file:///C:%20Documents%20and%20Settings%20jgr.%20Desktop%20Files%20for%20CDER%20Staff%20Training%20-%20IRB%20Q%20and%20A%20-%20Jerry%20Gray.htm?mode=print

From: Lee, Bonnie on behalf of OC GCP Questions
Sent: Thursday, February 23, 2006 2:20 PM
To: [snipped]
Subject: RE: Question

Dear [snipped],

Under FDA's IRB regulations, each IRB is required to follow written procedures "...(2) for ensuring prompt reporting to the IRB of changes in research activity; and (3) 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. For drug products, under FDA's IND regulations, sponsors are responsible for monitoring the study, ensuring it is conducted in accordance with the protocols contained in the IND, and ensuring that all participating investigators are promptly informed of significant new adverse effects or risks with respect to the drug." (21 CFR 312.56). Other parts of the IND regulations require sponsor notification of involved investigators, IRBs, and FDA if the sponsor determines that its investigational drug presents an unreasonable and significant risk to subjects. See 21 CFR 312.56(d). Under 21 CFR 312.66, it is the investigator who is responsible for promptly reporting "...to the IRB all changes in the research activity and all unanticipated problems involving risk to human subjects or others..." and assuring that he or she will make changes in the research without IRB approval.

Bottom line: Generally, it is the investigator who is required to submit protocol changes to the IRB for its review and approval.

I've assumed you asked the question in relation to drug products. For medical devices, the bottom line would be the same, although the regulatory citations are different (the investigational device regulations are generally in 21 CFR part 812).

I hope this information is helpful to you.

Sincerely,

Bonnie

Bonnie M. Lee
Associate Director for Human Subject Protection Policy
Good Clinical Practice Program, FDA
Their new email address: Bonnie.Lee@FDA.HHS.GOV
This communication does not constitute a surface advisory opinion under 21 CFR 10.85, but rather is an informal communication under 21 CFR 10.85(j) which represents the best judgement 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: [snipped]
Sent: Wednesday, February 15, 2006 1:05 PM
To: OC GCP Questions
Subject: Question

I would like to know if there are specific regulations
or FDA guidances to submit protocol deviations to
the IRB.

[snipped]

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