From: OC GCP Questions
To: [redacted]
Subject: RE: Form FDA 1572 questions
Date: Wednesday, December 30, 2015 1:35:00 PM

Dear [redacted] -

Thank you for your question. The FDA Form 1572 is a form the sponsor is responsible for obtaining (refer to 21 CFR 312.53(c)) and is meant to supply the study sponsor with pertinent information about a site who is conducting a particular study. The 1572 also serves as an agreement by the investigator, 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.

The regulations do not specifically address how to complete the Form FDA 1572. When the regulations are silent investigators, institutions, sponsors, and IRBs are free to develop their own procedures and practices as long as applicable regulatory requirements are met.

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. Your specific questions about box #1 and box #3 are addressed in sections II and IV of this guidance.

If after reading the guidance you have any additional questions about the 1572 form for a particular study, I suggest you discuss the expectations with the sponsor you are working with, as they may have suggestions and/or expectations that you need to be aware of.

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

Janet Donnelly, RAC, CIP
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Office of Special Medical Programs, Food and Drug Administration

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From [redacted]
Sent: Wednesday, December 30, 2015 11:25 AM
To: OC GCP Questions
Subject: Form FDA 1572 questions

Dear Reviewer,

I have two questions about addresses for the Form FDA 1572.

For *Field 1: Name and Address of Investigator*, the medical school that I work for is a site for an industry sponsored protocol, the research department of the medical school is not where the PI is located. The medical school's research department has both a mailing (business) address and a physical address, which are 2 separate locations. The PI is affiliated with the medical school, however the PIs practice is at a different location that is not part of the medical school. Which address should be used in this field for the investigator, the Medical School mailing address, the Research Department physical address, or the Investigators practice

address?

My second address question is for *Field 3: Name and Address of any Medical School, Hospital, or Other Research Facility where the Clinical Investigation(s) will be conducted.* I understand that any location that the subject will be seen at for the research will need to go in this field, but would I need to also include the address for the location where *only* the regulatory, data entry, and financial aspects of the sponsored research will take place?

Thank you for your guidance,

[redacted]