From: Lee, Bonnie on behalf of OC GCP Questions
Sent: Tuesday, November 01, 2005 4:27 PM
To: [Redacted]
Subject: FW:Continuing Review Lapse

Dear [Redacted],

The regulations are very specific in requiring continuing review of research at intervals appropriate to the degree of risk, but not less than once per year. See 21 CFR 56.109(f). Unless the studies were otherwise eligible for expedited review, the review by the chairman would not meet the regulatory requirements. The expedited review criteria can be found on the web at: http://www.fda.gov/oc/ohrt/irbs/expeditedreview.html. The criteria that pertain to continuing review reads as follows:
"(8) Continuing review of research previously approved by the convened IRB as follows:
(a) Where (i) the research is permanently closed to the enrollment of new subjects; (ii) all subjects have completed all research-related interventions; and (iii) the research remains active only for long-term follow-up of subjects; or
(b) Where no subjects have been enrolled and no additional risks have been identified; or
(c) Where the remaining research activities are limited to data analysis.
(9) Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where categories two (2) through eight (8) do not apply but the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified."

Under a strict reading of the regulations, the Chairman could suspend approval of those studies until the IRB could convene to review them. Suspensions are required to be reported to the IRB, appropriate institutional officials, and the FDA. Also, if you have an FWA, the suspension would need to be reported to OHRP as well. If the studies were suspended, no new subjects could be enrolled, and the Chair would need to decide whether, on a case by case basis, it was in the best interest of subjects in the study to continue or whether their participation should cease. None of this is good. You might want to consider convening your committee to review these studies before they expire. If there are problems getting members in the same room, you could probably justify using teleconferencing facilities. If you can't do that, you ought to consider the documentation necessary to explain the lapse of 2 to 3 weeks and why an alternative procedure was not used to either suspend the studies or teleconference to review them. Generally, it's better to review the studies early rather than late. If you use the "birthday" rule--that is, if a study is reviewed 30 days before its scheduled continuing review date, you can keep that review date to prevent a continued shortening of the review period.

I hope this information is helpful to you. Sorry that I can't be more upbeat...

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: CDER DRUGINFO
Sent: Friday, October 28, 2005 12:54 AM
To: OC GCP Questions
Subject: FW: DrugInfo Comment Form FDA/CDER Site

-----Original Message-----
From: [Redacted]
Sent: Thursday, October 27, 2005 11:55 AM
To: druginfo@cder.fda.gov
Subject: DrugInfo Comment Form FDA/CDER Site

Name: [Redacted]

E-Mail: [Redacted]

Comments: I am having difficulty finding the correct site to ask this question. My question is regarding the annual review of cancer protocols for continuation. [Redacted] has a situation whereby a meeting cannot be held with the full IRB until after the annual expiration of 3 or 4 protocols. The full board can meet within two to three weeks of the expiration dates. Can the chairman of the IRB approve continuation of the protocols with a full IRB review to follow?