From: Lee, Bonnie on behalf of OC GCP Questions
Sent: Friday, October 08, 2004 2:58 PM
To: [Redacted]
Subject: RE: FW: DrugInfo Comment Form FDA/CDER Site

Dear [Redacted],

If the basic qualifications of the investigator are the same as those approved by the IRB and if the location is the same (potential subject population; availability to treat adverse events should they occur; etc.), then it is possible that you could consider this additional investigator to be a minor change in previously approved research during the period for which approval is authorized by the IRB--in this case the study would be eligible for review through an expedited review process. If the circumstances surrounding the new investigator were significantly different (e.g., a different specialty, subject population, facilities, etc.), then full committee review would be needed.

I hope this helps.

Bonnie

Bonnie M. Lee
Associate Director for Human Subject Protection Policy
Good Clinical Practice Program, FDA

-----Original Message-----
From: [Redacted]
Sent: Thursday, October 07, 2004 10:56 AM
To: OC GCP Questions
Subject: Re: FW: DrugInfo Comment Form FDA/CDER Site

Thanks Bonnie,

The study is not FDA registered, and is being done in [Redacted], but they wanted to get it right as per the GCP guidelines.

The info you sent me does help confirm what I had tentatively said to them. There is one more thing though, everytime they add on an Investigator, do they have to go through a protocol amendment, cause they add the new name onto the title sheet or can they just notify the IRB with the updated title sheet and cover letter, under the same protocol amendment?

Thanks once again for helping with this,

[Redacted]

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

> Dear [Redacted],
>
> Your e-mail was forwarded to our office for a
> response. If the study you

> describe is FDA-regulated, the sponsor may set up
> their own IRB. The
> sponsor should be very careful, however, to avoid
> any conflict of interest
> in the establishment of the IRB. The study is not
> exempt from the
> requirements for informed consent; the only
> exceptions to obtaining informed
> consent are for life-threatening situations. There
> is no problem with the
> protocol listing the names of multiple
> sub-investigators. Finally, the IRB
> does need to review and approve additional
> investigators or sites joining
> the study after the IRB's initial review and
> approval. This is a way of
> providing additional protection to the subjects
> because the review by the
> IRB will, among other things, help to ensure that
> the new investigators are
> qualified, that new sites can handle the study and
> are prepared to deal with
> adverse events, and if the subject population is
> different at the new site,
> the IRB can consider additional safeguards needed to
> protect those subjects.
> For more information, see our information sheets,
> available online at
> http://www.fda.gov/oc/ohrt/irbs/default.htm. A
> Guide to Informed Consent
> and Non-Local IRB Review are two that address these
> issues. I hope this
> helps.
>
> Sincerely,
>
> 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.
>
>
>

> Bonnie
>
> Bonnie M. Lee
> Associate Director for Human Subject Protection
> Policy
> Good Clinical Practice Program, FDA
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> -----Original Message-----
> From: CDER DRUGINFO
> Sent: Monday, October 04, 2004 5:12 PM
> To: OC GCP Questions
> Subject: FW: DrugInfo Comment Form FDA/CDER Site
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> -----Original Message-----
> From: [Redacted]
> Sent: Thursday, September 30, 2004 2:53 PM
> To: druginfo@cder.fda.gov
> Subject: DrugInfo Comment Form FDA/CDER Site
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>
>
> Name: [Redacted]
>
> E-Mail: [Redacted]
>
> Comments: Hi,
>
> My questions are for retrospective oncology studies
> done mostly with [Redacted] and some blood collection where subjects are
> being followed for 5
> years in [Redacted].
>
> 1. Can the research company (sponsor) set up their
> own IRB?
> 2. Will a study like this be qualifed as an exempt
> study i.e. not requiring
> signed consent form, where the [Redacted] are available,
> but contacting the
> subject is impossible? What studies are considered
> exempt?
> 3. Can protocols list the names of multiple sub
> investigators?
> 4. Does the IRB need to only be notified of
> additional inv./sites joining
> the study or will the change to the cover sheet of
> the protocol (with the
> name of the new site/inv.) be considered to be an
> amendment (there are no
> changes to the body of the protocol.
>
> Thanks,
>

> [Redacted]
>