From: Beers Block, Patricia on behalf of OC GCP Questions
Sent: Friday, October 08, 2004 3:23 PM
To: [Redacted]
Subject: RE: Confirmation

Dear [Redacted],

Our position is that clinical research studies must be reviewed and approved by the IRB at least annually (more frequently is perfectly acceptable) for them to continue. If they are not approved by the IRB, the study is not to continue.

One other though came to mind. If your institution is covered by an assurance, you may want to check with the Office for Human Research Protection (OHRP) about their position on appropriate intervals during which research must be reviewed by IRBs. Here is contact information for OHRP:

Office for Human Research Protections
1101 Wootton Parkway, Suite 200
Rockville, MD 20852

Toll-Free Telephone within the U.S. (866) 447-4777
Telephone: (301) 496-7005
Fax: (301) 402-0527
e-mail: ohrp@osophs.dhhs.gov

I hope this information is helpful to you.

Sincerely,

Patricia M. Beers Block
Special Assistant to the Director
Good Clinical Practice Programs (HF-34)
Office of Science and Health Coordination
Office of the Commissioner

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: Wednesday, October 06, 2004 2:54 PM
To: Patricia Beers Block (E-mail)
Subject: Confirmation

Pat,

Thank you very much for all the time you spent answering my questions today. I'd like seek clarification in writing regarding expiration of IRB approval.

The FDA guidance document, "IRB Information Sheets" specifies on page 3: "The continuation of research after expiration of IRB approval is a violation of the regulations [21 CFR 56.103(a)]. If the IRB has not reviewed and approved a research study by the study's expiration date, i.e., IRB approval has expired, research activities should stop. No new subjects may be enrolled in the study. However, if the investigator is actively pursuing renewal with the IRB and the IRB believes that an over-riding safety concern or ethical issue is involved, the IRB may permit the study to continue for the brief time required to complete the review process."

Based on our conversation today, I understood that enrollment cannot continue after expiration of IRB approval--even when it is the IRB's fault for the expiration.

Is this correct?

Thanks again for your guidance,
[Redacted]