From: Beers Block, Patricia on behalf of OC GCP Questions
Sent: Tuesday, October 05, 2004 7:47 AM
To: [Redacted]
Subject: RE: [Redacted]'s email address

Dear [Redacted],

In answer to your question about an IRB's responsibility for reviewing research proposals, 21 CFR 56.109(f) states, in part, that an IRB must conduct continuing review of research at intervals appropriate to the degree of risk, but not less than once per year. This means that IRBs can review research more often than once per year but are expected to review all research at least once per year.

Also, the regulations require that an IRB follow written procedures for conducting its initial and continues review of research (21 CFR 56.108(a)). Presumably, these written procedures would require IRB continuing review of research to be conducted in accordance 21 CFR 56.109(f) (i.e., at least annually). By not reviewing research at least annually, the IRB would be operating at odds with its own SOPs and the regulations governing IRBs (Part 56).

There is a special provision in the regulations that addresses clinical investigations conducted under the IND, and IDE regulations about which you need to be aware. Under 21 CFR 56.103, any clinical investigation which must meet the requirement for prior submission (as required in 21 CFR 312 (INDs), 812 (IDEs) and 813) to the Food and Drug Administration shall not be initiated unless that investigation has been reviewed and approved by, and remains subject to continuing review by an IRB meeting the requirements of Part 56. This means that IRBs must review studies under an IND or IDE at least once a year in order for those studies to continue.

You mentioned in your fax that at the most recent IRB meeting, the IRB did not meet "quorum". The regulations address the need to have a majority of IRB members present in order for an IRB to review any proposed research. Specifically, 21 CFR 56.108(c) states, in part, the IRB shall review proposed research at convened meetings at which a majority of the members of the IRB are present. In order for the IRB to approve any research, it shall receive the approval of a majority of those members present at the meeting. Basicially what this regulations states is that if a majority of members are not present at a meeting, the IRB cannot review (and certainly not approve) any research.

I hope this information is helpful to you. Please let me know if there is anything more I can provide to address your questions.

Sincerely,

Patricia M. Beers Block
Special Assistant to the Director
Good Clinical Practice Programs
OSHC/Office of the Commissioner
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: [Redacted]
Sent: Monday, October 04, 2004 3:47 PM
To: Patricia Beers Block (E-mail)
Subject: [Redacted]'s email address

Pat,

Sorry for the delay. I had an appointment this morning.

Here is my email address: [Redacted]

I appreciated your phone message. Anything you can provide in writing would be greatly appreciated.

[Redacted]