From: Lee, Bonnie on behalf of OC GCP Questions
Sent: Sunday, February 06, 2005 11:27 AM
To: [Redacted]
Subject: RE: IRB Continuing Review Question

[Redacted], I apologize for the delay in getting back to you. I don't believe that we have a total consensus in the agency on this issue. Some people note that the regulations don't address the issue of expiration and therefore IRB approval cannot expire--they argue for a reasonable grace period. Others note that the regulations do require, at a minimum, annual review of studies and if that doesn't occur then the approval has, in effect, expired. Ideally, to conform to our regulations, one ought to have continuing review of the studies performed prior to the time when it is due. That is, if the study's approval will expire on 12/31, it ought to be reviewed and approved in the month preceding the "expiration" date. If the IRB wants to keep the 12/31 date, it can, as long as it has re-reviewed the study within a month of that date. In your scenarios below, you might want to check with CDRH's IDE Staff (Marsha Melvin), but I'd think in both situations you might need to reconsider what you've done if, upon re-review, the IRB changes the consent form which would then necessitate another consent process. Further, in both, if the screening process involved a procedure that was done solely for research purposes (and not for medical treatment), it is possible that the IRB would require a screening consent form which would also need IRB review before use. Between the two scenarios, the first is less likely to be problemmatic...although the problems always seem to crop up in the details... I know that for the second scenario, OHRP and we would most likely say that you can't enroll subjects in a study for which there is no active IRB approval and begin the research procedures (e.g., use of the device) without IRB approval. I hope I haven't confused the issues further and that this is helpful to you.

Bonnie

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

-----Original Message-----
From: [Redacted]
Sent: Friday, January 21, 2005 6:33 PM
To: Lee, Bonnie
Subject: IRB Continuing Review Question

Hi Bonnie,

According to the IRB Information Sheets, if the IRB has not reviewed and approved a research study by the study's expiration date, research activities should stop & no new subjects may be enrolled. If the investigator is actively seeking reapproval, IRB's allow patients already in the study to continue. The guidance seems clear that if IRB approval expired and the IRB has not convened to conduct continuing review, new subjects should not be screened, enrolled, and given investigational treatments.

However, if IRB approval expired and the IRB has not reapproved the study yet (the investigator is seeking reapproval) :

1) For a device study, can subjects be consented/screened ("enrolled") as long as the investigation procedure is not performed until the study is reapproved?

2) For a device study, can a subject who was consented prior to expiration of IRB approval be screened & have the investigational device procedure during the period when IRB approval expired?

I hope that makes sense. Thanks for your help, [Redacted]