MessageFrom: Beers Block, Patricia
Sent: Friday, April 28, 2006 10:40 AM
To: [purged]
Subject: RE: Questions

Dear [purged],

I suggest you look through the ICH E6 Good Clinical Practice Consolidated Guidance (http://www.fda.gov/cder/guidance/959fnl.pdf) and, depending on whether you are reviewing drug or device studies, 21 CFR 312 and 21 CFR 812 (http://www.fda.gov/oc/gcp/regulations.html) respectively.

Sincerely,

Patricia M. Beers Block
Good Clinical Practice Program (HF-34)
Office of the Commissioner/ FDA
Telephone: 301-827-3340
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: [purged]
Sent: Thursday, April 20, 2006 9:44 PM
To: Beers Block, Patricia
Subject: Re: Questions

Thank you Ms. Beers Block. I have yet another question. I am a GCP auditor and have been asked to organize the trial master file for a pivotal trial at my company to be sure everything that is suppose to be there is indeed there for a possible upcoming FDA inspection. Where shall I begin? I understand that all documentation that is at the site should also be at the sponsor including contracts, protocol signature pages, etc. etc., what else should I be sure is there? This is for several countries outside the US who undoubtedly have separate IRB's, as they would be out of the US-central IRB jurisdiction.
Cordially,
[purged]

----- Original Message -----
From: Beers Block, Patricia

To: [purged]
Sent: Tuesday, April 18, 2006 9:14 AM
Subject: RE: Questions

Dear [purged],

There is no regulatory requirement that addresses what needs to be in an approval letter; only that the IRB approves a study and so notifies the clinical investigator.

I hope this is helpful.
Sincerely,
Patricia M. Beers Block
Good Clinical Practice Program (HF-34)
Office of the Commissioner/ FDA
Telephone: 301-827-3340
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-----Original Message-----
From: [purged]
Sent: Monday, March 27, 2006 5:37 PM
To: OC GCP Questions
Subject: RE: Questions

Thank you so much. One more question..Does the IRB have to specifically state in the approval letter for an amendment that the revised informed consent does or does not need to be signed by enrolled subjects at the time of the approval?
Cordially,
[purged]

---------- Original message ----------
From: "OC GCP Questions" <gcp.questions@fda.hhs.gov>

Dear [purged],

Informed consent documents are valid until information changes (or needs to be changed) in the document due to, for instance, the adoption of protocol amendments or the existence of new benefit/risk information about which the subject should be aware. Protocol amendments must receive IRB review and approval before they are implemented, unless an immediate change is necessary to eliminate an apparent hazard to the subjects (21 CFR 56.108(a)(4)). Those subjects who are presently enrolled and actively participating in the study should be informed of the change if it might relate to the subjects' willingness to continue their participation in the study (21 CFR 50.25(b)(5)). FDA does not require reconsenting of subjects that have completed their active participation in the study, or of subjects who are still actively participating when the change will not affect their participation, for example when the change will be implemented only for subsequently enrolled subjects.

I hope this information is helpful to you.

Sincerely,
Patricia M. Beers Block
Good Clinical Practice Program (HF-34)
Office of Science and Health Coordination
Office of the Commissioner
5600 Fishers Lane, Rm. 9C24
Rockville, MD 20857
Telephone: 301-827-3340
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From: [purged]
Sent: Thursday, March 16, 2006 3:12 PM
To: Beers Block, Patricia
Subject: RE: Questions

Hi Ms. Beers-Block!
Thank you so much for your responses. I have another question. How long is a informed consetn valid? This is relative to my first question and your response.
Thank you so much!
[purged]

---------- Original message ----------
From: "Beers Block, Patricia" <patricia.beersblock@fda.hhs.gov>

Dear [purged],

You raise two interesting questions that are not explicitly addressed our regulations or guidances. I'll answer your questions in the order you provided them.

1) If the protocol in a drug trial does not call (state either way)for a subject to be re-entered into a clinical trial can the site just go ahead an re-enter a subject if the subject had to drop out due to an adverse event that had nothing to do with study med, but did preclude him from continuing in the study?

If a decision is made to possibly re-enter a subject into the study, there would need to be a decision made as to whether the consent form previously signed could cover that re-entry and whether there are reasons to seek consent for the subject again (e.g., the risk/benefit ratio has changed, sufficient time has elapsed such that the earlier consent is no longer considered valid, etc.). Also, it would be important for the investigator to evaluate the eligibility status of the subject after this adverse event; namely whether the subject continued to meet all protocol specified inclusion criteria.

2) If a site's policy (academia) is to not allow a physician to be a PI due to being a lecturer, yet places someone else that is an associate professor to be PI for the purposes of getting IRB approval does the FDA have a problem with that or shoukd the site have two PI's or the lecturer be a co-PI.

Under 21 CFR 312.53(a), sponsors are required to select only investigators qualified by training and experience as appropriate experts to investigate the product. Under 21 CFR 312.53(c), the

sponsor must also obtain a signed investigator statement that contains, among other things, a commitment by the investigator that he or she will:

- conduct the study in accordance with the relevant, current protocols and make changes in the protocol after notifying the sponsor;
- comply with all requirements regarding the obligations of clinical investigators and all other pertinent requirements in part 312;
- personally conduct and supervise the investigation;
- inform any potential subjects that the drugs are being used for investigational purposes and ensure that the informed consent and RIB review/approval is obtained;
- report to the sponsor adverse experiences that occur in the course of the investigation;
- read and understands the information in the investigator's brochure;
- ensure that all associates, colleagues, and employees assisting in the conduct of the study are informed about their obligations in meeting these commitments; and
- comply with the requirements in part 56 regarding IRB review/approval, reporting to the IRB all changes in the research activity and all unanticipated problems, and will not make any changes in the research without IRB approval with one exception when its needed to eliminate apparent immediate hazard to subjects.

It is important that these requirements be met; it is not acceptable to use an investigator who has not met these conditions simply to gain IRB approval. Whoever signs the Form FDA-1572 is recognized as the "principal investigator". We do not the recognize the concept of "co-PI".

I hope this information is helpful to you.

Sincerely,
Patricia M. Beers Block
Good Clinical Practice Program (HF-34)
Office of Science and Health Coordination
Office of the Commissioner
5600 Fishers Lane, Rm. 9C24
Rockville, MD 20857
Telephone: 301-827-3340
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-----Original Message-----
From: [purged]
[mailto:integritrials@comcast.net]
Sent: Wednesday, February 22, 2006 7:58 PM
To: Beers Block, Patricia
Subject: Questions

Hi Ms. Beers Block!
I have two questions...
1. If the protocol in a drug trial does not call (state either way)for a subject to be re-entered into a clinical trial can the site just go ahead an re-enter a subject if the subject had to drop out due to an adverse event that had nothing to do with study med, but did preclude him from continuing in the study?
2. If a site's policy (academia) is to not allow a physician to be a PI due to being a lecturer, yet places someone else that is an associate professor to be PI for the purposes of getting IRB approval does the FDA have a problem with that or shoukd the site have two PI's or the lecturer be a co-PI.
Cordially,
[purged]