From: Lee, Bonnie on behalf of OC GCP Questions
Sent: Monday, June 27, 2005 4:07 PM
To:[Redacted]
Subject: RE: Questions
Dear [Redacted], In regard to your first question, the regulations require minutes to be written (note the "written" in 21 CFR 56.115(a)(2)). Therefore, if you tape your minutes, they also need to be written--this facilitates access to the information they contain. The regulations require these records to be retained for at least 3 years after completion of the research (see 21 CFR 56.115(b)). In regard to your second question, the regulations state that you are to follow written procedures for ensuring prompt reporting to the IRB...of any unanticipated problems involving risks to human subjects or others (see 21 CFR 56.108(b)). (21 CFR 56.108(a) is also partially relevant here.) It is up to the IRB to decide what it will consider to be "prompt". 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
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, June 22, 2005 6:29 PM
To: FDA
Subject: Questions
Importance: High
In reviewing the regulations and guidelines I have been unable to locate information regarding the following:

1. If the minutes of a convened board meeting are taped, when can they be discarded/destroyed?
2. Is there a regulation specifying a time frame in which the IRB must take action on adverse event reports? If so, what is the time frame?

Thank you for your attention to these questions.

Regards,

[Redacted]
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