From: OC GCP Questions
To: [redacted]
Cc: CDER DRUG INFO
Subject: Question regarding research trials
Date: Monday, June 02, 2014 2:09:15 PM

Good afternoon --

You email was forwarded to my office for a response. Please see our answers below.

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.

-----Original Message-----

From: CDER DRUG INFO

Sent: Monday, June 02, 2014 11:05 AM

To: OC GCP Questions

Subject: FW: Question regarding research trials

Dear OC GCP Questions,

Please assist with the questions in the below email about clinical research. Thanks very much for your help!

Sincerely,

Sonia

Drug Information Specialist

Division of Drug Information

Center for Drug Evaluation and Research

Food and Drug Administration

For up-to-date drug information, follow the FDA's Division of Drug Information on Twitter: http://twitter.com/fda_drug_info

This communication is consistent with 21 CFR 10.85 (k) and constitutes an informal communication that represents our best judgment at this time but does not constitute an advisory opinion, 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: Friday, May 30, 2014 1:21 PM

To: CDER DRUG INFO

Subject: Question regarding research trials

Good morning [redacted],

I am the [redacted]

We are a Rheumatology practice that conducts clinical research Phase II and III studies with Biologics through different sponsors.

As a Research group within our practice; we conduct monthly research meetings and often have questions that are related to Clinical research and do not get the answers from sponsors or the Central IRB.

A few example questions our site has: Why must all original documents be written in black ink?

The regulations only require that study records be adequate and accurate - which is very broad. (See 21 CFR 312.62 and 812.140.) They do not specify what color ink (black or blue) should be used in research. If handwritten, it needs to be in pen, not pencil, however, so that any change is made in a way that is obvious.

A number of years back, an FDA BIMO staff member coined the acronym ALCOA to describe what is expected of data, and the industry readily adopted it. A = attributable, L = Legible, O = original, C = contemporaneous, and A = accurate. While the old norm for source documents was handwritten notes in the subject's file, PDAs, laptops, etc. have rapidly changed that world, so as long as the data accrued has the integrity required, the means of capturing it is not proscribed but flexible.

Would it not be possible to write in blue?

See above.

Is it a conflict of interest to have a physician serve as a sub-Investigator for the same clinical trial study but for 2 completely different sites?

FDA believes that each individual clinical study site is best served by a separate CI - who for drug and biologics studies is the individual who signs the Form FDA 1572 (the 1572).

FDA encourages each of the separate study sites to have their own CI, who signs a 1572, for the conduct of the study at the specific site. Sub-investigators are intended to assist the CI conduct the study at a specific site and not to substitute for the CI at a secondary site. The intention of FDA regulations are for the CI to conduct and/or supervise all aspects of a clinical study for which he/she agrees to conduct, according the investigational plan and applicable regulations, when he/she signs the 1572.

Does a site have to place the coordinators and joint assessors in box 6 of the 1572 since they do have contact with the subjects during the trial?

Please see the guidance link below.

http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM214282.pdf Question 33 states --

33. Should pharmacists or research coordinators be listed in Section #6?

The decision about whether to list a pharmacist or research coordinator on the 1572 is a matter of judgment, dependent upon the contribution that the individual makes to the study. For example, a research pharmacist may prepare test articles and maintain drug accountability for many clinical studies that are ongoing concurrently at an institution. Because the pharmacist would not be making a direct and significant contribution to the data for a particular study, it would not be necessary to list the pharmacist as a subinvestigator in Section #6, but he/she should be listed in the investigator's study records. Generally, a research coordinator has a greater role in performing critical study functions and making direct and significant contributions to the data. For example, a research coordinator often recruits subjects, collects and evaluates study data, and maintains study records. Therefore, the research coordinator should usually be listed in Section #6 of the 1572.

I am looking for a contact person within the FDA to correspond with regarding question we have as a site that conducting clinical trials.

For good clinical practice questions, you may email us at gcp.questions@fda.hh.gov .

If you could direct me to the right department, I would be most grateful.

Kind regards,

[Redacted]