From: OC GCP Questions

Sent: Friday, February 27, 2015 1:21 PM

To: [redacted]

Subject:RE: Ref : Question on Interpretation of GCP

Good afternoon:

In regards to your questions concerning the guidance on Transferring Clinical Investigation Oversight to Another IRB, I am providing the following responses:

(a) Can the second IRB review the research protocol and processes , for a second time , even though it was cleared by the first IRB .

Because the regulations do not address transfer of IRB oversight, it is left to the receiving IRB to decide whether to conduct a review of the clinical investigation prior to the next continuing review date established by the original IRB. In practice, most IRBs often choose to perform some type of review before accepting responsibility for a study.

(b) If the second IRB has a conflict of views on the decisions and approval of the first IRB, will it vitiate further research .

IRBs have the authority under 21 CFR Part 56.113 to suspend or terminate approval of research in circumstances where the clinical investigation is not being conducted in accordance with the receiving IRB's requirements or has been associated with unexpected serious harm to subjects. The receiving or second IRB must promptly report any suspension or termination of IRB approval, including the reasons

for the action, to the clinical investigator, appropriate institutional officials, and FDA.

(c) Is there any appeal provision to FDA in such kind of situation .

Again, the IRB has the authority to suspend or terminate approval of the study received. As far as I am aware, there is no appeal provision to FDA that is available regarding this type of matter.

I hope that this information is helpful. Please contact us at gcp.questions@fda.hhs.gov if you have further questions. Since many questions and concerns regarding good clinical practices have been addressed over time, some individuals may find it useful to access a set of redacted GCP inquiries found at the following web address: http://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/RepliestoInquiriestoFDAonGoodClinicalPractice/default.htm .

Sincerely,

Bridget A. Foltz, MS, MT(ASCP)
Policy Analyst, Office of Good Clinical Practice
Office of the Commissioner, Food and Drug Administration

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.

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From: [redacted]

Sent: Thursday, February 19, 2015 1:58 AM

To: OC GCP Questions

Subject: Ref : Question on Interpretation of GCP

Madam/ Sir,

Ref : Guidance for IRBs, Clinical Investigators, and Sponsors Considerations When Transferring Clinical Investigation Oversight to Another IRB,

Let me introduce myself as a research scholar on legal and ethical issues in HIV Vaccine Clinical Trials in India .As a part of my research I have gone through various Federal Regulations and FDA Guidance documents .

It is very interesting that your esteemed office has issued a non binding recommendation on Transferring Clinical Research oversight from one IRB to another IRB , which is not very common in other countries .

However on going through the documents, one doubt arose in my mind which may require clarification .

(a) Can the second IRB review the research protocol and processes , for a second time , even though it was cleared by the first IRB .

(b) If the second IRB has a conflict of views on the decisions and approval of the first IRB, will it vitiate further research .

(c) Is there any appeal provision to FDA in such kind of situation .

It will be great , if you could be very kind enough to respond and clarify my doubts .

with regards

[redacted]