From: OC GCP Questions
To: [redacted]
Subject: RE: doubts about GCP
Date: Wednesday, December 03, 2014 11:19:00 AM

Good morning,

Your question is quite broad depending on your involvement in the clinical research enterprise. I am interpreting your question to mean that you may be involved as a clinical investigator and would like information related to that particular role. As noted in FDA guidance, good clinical practice (GCP) is an international ethical and scientific quality standard for designing, conducting, recording, and reporting trials that involve the participation of human subjects. Compliance with this standard provides public assurance that the rights, safety, and wellbeing of trial subjects are protected, consistent with the principles that have their origin in the Declaration of Helsinki, and that the clinical trial data are credible.

There are many resources (in addition to those listed here) available to you concerning clinical trials and the responsibilities of clinical investigators. To get you started, see the regulations in Title 21 Code of Federal Regulations (21 CFR) §§ 312.60 through 312.69, for studies of drugs (including biologics). For devices, see 21 CFR §§ 812.100 through 812.150. An investigator is an individual who actually conducts a clinical investigation, i.e., under whose immediate direction the test article is administered or dispensed to, or used involving, a subject, or, in the event an investigation is conducted by a team of individuals, the investigator is the responsible leader of the team (see 21 CFR §§ 312.3 and 812.3(i)). (For purposes of financial disclosure, see the definition of a clinical investigator in 21 CFR § 54.3(d)).

A sponsor shall select only investigators qualified by training and experience as appropriate experts to investigate the test article (see 21 CFR §§ 312.53 and 812.43(a)). The regulations do not specify however what must be included to be considered qualified. Therefore, sponsors have discretion in determining what qualifications will be needed based on the general recognition that familiarity with human subject protection requirements and practices as well as good clinical practice standards for the conduct of clinical studies, would be essential. Sponsors would also take into consideration any specific education, training and experience pertinent to the particular clinical study and its design and execution.

For FDA regulations (requirements) and preambles (information about the regulation) relating to good clinical practice and clinical trials, see www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/ucm155713.htm. In October 2009, FDA issued a guidance document (recommendations) on “Investigator Responsibilities - Protecting the Rights, Safety, and Welfare of Study Subjects” (see www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM187772.pdf). Another helpful resource is the Guidance for Industry, E6, Good Clinical Practice: Consolidated Guidance. See especially section 4 - “Investigator” of this E6 guidance (www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm073122.pdf).

To help develop a cadre of well-trained investigators, FDA's Critical Path Initiative launched a Clinical Investigator Training Course targeted at medical professionals (experts who sign FDA Form 1572 before participating in an investigation - see 21 CFR 312.53(c)(1)). The 3-day course includes lectures given by

senior FDA experts and guest lecturers from industry and academia, providing FDA's perspectives on new safety concerns, adverse event monitoring, compliance with legal and ethical obligations of clinical research, and acceptable scientific and analytic standards in clinical study design and conduct. Also, the National Institutes of Health has offered training on clinical research in the past. The Department of Health and Human Services, Office for Human Research Protections, Web site (www.hhs.gov/ohrp/) also has references pertaining to human subject protection issues, as well as online training materials.

You might also want to check with teaching hospitals or other institutions that you may be affiliated with and the institutional review boards of those institutions. These institutions may have training suggestions for you, particularly in the area of human subject protection and clinical trial ethics. In addition, there are many professional groups and organizations that offer good clinical practice training programs. These include the Association for Clinical Research Professionals, the Drug Information Association, the Regulatory Affairs Professionals Society, and the Pharmaceutical Education and Research Institute, among others. Please note that FDA does not endorse any particular training or certification program offered by private organizations.

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

Patrick J. McNeilly, Ph.D., C.I.P.
Office of Good Clinical Practice
Food and Drug Administration

From: [REDACTED]
Sent: Monday, December 01, 2014 9:07 AM
To: OC GCP Questions
Subject: doubts about GCP

respected madam / sir.
My name is [REDACTED]. I completed my Physician assistant course 2 months back, i would like to know that what is the purpose of GCP for a PA.?? sir i know its means good clinical practice other than i don't know any other details., shall i know what is that and how it help me for my future ??.
i am living at [REDACTED].