From: OC GCP Questions
To: [redacted]
Subject: RE: Close out study
Date: Tuesday, December 26, 2017 11:33:00 AM
Attachments: [redacted]

Dear [redacted],
FDA does not have specific guidance that addresses a study close out visit or data queries. The activities a sponsor, CRO and investigator/site follow for a close out visit and any data query follow-up are usually addressed in Standard Operating Procedures (SOPs) of the sponsor, CRO, and site. That said, it is also important to understand that some IRBs, and any institution where the IRB is located, may have written procedures that specify when the investigator can close out with the IRB, and such written procedures must followed.

We recommend discussing expectations for submitting documents and progress/final reports with the sponsor and IRB, to be sure everyone has the same expectations for reporting. 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 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 study (at all sites) to the IRB. For medical device studies, you may want to send the study final report 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 21 CFR 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

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otherwise obligate or commit the agency to the views expressed.

From: [redacted]
Sent: Tuesday, December 19, 2017 12:03 PM
To: OC GCP Questions <gcp.questions@fda.hhs.gov>; gcp.questions@fda.gov
Subject: Close out study

Our sponsor has several of our sites in a study and have requested they close out the IRB prior to data base lock. Normally we perform the majority of close out activities PRIOR to DBL.They study met enrollment milestones and the last subjects were randomized 28Nov2017. The CRA will be closing sites that have NO ongoing subjects.Our concerns are regarding open queries that the sites would not respond to if they were closed out administratively. So it was possible we could be closed with opened queries? What would happen if it was discovered that a serious deviation was discovered and we could not report it to the IRB since they dont accept anything after we close the study with them. Our QA team is unsure of what we should do. Please provide your opinion.