From: Beers Block, Patricia on behalf of OC GCP Questions
Sent: Tuesday, August 30, 2005 2:17 PM
To: [purged]
Subject: RE: question regarding submission of 1572

Dear Dr. [purged],

In your message below, you mention a "change in the clinical research associate". I'm not completely certain what this change involves and therefore not certain about the exact situation to which you allude in your message below. For that reason I am providing you information on two scenarios: one where a new investigator will lead the conduct of the study; the second where a subinvestigator is now working with the (lead) investigator. If this person is a new investigator responsible for the conduct of the study (also colloquially known as the "principal" or "lead" clinical investigator), the new investigator would need to prepare and sign a Form FDA-1572. If this clinical research associate is a subinvestigator (who would normally be included in block #6 of the 1572), the existing 1572 would not need to be replaced by a new one. The sponsor could provide this information to FDA in an amendment; and the study records would need to reflect the responsibilities of this new subinvestigator.
I hope this information is helpful to you.

Sincerely,

Patricia M. Beers Block
Special Assistant to the Director
Good Clinical Practice Programs
OSHC/Office of the Commissioner
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.

-----Original Message-----
From: [purged]
Sent: Monday, August 22, 2005 5:38 PM
To: gcpquestions@oc.fda.gov
Subject: question regarding submission of 1572

Hi,
The question is, if the gene therapy study is closed to accrual, no patients are being treated, and only long follow up of the patients is being conducted, do I need to submit a 1572 updating the FDA in change of the clinical research associate (involve in contacting the institutional regulatory committees, drafting the annual report)? The PI is overseeing the study activities and signs off all paperwork.
Thank you for your help and reply.

[purged]

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