From: Hommel, Carolyn - OC on behalf of OC GCP Questions
Sent: Friday, July 14, 2006 2:44 PM
To: '**[Redacted]**'
Subject: RE: 1572 question

Dear Ms. **[Redacted]**:

I apologize for the delay in responding to your question.

Because blood or tissue samples that are collected from subjects *during the study* are going to undergo additional biomarker or other testing at another lab, the lab carrying out this testing should be listed in block #4 of the 1572.

Also, note that 21 CFR 50.25(a)(1) requires that subjects be provided with "...an explanation of the purposes of the research,... a description of the procedures to be followed..." For this reason, the informed consent should provide study subjects with information about the additional testing that will be done on their samples.

I hope this is helpful, and again, apologize for the delay in getting back to you.

Sincerely,

Carolyn Hommel
Consumer Safety Officer
Good Clinical Practice Program
Office of Science and Health Coordination
Office of the Commissioner
U.S. Food and Drug Administration (HF-34)
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Rockville, MD 20857

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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, June 02, 2006 3:51 PM
To: CDER DRUG INFO
Subject: 1572 question

Hello,

I have a question on whether or not a lab needs to be added to Section 4 of the 1572 that I was hoping to get your assistance with:

- We have a study that is using a central lab, **[Redacted]**. This lab will be listed on the 1572s, but my question is there is a lab that is just looking at biomarkers that may or may not be relevant to the disease. The results of these tests will not change the way the investigators are treating the patients for this study and the results will only be sent to the sponsor for analyzing. The sites will send the blood for the biomarker testing to the central lab. **[Redacted]** will then send the blood to the other lab for the biomarker testing. My question is does this other lab need to be listed on the 1572 since the sites will not be using it directly?

Thanks so much for your assistance with this inquiry!

[Redacted]