From: OC GCP Questions
To: [redacted]
Subject: QUESTION ABOUT NEW DRUG TRIALS
Date: Thursday, February 23, 2017 7:01:00 AM
Attachments: [redacted]

Good morning –

I am not sure what you mean my “register with FDA”. Below is what we have stated in the past regarding GCP and human subject protections.

GCP training is universally recognized necessity to protect human subjects in clinical trials. As our website states –

Adherence to the principles of good clinical practices (GCPs), including adequate human subject protection (HSP) is universally recognized as a critical requirement to the conduct of research involving human subjects. Many countries have adopted GCP principles as laws and/or regulations. The Food and Drug Administration’s (FDA’s) regulations for the conduct of clinical trials, which have been in effect since the 1970s, address both GCP and HSP.

Please see the link to our website below. It has many useful links to guidance and information sheets.
Clinical Trials and Human Subject Protection

Investigator Responsibilities – Protecting the Rights, Safety, and welfare of Study Subjects
https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM187772.pdf

Please also see the E-6 Guidance for Good Clinical Practice -
http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM073122.pdf

Additionally below is what we have said in the past regarding GCP training –

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 monitors that are qualified by training and experience. Logically, clinical investigators and monitors 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.

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

From: [redacted]
Sent: Wednesday, February 22, 2017 11:02 PM
To: OC GCP Questions
Cc: [redacted]
Subject: QUESTION ABOUT NEW DRUG TRIALS

Dear Office of Good Clinical Practice:

I have a question about something I'm not clear on. If an experiment is being done by a pharmaceutical company on a drug to get FDA approval, and the experiment is being done by a doctor in a doctor's office - and the goal of the study is for the drug to get FDA approval:

1. Does the doctor have to register with the FDA in some manner if the experiment is not federally funded; and

2. Does the doctor have to be registered with the FDA in some fashion in order to be able to do such testing; and

3. Does the FDA have to oversee or supervise or do something in some fashion where they're making sure the tests are being conducted on humans ethically?

[redacted]