From: Beers Block, Patricia
Sent: Tuesday, October 31, 2006 7:19 AM
To: '**[Redacted]**'
Subject: RE: "Outside Laboratory" Documentation
Dear Dr. **[Redacted]**,

I'm glad you find the web site containing redacted e-mail messages useful. We hope these questions/answers will help others who might have similar questions. With regard to your inquiry, I am answering your questions in the order you provided them.

Question 1.) Do researchers have to constantly modify this FDA Form 1572 section to include any lab which contributes data to the study? For instance, our research subjects may often have standard of care lab tests conducted at a doctor's office more local to their own home, for the sake of the subjects' convenience. We would receive the results of those lab tests, and that information would be enter the study data.

Answer: The 1572 has two purposes: 1) to provide the sponsor with information about the clinical site and investigator qualifications that will enable the sponsor to establish and document that the investigator is qualified and the site is an appropriate location at which to conduct the study, and 2) to inform the investigator of his/her obligations and obtain the investigator's commitment to follow pertinent FDA regulations. Investigators should complete the form as accurately as they can, recognizing that while many things may need to be documented in study records, not everything needs to be documented on the 1572.

If there are changes to information contained on the 1572 (e.g., an IRB address change, the addition of new subinvestigators, discontinuing the use of a clinical lab), the investigator should document the changes and inform the sponsor, so that the sponsor can appropriately update the IND. The 1572 itself does not need to be revised and signed by the investigator

Regarding information that should be included about the various labs you intend to use, Block #4 of the 1572 is intended to identify clinical laboratories or testing facilities directly contributing to or supporting the clinical trial (for example, diagnostic labs performing blood work, imaging centers, cardiology labs, etc.). Therefore you should identify labs directly contributing to or supporting the clinical trial should in Block #4 of this form.

Question 2.) Do you know of the FDA regulation which requires this?
Answer: The regulation governing the preparation and completion of the 1572 can be found at 21 CFR 312.53(c). This regulation states that the sponsor must

obtain a completed and signed 1572 before it permits an investigator to begin participation in a clinical study [21 CFR 312.53(c)].

Question 3.) Furthermore, is there a requirement to then also obtain those labs' licenses, CAP (or COLA, JCAHO) accreditations, reference ranges and the like?
Answer: Having this documentation available for FDA inspection can be helpful but it is not required by FDA regulations.

I hope this information is helpful to you.

Sincerely,

Patricia M. Beers Block
Good Clinical Practice Program (HF-34)
Office of the Commissioner/ FDA
Telephone: 301-827-3340

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.

From: [Redacted]
Sent: Friday, October 20, 2006 3:05 PM
To: OC GCP Questions
Subject: "Outside Laboratory" Documentation

Dear Ms. Beers-Block,

First of all, thank you for the excellent new tool allowing the public to view other questions to the GCP program and their responses.

My questions pertain to the requirement for listing "outside labs" on the FDA Form 1572, section 4:

1.) Do researchers have to constantly modify this FDA Form 1572 section to include any lab which contributes data to the study? For instance, our research subjects may often have standard of care lab tests conducted at a doctor's office more local to their own home, for the sake of the subjects' convenience. We would receive the results of those lab tests, and that information would be enter the study data.

2.) Do you know of the FDA regulation which requires this?

3.) Furthermore, is there a requirement to then also obtain those labs' licenses, CAP (or COLA, JCAHO) accreditations, reference ranges and the like?

My practice are regularly required to obtain these items from sponsors for our FDA-governed trials, and to make these modifications to the 1572 to include all labs. I just wanted to get a clear read on why this is required and if there is a particular regulation. I'm wondering if the FDA requires this documentation to allow the use of that lab data.

Thank you.

[Redacted]