From: Lee, Bonnie on behalf of OC GCP Questions
Sent: Tuesday, March 22, 2005 7:37 PM
To: [Redacted]
Subject: RE: Expedited review question
[Redacted], In your original email, you said that this study did not involve an investigational drug. Can you tell me whether it is an FDA-regulated study? I would think that although there was an initial mistake made, that because you found that mistake and corrected it, we would not punish the data. I would, however, document what was done (from the mistake through to the correction of reviewing the study at a convened meeting) and provide that documentation upfront. Mistakes do happen and if responsible corrective action is taken and documented, then it should be okay.

Bonnie
Bonnie M. Lee
Associate Director for Human Subject Protection Policy
Good Clinical Practice Program, FDA
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: [Redacted]
Sent: Tuesday, March 22, 2005 5:06 PM
To: OC GCP Questions
Subject: RE: Expedited review question
Importance: High
Bonnie,

Thank you so much for your prompt response. We have another question related to this specific study.

Inadvertently, the study was initially reviewed by expedited review. This was discovered during an internal audit and it was our opinion that the study did not meet the criteria. Therefore, although the study was near completion, it was reviewed at a convened full-board meeting. The sponsor is concerned that the FDA will not accept data due to the initial expedited review performed by the IRB.

What is your opinion?

Regards,
[Redacted]
_____
-----Original Message-----
From: Lee, Bonnie [mailto:BLee@OC.FDA.GOV]On Behalf Of OC GCP Questions
Sent: Tuesday, March 22, 2005 3:45 PM
To: [Redacted]
Subject: RE: Expedited review question
Dear [Redacted],

The expedited review list states both the amount of blood as well as the frequency with which it can be drawn to be eligible for expedited review. Specifically, category 2 of the list describes the criteria for "Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:

(a) From healthy, nonpregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week; or

(b) from other adults and children, ...For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week." [Emphasis added. 63 FR 60353 at 60355, November 9, 1998.]

To be eligible for expedited review blood sample cannot be collected by catheter and cannot be collected more frequently than 2 times per week. Clearly the proposed collection of nineteen blood samples over a 32-hour time period exceeds that frequency and would make the study ineligible for expedited review. I should note that without knowledge of the proposed subject population, it is possible that other aspects of this proposed study could also make the study ineligible for expedited review, e.g., the size and condition of the subjects (see (a) and (b) above); if the samples were to be collected by catheter as your email suggests (see (2) above); and whether the study involves minimal risks (to be eligible for expedited review the study must involve minimal risk and involve a category of research on the expedited review list). Finally, it is up to the IRB to determine whether a study is eligible for expedited review--even if the IRB determines that a study is eligible, the IRB may choose to review it at a convened meeting.

I hope that this information is helpful to you. If you need clarification, please don't hesitate to contact me.

Sincerely,

Bonnie
Bonnie M. Lee
Associate Director for Human Subject Protection Policy
Good Clinical Practice Program, FDA
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-----Original Message-----
From: [Redacted]
Sent: Tuesday, March 22, 2005 4:02 PM
To: FDA
Subject: Expedited review question
Importance: High
Due to a conflict of opinions between [Redacted] and a pharmaceutical company, we pose the following question.

Can a Phase I study not involving an investigational drug but including the collection of nineteen 10ml blood samples over a 32-hour time period be reviewed utilizing the expedited review procedure? Blood samples will be collected by venipuncture or catheter.

Your prompt response is greatly appreciated.

Regards,
[Redacted]