From: OC GCP Questions
To: [redacted]
Subject: RE: IRB oversight for ongoing post-trial assessments of study-related safety events
Date: Monday, October 03, 2016 12:42:00 PM

Dear [redacted] -

Thanks again for your patience in the response to your questions as I had to consult others within FDA.

As you know, the answers to some questions we receive depend greatly upon the circumstances of a specific study. It is often difficult to provide specific responses to general questions, such as in the scenarios you describe, because many details are missing. Follow-up questions regarding specific products or trials should be directed to the appropriate FDA review division by the sponsor.

Neither the FDA regulations nor the guidance specifically address "reinstating IRB oversight". When the regulations are silent, IRBs, institutions, sponsors, investigators are free to develop their own procedures and practices as long as applicable regulatory requirements are met. However, with regard to the duration of IRB oversight, FDA's Guidance for IRBs, Clinical Investigators, and Sponsors - IRB Continuing Review after Clinical Investigation Approval (see http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM294558.pdf) states on page 13:

> Once the data collection from all trial sites is complete and the overall study results database has been locked and the only remaining activity is analysis of the aggregate data by the study sponsor, further continuing review of the research is generally no longer required.

As you know, the IRB is required by 21 CFR 56.108(a)(1) to follow written procedures for conducting initial and continuing review of research and for reporting its findings and actions to the investigator and the institution. The IRB's written procedures should reflect the IRB's process for continuing review of research and may address when IRB oversight is no longer required. Keep in mind that it is also important to communicate with your investigators and any sponsor/CRO you are working with to find out if they have any specific requirements or SOPs dictating when IRB oversight can be closed out/completed.

I am sorry I can't be more helpful. If you need further information and/or have additional questions, please feel free to contact us at the official GCP mailbox, gcp.questions@fda.hhs.gov. You may also find it useful to access the set of redacted GCP e-mails found at http://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/RepliestoInquiriestoFDAonGoodClinicalPractice/default.htm since we find that many questions and concerns are repeated over time.

Best Regards,

Janet

Janet Donnelly, RAC, CIP
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Office of Special Medical Programs, Food and Drug Administration

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From: [redacted]
Sent: Friday, September 09, 2016 7:18 PM
To: OC GCP Questions
Subject: IRB oversight for ongoing post-trial assessments of study-related safety events

Good afternoon,

We are seeking guidance on FDA expectations related to IRB oversight for ongoing post-trial assessments of study-related safety events. In particular, cases where trial databases are locked and studies have previously closed to IRB review.

For which, if any, of the following scenarios would FDA expect that IRB oversight be reinstated?

1. Trial database is locked, investigators are reviewing existing subject data (collected during the study) to verify data for study sponsor during data analysis.
2. Trial database is locked, investigators are reviewing subject medical records generated *after* study closure to continue assessment of safety events unresolved at the time of study closure; results of records reviews are communicated to study sponsor.
    a. For this scenario, please comment upon whether FDA's expectation varies if the investigator also serves as the subject's primary care physician.
3. Trial database is locked, investigators are conducting visits with and performing physical assessments of subjects following study closure to continue assessment of safety events unresolved at the time of study closure; data resulting from visits/assessments is communicated to study sponsor and subjects may receive compensation for their participation in the visits/assessments.
    a. For this scenario, please comment upon whether FDA's expectation varies if the investigator also serves as the subject's primary care physician.

Thank you for your consideration of this matter.