From: Toth-Allen, Jean
Sent: Friday, March 03, 2006 1:20 PM
To: [Redacted]
Subject: RE: FDA question

Dear [Redacted]:

Thank you for your follow-up question.

There is no FDA regulation requiring registration of Contract Research Organizations (CROs) or other 3rd parties who are contracted to conduct some or all of the sponsor and/or investigator responsibilities in a clinical trial. However, such parties who assume responsibilities for pharmaceutical clinical studies are held responsible for complying with applicable regulations (312.52). There are also multiple references to CROs throughout the regulation that spells out bioavailability and bioequivalence study requirements (part 320).

While I am not sure exactly what you are referring to with regard to the data submitted to FDA, there are no independent/specific regulatory requirements if the data is generated and/or maintained by 3rd parties. No matter who oversaw the conduct of the study and/or maintains the study information, all study records must be available during any FDA inspection that may be conducted and all study data must be available for audit.

Hope this information is useful.

If you need further information and/or have additional questions, please submit them once again to the official GCP mailbox, gcpquestions@oc.fda.gov, in lieu of responding to my personal e-mail address.

Sincerely yours,
Jean Toth-Allen, Ph.D.
Good Clinical Practices Program
OSHC, Office of the Commissioner, US 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.

From: [Redacted]
Sent: Thursday, March 02, 2006 5:43 PM
To: OC GCP Questions
Subject: RE: FDA question

Dear Bonnie,

Thank you so much for providing me with this information. I found it really helpful. I also have the question about the Clinical Research Organization;

- Is FDA registration required for Clinical Research Organizations performing Bioquivalance/Bioavability Studies and Clinical Trials?
- Data which is submitted to the FDA?

Thank you.

[Redacted]

OC GCP Questions <GCPQuestions@OC.FDA.GOV> wrote:

> Dear [Redacted],
>
> Currently, FDA does not require the registration of any Institutional Review Boards (IRBs), neither foreign or domestic. FDA did propose a regulation that would in the future require IRB registration, but that has not yet been finalized. If IRBs outside the United States were to be included, I believe it would likely be on a voluntary basis. I hope this information is helpful to you.
>
> Sincerely,
>
> Bonnie
>
> Bonnie M. Lee
> Associate Director for Human Subject Protection Policy
> Good Clinical Practice Program, FDA
> Note new email address: Bonnie.Lee@FDA.HHS.GOV
> 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, February 28, 2006 2:51 PM
> To: OC Webmail
> Subject: FDA question
>
> Name: [Redacted]
>
> E-Mail: [Redacted]
>
> URL:

Comments: Does Clinical Research Organizations and Institutional Review Board ,located in Europe have to be registered with the USFDA. If they do what forms are needed for the registration?