From: OC GCP Questions
To: [redacted]
Subject: RE: Study Activities post IRB closure
Date: Monday, April 18, 2016 6:09:00 PM

Dear [redacted] -

Thank you for your question. From the limited information provided, it appears that all human subject interactions and interventions for the study are completed and the sponsor/CRO has performed a study close out visit with the site presumably because all subjects have completed all protocol required visits, and no new data is being collected. In other words, the investigator's participation in the study is finished and the sponsor/CRO is in the process of closing out the participating investigator sites and collecting the data.

If I understand your question correctly, the CRO continues to generate electronic data capture (EDC) queries for your site. In other words, the CRO continues to ask you for data clarifications as they work to ensure that they have all queries related to the data generated at your site accounted for. I believe your question asks whether a CRO can query study data (data already collected for the study) once the close out visit has occurred and IRB oversight is finished.

Access to the study data that has been collected by authorized parties is expected for data analysis, so I'm not sure where the concern might be, other than maybe you are questioning the timing of the close out visit and close out with the IRB at the site given that data queries are still being generated?

FDA does not have specific guidance that addresses study close out visits or data query follow-up. 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. Some institutions and IRBs may also have written procedures that specify when the investigator should close out with the IRB, and such written procedures must be followed by the investigator.

You may wish to consult your site SOPs, your IRB, your institution, the sponsor, and the CRO on this study about your concerns to clarify their expectations in accordance with any relevant SOPs. You may also wish to consult any written agreements you have for this study to see whether this issue is addressed at all in that agreement.

I hope this information is useful. 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
Policy Analyst, Office of Good Clinical Practice
Office of Special Medical Programs, Food and Drug Administration

From: [redacted]
Sent: Monday, April 18, 2016 11:21 AM
To: OC GCP Questions
Subject: Study Activities post IRB closure

To whom it may concern:

We recently concluded a study in January 2016. The site was closed by both the sponsor and the IRB . The CRO continues to generate EDC queries but we are concerned because all delegated tasks ended on the date the site was closed. We believe that under FDA guidelines the site cannot continue on trial activities because there is currently no IRB oversight.

Would you kindly, clarify for us?

Thank you.

[redacted]