MessageFrom: Beers Block, Patricia on behalf of OC GCP Questions
Sent: Tuesday, November 29, 2005 9:34 AM
To: [purged]
Subject: RE: Q on the 1572

Dear Mr. [purged],

The answers to the 2 questions you present in your e-mail message dated October 24 (below) are as follows (using your numbering):

1) Block #4 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.) so that FDA knows where tests are being conducted and can, if needed, conduct inspections of these facilities. We are frequently asked whether all satellite labs that perform additional testing that are used by a central laboratory need to be identified in Block #4 . It is only necessary to list the central laboratory, provided that the central laboratory can trace the samples to the satellite labs where the tests were performed. There is no "rule of thumb" with regard to the number of tests performed by laboratories and identifying laboratories in block #4. If a laboratory conducts any tests, it should be listed in block #4 (except as described above re: satellite labs).

2) 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. If a new investigator is added to a study, a 1572 must be completed and signed by the investigator. This document must be provided to the sponsor.

I hope this information is helpful to you.

Sincerely,

Patricia M. Beers Block
Good Clinical Practice Program
Office of the Commissioner/ FDA
301-827-3340

-----Original Message-----
From: [purged]
Sent: Monday, October 24, 2005 3:49 PM
To: gcpquestions@oc.fda.gov
Subject: Q on the 1572

I have two brief questions regarding the 1572 on which I would appreciate whatever input you can offer. Thanks,
Mark
Q. Block #4 of the FDA Form 1572-Statement of Investigator requires the clinical trial site to list the "Name and address of any clinical laboratory facilities to be used in the study." What is the FDA's view of whether all laboratory facilities, even those that are infrequently used or even subcontractors to the principal laboratory facilities, must be listed on the 1572? What is a reasonable cutoff, if there is one? One industry rule of thumb is that if a lab performs less than 1% of all lab tests performed during the study, then it will not list the laboratory facility. However, even for a laboratory that does not conduct many tests, the rule of thumb says that it should be listed if it provides specialized tests whose results are used to change the course of a study subject or his/her treatment. Also, some have written that it is uncertain whether labs that do NOT provide results directly to the clinical investigator (such as plasma/bioanalytical labs that test for the presence of study drug or metabolite). Would appreciate your comments.
Q. In the FDA's view, when must a site revise a 1572 for changes in study personnel? Although FDA regs are largely silent on this issue, it is clear that a 1572 is a requirement for a new investigator (including a change in the principal investigator or the addition of a new investigator) to participate in an ongoing study. But, in the FDA's view, what other types of changes in study site personnel or other study-related entities identified in previously submitted 1572s require a revised 1572 to be submitted to the sponsor? For example, the addition of a new subinvestigator? The addition of a local lab or health care facility to which study participants make visits? A change in the IRB or IRB's name?