From: Lee, Bonnie on behalf of OC GCP Questions
Sent: Monday, February 28, 2005 11:34 AM
To: [Redacted]
Subject: RE: Question re. inclusion/exclusion criteria

Dear [Redacted],

The IRB regulations are quite specific in stating that the IRB is responsible for following written procedures "...for ensuring that changes in approved research, during the period for which IRB approval has already been given, may not be initiated without IRB review and approval except where necessary to eliminate apparent immediate hazards to the human subjects." (See 21 CFR 108(a)(4)). Therefore, unless the inclusion of the subject into the trial met the condition of eliminating apparent immediate hazards to the subject [see my note], prior IRB review and approval of the protocol change would be needed. (I'd note that the immediate hazards referred to in the regulations have typically been applied to hazards faced by those subjects enrolled in the trial as opposed to hazards to those not in the trial.) Depending upon the nature of the change in the inclusion/exclusion criteria allowed by the sponsor, the change may be able to be reviewed by the IRB through an expedited review process if it is a "...minor change in previously approved research during the period...for which approval is authorized." See 21 CFR 56.110(b)(2).

I hope this information 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: Wednesday, February 23, 2005 6:59 PM
To: gcpquestions@oc.fda.gov
Subject: Question re. inclusion/exclusion criteria

Hello - I need some guidance on waiver of inclusion/exclusion criteria by the sponsor. Does the IRB need to give their approval before a patient can be started on a protocol who does not meet the criteria, but the sponsor has given a waiver and approves of this particular patient being enrolled in the study? Or can the research coordinator go ahead and start the patient on protocol and notify the IRB afterwards?

Thank you,
[Redacted]

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