From: OC GCP Questions
To: [redacted]
Subject: Question End of clinical trial
Date: Wednesday, November 08, 2017 8:09:00 AM
Attachments: [redacted]

Good morning –

You should work with the sponsor of your study and the reviewing IRB if you decided to close your site.

Trial master files should be established at the beginning of the trial, both at the investigator/institution's site and at the sponsor's office. A final close-out of a trial can only be done when the monitor has reviewed both investigator/institution and sponsor files and confirmed that all necessary documents are in the appropriate files.

Any or all of the documents addressed in this guidance may be subject to, and should be available for, audit by the sponsor's auditor and inspection by the regulatory authority(ies).

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. The clinical investigator must ensure that any requirements to maintain IRB oversight per the regulations are met, and additionally, that any pertinent SOPs are followed.

When study enrollment and subject follow-up have been completed at a given site, the clinical investigator will often (usually for FDA-regulated studies) send the required final report to the IRB, thus closing out the study at the site.

If you are still unclear as to what to do you can contact the regulatory project manager of the IND at FDA for further guidance.

I hope this information is helpful.

Kind regards,

Doreen M. Kezer, MSN
Senior Health Policy Analyst
Office of Good Clinical Practice
Office of the Commissioner, FDA

From: [redacted]
Sent: Tuesday, November 07, 2017 7:08 PM
To: OC GCP Questions <gcp.questions@fda.hhs.gov>
Subject: Question End of clinical trial

Hello:

We would like to end one of our monotherapy trial program in US.
Do we have to notify FDA? Or, we just need to submit an abbreviated CSR?
Could you please advise?

Best regards,