From: OC GCP Questions
To: [redacted]
Subject: IRB Acceptance of Final Sponsor Report
Date: Tuesday, December 15, 2015 8:19:00 AM
Attachments: [redacted]

Dear [redacted]

FDA regulations or guidance do not specifically address this situation. The IRB's SOPs should indicate what documentation/report is to be submitted at what time period, and shared with the investigators in the information sent when approving the study.

Once all study-required follow up is complete for all subjects enrolled at a site, some IRBs consider the study closed and expect a final report from the clinical investigator, which seems to be the case here. Since the study might be on-going at other sites, however, it is possible for the investigator to receive updates that may affect the completed study subjects, and therefore they may need to communicate with the subjects and also forward the information to the IRB. In addition, the study sponsor will likely be contacting the site as they clean-up their database, submitting queries and possibly requiring a review of study documents to ensure data accuracy. As a result, some IRBs prefer to leave the study open until all such procedures are completed, such that the progress report covering the last subject follow-up visits, so what would usually be written as a final study report from the investigator will not actually be the final report for the IDE study received by the IRB from the investigator; rather it will be a notification that this particular site has completed the study, with the caveat that the study is ongoing at other sites.

This IRB has indicated that they will consider the study closed when the final report for this site is submitted, and not accept any further documentation. You have a choice to either keep the study open for that site until the entire study is completed, or to submit a final report for the single study completed at that site, and close the study at that single site. If you choose to close this single site with a final site report when follow-up is completed, you may still send the final study report for the completed IDE study to the IRB. You may want to send it with a return receipt requested, or other method to document that the submission was received, which fulfills your responsibility as a sponsor to provide the report per 812.150(b)(7).

I hope this information is helpful to you. If you need further assistance, please feel free to contact the GCP mailbox at gcp.questions@fda.hhs.gov .

Best regards,

Sheila

Sheila Brown, RN, MS
Policy Analyst, Office of Good Clinical Practice
Office of Special Medical Programs, Food and Drug Administration

From: [redacted]
Sent: Wednesday, December 09, 2015 11:24 AM
To: OC GCP Questions
Subject: IRB Acceptance of Final Sponsor Report

Hello,

I work on multiple FDA regulated significant risk IDE studies

We often have sites that enroll one or two subjects and our study follow-up is typically 5yrs. For sites that were early enrollers, or only had one subject they often have all of their subjects completed early and as the Sponsor we see no reason to keep the site open. For a study I am currently working on, the site completed all follow-up in July 2015; however the study has 3 phases, and while this site didn't participate in the 2nd and 3rd phase, we are still enrolling in those portions. In theory, the study could be ongoing until 2022, and we see no reason to keep submitting annually to the IRB just so they can accept the final Sponsor Report in 7 years or so. The IRB at this site indicated that they will not accept anything for review after they have closed a study except information that would indicate that the patients are at some unknown harm due to their past participation in the research study.

As a Sponsor, what should we do with IRBs that won't accept the final Sponsor report once the study is closed? Is it enough that we provide it to them? The regulation 812.150 b(7) only says we have to provide a final report to all reviewing IRBs.

I look forward to your feedback.

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