From: Donnelly, Janet
To: [redacted]
Subject: FDA"s Office of Good Clinical Practice
Date: Monday, July 27, 2015 10:02:00 AM

Good Morning [Redacted]-

Thanks for your inquiry last week as it was nice talking to you on the phone. As I mentioned to you, I wanted to share our public email mailbox where we encourage you to send your future GCP questions. Information about our public email mailbox can be found on our web page at http://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/ucm134476.htm, and the mailbox address where you can send your questions is gcp.questions@fda.hhs.gov. As I mentioned on the phone, it is best to send your questions via email as we monitor our mailbox Monday through Friday and find that it is more efficient to respond via email so that we don't keep missing you via telephone.

As follow up to our discussion, I wanted to share a few links I said I would send you. The IND regulations found at 21 CFR 312 have a section on definitions at 312.3 and I've copied just a few definitions here that may be helpful to you (you can access these regulations online at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=312.3):

> PART 312 -- INVESTIGATIONAL NEW DRUG APPLICATION
>
> Subpart A--General Provisions
>
> Sec. 312.3 Definitions and interpretations.
>
> (a) The definitions and interpretations of terms contained in section 201 of the Act apply to those terms when used in this part:
>
> (b) The following definitions of terms also apply to this part:
>
> ***Clinical investigation*** means any experiment in which a drug is administered or dispensed to, or used involving, one or more human subjects. For the purposes of this part, an experiment is any use of a drug except for the use of a marketed drug in the course of medical practice.
>
> ***Contract research organization*** means a person that assumes, as an independent contractor with the sponsor, one or more of the obligations of a sponsor, e.g., design of a protocol, selection or monitoring of investigations, evaluation of reports, and preparation of materials to be submitted to the Food and Drug Administration.
>
> ***Investigator*** means an individual who actually conducts a clinical investigation (*i.e.* , under whose immediate direction the drug is administered or dispensed to a subject). In the event an investigation is conducted by a team of individuals, the investigator is the responsible leader of the team. "Subinvestigator" includes any other individual member of that team.
>
> ***Sponsor*** means a person who takes responsibility for and initiates a clinical investigation. The sponsor may be an individual or pharmaceutical company, governmental agency, academic institution, private organization, or other organization. The sponsor does not actually conduct the investigation unless the sponsor is a sponsor-investigator. A person other than an individual that uses one or more of its own employees to conduct an investigation that it has initiated is a sponsor, not a sponsor-investigator, and the employees are investigators.
>
> ***Sponsor-Investigator*** means an individual who both initiates and conducts an investigation, and under whose immediate direction the investigational drug is administered or dispensed. The term does not include any person other than an individual. The requirements applicable to a sponsor-investigator under this part include both those applicable to an investigator and a sponsor.
>
> ***Subject*** means a human who participates in an investigation, either as a recipient of the investigational new drug or as a control. A subject may be a healthy human or a patient with a disease.

You also inquired about the transfer of regulatory obligations to a CRO. As I mentioned, the regulations for drugs/biologics addresses such transfer in the regulations found at 21 CFR 312.52 (see http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=312.52).

You also had a question about listing a CRO who is acting as an imaging center on the Form FDA 1572. FDA has a guidance document titled, "Information Sheet Guidance for Sponsors, Clinical Investigators, and IRBs

Frequently Asked Questions – Statement of Investigator (Form FDA 1572)" that can be found at http://www.fda.gov/downloads/regulatoryinformation/guidances/ucm214282.pdf. Question #28 in section V (page 12) addresses your question and says:

> ***28. What qualifies as a clinical laboratory facility for Section #4?***
>
> Section #4 is intended to identify clinical laboratories or testing facilities directly contributing to or

supporting the clinical study (for example, diagnostic labs performing blood work, imaging centers, cardiology labs, etc.). This may include analytical labs that provide pharmacokinetic analysis, and laboratories supplying efficacy data for clinical investigations conducted under an IND.

The FDA Form 1572 is a sponsor form, and the sponsor is responsible for obtaining it (refer to 21 CFR 312.53(c)). The 1572 is meant to supply the study sponsor with pertinent information about a site who is conducting a particular study, and it also serves as an agreement by the clinical investigator (CI), once signed, to comply with the investigational plan/protocol and pertinent regulations. For studies being conducted under an IND, the sponsor is required to submit information on investigators participating in a study to their IND (refer to 21 CFR 312.23(a)(6)(iii)(b) and 312.30(c)). Since the information required to be submitted to the IND is the same information collected on the 1572, sponsors usually submit copies of 1572s to FDA to fulfill this requirement because it provides a convenient means of supplying the required information.

If you have questions about how to fill out a 1572 for a particular study you are working on, I suggest you confer with the sponsor of that study.

I hope this information is useful. If you need further information and/or have additional questions, please feel free to contact us at the official GCP mailbox, gcp.questions@fda.hhs.gov. You may also find it useful to access the set of redacted GCP e-mails found at http://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/RepliestoInquiriestoFDAonGoodClinicalPractice/default.htm since we find that many questions and concerns are repeated over time.

Best Regards,

Janet

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