From: OC GCP Questions
To: [redacted]
Subject: FW:
Date: Wednesday, July 16, 2014 11:10:39 AM

Good morning --

I am unclear as to what you mean by certificate or license. I can provide the following information regarding good clinical practice training and qualifications to conduct clinical trials.

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. 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 http://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."

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. 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, 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.

Additionally, FDA does have information about available GCP training on the GCP website, specifically at http://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/EducationalMaterials/ucm112925.htm

Both the Center for Drug Evaluation (CDER) and the Center for Devices and Radiological Health (CDRH) provide online training relevant to clinical trials on their respective websites. These training programs are accessible at CDER Learn http://www.fda.gov/Training/ForHealthProfessionals/default.htm and CDRH (Center for Devices) Learn http:///www.fda.gov/Training/CDRHLearn/default.htm respectively.

Additionally if you are conducting clinical trials with FDA-regulated products, you should contact the appropriate center to see if you need an investigational device exemption (IDE) or investigational new drug (IND) application. Please see the contact information below.

IND/IDE Contacts:
Questions about **medical devices** (other than gcp questions)
DICE@fda.hhs.gov
Manufacturer's assistance: 800-638-2041
Consumer assistance: 888-INFO-FDA
Questions about whether a product is subject to IDE regulations: call 301-796-5640

Questions about **drug products** (other than gcp questions)
301-796-3400
Druginfo@fda.hhs.gov
Questions about whether a product is subject to IND regulations: call 301-796-3400

Questions about **biologics** (other than gcp questions)
301-827-2000
OCOD@fda.hhs.gov (consumer oriented)
Industry.Biologics@fda.gov (manufacturers's assistance)
Questions about whether a product is subject to IND regulations: call 301-827-2000

You may also wish to look through our GCP webpage for additional guidances and regulations, including

IRB oversight of clinical trails.
Clinical Trials and Human Subject Protection

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

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

From: [Redacted]
Sent: Tuesday, July 15, 2014 3:56 PM
To: OC GCP Questions
Subject:

To whom it may concern,

I was told by clinical monitor that the FDA has a new program or guideline that requires new clinical research sites to get a certificate or a license in order to conduct and gather data for research trials? Can you help to find the new guidelines or compliance rule ?

Thank you

[redacted]