From: OC GCP Questions
To: [redacted]
Subject: Inquiry regarding completion of the research and IRB record retention
Date: Wednesday, May 11, 2016 1:32:36 PM

Good afternoon –

Yes it appears the approach you are suggesting would be consistent with 21 CFR 56.115(7(b) which states "The records required by this regulation shall be retained for at least 3 years after completion of the research and the records shall be accessible for inspection and copying by authorized representatives of the Food and Drug Administration at reasonable times and in a reasonable manner."

ICH E-6 states --
http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm073122.pdf states --

3.4 Records
The IRB/IEC should retain all relevant records (e.g., written procedures, membership lists, lists of occupations/affiliations of members, submitted documents, minutes of meetings, and correspondence) for a period of at least 3 years after completion of the trial and make them available upon request from the regulatory authority(ies). The IRB/IEC may be asked by investigators, sponsors, or regulatory authorities to provide copies of its written procedures and membership lists.

You might want to think about placing an addendum in your standard operating procedure that will capture safety information after you have closed the study. The second scenario would seem to make sense as sites enroll subjects at different rates and others may be delayed in enrolling subjects and closing the study.

I hope this information is helpful. Please contact us again at gcp.questions@fda.hhs.gov should you have additional questions.

Kind regards,

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

From: [redacted]
Sent: Wednesday, May 11, 2016 12:44 PM
To: OC GCP Questions
Subject: Inquiry regarding completion of the research and IRB record retention

Good Morning,

Our IRB currently requires notification from the Sponsor that the research is complete at all study sites including study sites that are not under our IRB's review in order for our IRB to consider the study to be closed and to begin the 3 year record retention period. In many cases, the study remains open to

IRB review for many years after the last site under our IRB's review has completed the study. We would like to revise our policy so that the research may be considered complete when all sites under our IRB's review have closed. Therefore, the 3 year record retention period would begin at this point.

Can you comment as to whether the proposed approach would be consistent and in keeping with the current regulations (21 CFR 56.115) regarding IRB recordkeeping.

Kind Regards,

[redacted]