From: OC GCP Questions
To: [redacted]
Subject: RE: Device Trials and GCP
Date: Friday, March 23, 2018 1:07:00 PM
Attachments: [redacted]

Dear [redacted],

FDA is unable to provide responses to specific situations outside of an inspection or protocol-specific meeting. I am providing general information about GCP training below.

As you know, 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. As defined in section 1.24 of the ICH GCP E6 Good Clinical Practice: Consolidated Guidance, (which is recognized as official FDA guidance), GCP is a standard for the design, conduct, performance, monitoring, auditing, recording, analyses, and reporting of clinical trials that provides assurance that the data and reported results are credible and accurate, and that the rights, integrity, and confidentiality of trial subjects are protected. You can access this guidance at
www fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm073122.pdf.

FDA's regulations are not explicit as to what comprises adequate training for study staff (e.g., GCP training) or how often training should be completed. Instead, FDA's regulations broadly require that clinical investigators be qualified by education, training, and experience to perform their assigned duties. 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.

FDA has a guidance document on investigator responsibilities that provides an overview of the investigator's responsibilities, to help investigators better meet their responsibilities with respect to protecting human subjects and ensuring the integrity of the data from clinical investigations. This guidance also clarifies for investigators and sponsors FDA's expectations concerning the investigator's responsibility (1) to supervise a clinical study in which some study tasks are delegated to employees or colleagues of the investigator or other third parties and (2) to protect the rights, safety, and welfare of study subjects.

Section III.2. specifies some areas of training for study staff:

The investigator should ensure that there is adequate training for all staff participating in the conduct of the study, including any new staff hired after the study has begun to meet unanticipated workload or to replace staff who have left. The investigator should ensure that staff:

- Are familiar with the purpose of the study and the protocol
- Have an adequate understanding of the specific details of the protocol and attributes of the investigational product needed to perform their assigned tasks
- Are aware of regulatory requirements and acceptable standards for the conduct of clinical trials and the protection of human subjects
- Are competent to perform or have been trained to perform the tasks they are delegated
- Are informed of any pertinent changes during the conduct of the trial and receive additional training as appropriate

If the sponsor provides training for investigators in the conduct of the study, the investigator should ensure that staff receive the sponsor’s training, or any information (e.g., training materials) from that training that is pertinent to the staff's role in the study.
You can access this guidance document at
www fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm187772.pdf.

Some resources for GCP training may be found on FDA’s website at
https://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/EducationalMaterials/ucm112925.htm.
Of course, there are also many GCP training courses provided be various professional organizations that may also be acceptable.

I hope this information is helpful to you. If you need further assistance, please feel free to contact the GCP mailbox at gcp.questions@fda.hhs.gov .

Best regards,

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From: [redacted]
Sent: Thursday, March 22, 2018 11:47 AM
To: OC GCP Questions <gcp.questions@fda.hhs.gov>
Subject: Device Trials and GCP

To whom it may concern,

I am looking for guidance surrounding GCP training and study staff for Sponsor-funded Device Trials. NIH has clear guidance of who is required to have GCP training for federally funded studies (those who conduct, oversee and manage the trial). ISO14155 and the CFR are not so specific, especially when a Sponsor is reviewing these standards and Regs for guidance. When creating SOPs and executing studies against them, we include the collection of essential documents for study staff, which includes evidence of GCP/HSP training and this is becoming a topic of escalation and debate specifically with sites.

Specific questions:

1- Device trials that include operators performing their job with post-market devices and not collecting data – we do not require GCP training. Would you agree?
2- What is the FDA recommendation for retrospective Reader evaluations in which Radiologists are reviewing post-processed images (deidentified) and completing Case Report Forms? Is GCP (i.e. CITI training) required for each of those readers)
3- Are there specific Delegations (on DOA) that we could classify in a way where CITI/GCP training would not be required?
    a. Example A: Providing feedback on a device (knobs/screen/issues). This would be considered data for the purposes of the example.
    b. Example B: [redacted]
    c. Example C: [redacted] nurses documenting vitals on a [redacted] during a 7-day [redacted] period using an investigational device. She is performing her job but it's an investigational device and she's collecting data. (device training and protocol/CRF training would be provided)

Your feedback would be greatly appreciated! I will be available by email or phone (mobile) if you have any questions or additional points of information are required.