From: Hommel, Carolyn - OC on behalf of OC GCP Questions
Sent: Tuesday, July 05, 2005 8:12 AM
To: [Redacted]
Subject: RE: Central IRB continuing review

Dear Ms. [Redacted]:

You seem to be asking, if an IRB reviews a study protocol and issues a favorable opinion for several sites (A, B, and C) to begin the study, and another site (D) approaches the IRB 6 months later, would the IRB have to complete a separate continuing review for the site that joined later?

The regulations state (21 CFR 56.109(f)): "An IRB shall conduct continuing review of research covered by these regulations at intervals appropriate to the degree of risk, but not less than once per year..."

If the IRB wants to consolidate all of the continuing reviews for this study (because of the commonality of the protocol), the IRB could do so, provided that the review for all of the sites occurs before the expiration of the anniversary date for any one site, as required by the regulations.

To go back to our original example, say the initial review for sites A through C was done on January 6, 2004, and initial review for site D was completed on June 6, 2004. Continuing review for A through C would have to be completed by January 6, 2005, and for site D, by June 6, 2005. The IRB could consolidate the date of continuing review by performing it for all sites on January 6, 2005. Thus, the review for site D would be done sooner than its "required" review date, June 6, 2005.

Bear in mind, however, that it is important for the IRB to initially review each site's application individually, for example to evaluate a site's qualifications, and to take into account any special issues that may require continuing review more than just once a year. It is also important for the IRB to conduct individual "continuing review" to ensure that issues pertinent to each site are addressed (for example, vulnerable populations, rapid turnover of study staff; more AEs at a particular site).

I hope this is helpful.

Sincerely,

Carolyn Hommel
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-----Original Message-----
From: [Redacted]
Sent: Wednesday, June 22, 2005 12:17 PM
To: gcpquestions@oc.fda.gov
Subject: Central IRB continuing review

Hi,

This question came up in discussion: Can central IRBs set an annual review date for the protocol and all site utilizing this protocol have the same review date? Or, must the central IRB review the ENTIRE protocol each time one of the sites has a renewal date?

Thanks,

[Redacted]