [OC GCP Questions](#)
To: [REDACTED]
Subject: NIH HSP Training
Date: Wednesday, November 25, 2015 9:08:00 AM

Good morning –

While I am not entirely familiar with the content of the NIH GCP training, I would assume that it may be considered adequate. I can offer you the following additional information on GCP training.

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.

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 www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM187772.pdf) 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." Please remember while the clinical investigator can delegate tasks, he/she is ultimately the one responsible for overseeing the study and protecting the subjects from harm.

The expectation is that investigators and sub-investigators and study staff will be knowledgeable about good clinical practice, including human subject protection, data integrity, recordkeeping, etc. Note that 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 and well as documentation of training, in which case the investigator and sub-investigators and study staff would be expected to meet that frequency of training in order to comply with the sponsors requirements.

Documentation that demonstrates what training any member of the study staff has participated in is useful to maintain as part of the relevant study files.

You may wish to consult the sponsor of your study to see if they agree that NIH HSP training of staff is acceptable.

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

Kind regards,

Doreen M. Kezer, MSN
Senior Health Policy Analyst
Office of Good Clinical Practice
Office of the Commissioner, FDA

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: Tuesday, November 24, 2015 2:07 PM
To: OC GCP Questions
Subject: NIH HSP Training

Hello,

Is the NIH Human Subjects Protection training considered adequate "GCP" training? This office issues a training certificate.

Thank you and kind regards,

