From: Beers Block, Patricia on behalf of OC GCP Questions
Sent: Wednesday, February 19, 2003 8:00 AM
To: [Redacted]
Subject: RE: FDA Comments

Dear Dr. [Redacted],

I'm replying to your latest question re: the need for informed consent for observational research studies. FDA defines clinical investigations (21 CFR 312.3(b)) as any experiment in which a drug is administered or dispensed to or used involving one or more human subjects. Unless these observational studies are done in conjunction with the administration of an investigational drug product, the kind of research you are describing would not fall under FDA's jurisdiction. (If these observations are made concurrent with investigational drug use, then our answer would differ; please let me know if that is the case and I would be happy to provide a response that represents FDA's position on the products we regulate.)

This kind of research falls under the "Common Rule" and is subject to further regulation. I believe you should consult with the Department of Health and Human Services (DHHS) Office for Human Research Protections (OHRP) as they will be able to give the most current guidance as to how to prepare standard operating procedures on this matter for use by your IRB. You can contact OHRP either via their email (ohrp@osophs.dhhs.gov) or by calling their main phone number 301-496-7005. You can learn more about OHRP through the following web link: http://ohrp.osophs.dhhs.gov/

I hope this information is helpful. Please contact us again should you need any further assistance.

Sincerely,

Pat Beers Block
Special Assistant to the Director
Good Clinical Practice Program

-----Original Message-----
From: [Redacted]
Sent: Thursday, February 13, 2003 9:18 AM
To: OC GCP Questions
Subject: Re: FDA Comments

on 12/02/2003 8:33 AM, OC GCP Questions at GCPQuestions@OC.FDA.GOV wrote:

> Dear Dr. [Redacted],
>
> You can find a number of references and guidances that address how IRBs can
> effectively review and monitor investigational studies conducted in human
> subjects by going to our Good Clinical Practice web site
> (http://www.fda.gov/oc/gcp/). I would suggest you start your exploration by
> looking over the FDA Information Sheets that can be found under the heading
> "Guidances and Information Sheets" on our home page. The direct url for the
> Information Sheets is: (http://www.fda.gov/oc/ohrt/irbs/default.htm). There
> is a "frequently asked questions" section in these sheets that is very
> informative and may be a good place to start as you review these sheets.
> Other sections that may be of interest to you are entitled

> "Sponsor-Investigator-IRB Relationships", "Continuing Review after Approval"
> and "Informed Consent; A guide to". These information sheets reflect the
> agency's current guidance on protecting human research subjects.
>
> I hope this helps. Please let me know if we can be of any further service.
>
> Sincerely,
>
> Pat Beers Block
> Good Clinical Practice Program
>
>
> -----Original Message-----
> From: CDER DRUGINFO
> Sent: Monday, February 10, 2003 11:32 AM
> To: OC GCP Questions
> Subject: FW: FDA Comments
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>
> -----Original Message-----
> From: [Redacted]
> Sent: Saturday, February 08, 2003 7:25 PM
> To: druginfo@cder.fda.gov
> Subject: FDA Comments
>
>
>
>
> Name: [Redacted]
>
> E-Mail: [Redacted]
>
> Comments: After several hours of searching the FDA site(s) and not finding
> much, I must ask for help. I am a member of [Redacted], which
> reviews many FDA approved trials. We are looking for information on
> guidelines/regulations/practices for reviewing observational studies in
> human beings.
> Thank you very much for your help.
>
> [Redacted]

Dear Ms. Beers -

Thank you very much for your response and for your offer of continuing help.

Although I had already searched the references you have provided me, I did so again and unfortunately did not find what we are looking for. Specifically, we were asked to review an epidemiological "observational" study, that is, one where no real medical/clinical intervention on human subjects will take place but the researchers wanted to have the subjects sign an informed consent form to gather observational data. Our IRB does not have a specific procedure for such studies and would like to develop one. The IRB has developed procedures that fulfill most FDA requirements for IRBs and thus it is very important for us to know what the FDA position on observational studies is.

Thank you very very much for your help.
[Redacted]