From: OC GCP Questions
To: [redacted]
Subject: Question for Clinical Trial Specimen Retention
Date: Thursday, August 31, 2017 8:52:00 AM
Attachments: [redacted]

Good morning –

I am not aware of any general requirements regarding the retention of patient samples used for diagnostic testing during clinical trials. Usually, for any specific study, the need to retain patient samples and the length of time for retention would be specified in the study protocol. In product specific areas, however, FDA may have determined a need to retain samples. An area where I am aware that FDA has indicated a need to retain patient samples is for xenotransplantation products. More information on the retention of patient samples for xenotransplantation products is available in the following guidances:

"Guidance for Industry: Source Animal, Product, Preclinical, and Clinical Issues Concerning the Use of Xenotransplantation Products in Humans" available at
https://www.fda.gov/OHRMS/DOCKETS/98fr/001662gd.pdf (see section VIII.H)

"PHS Guidelines on Infectious Disease Issues in Xenotransplantation" available at

www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/Xenotransplantation/ucm074727.htm (see section 4.1.2)

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: Tuesday, August 29, 2017 8:57 PM
To: OC GCP Questions
Subject: Question for Clinical Trial Specimen Retention

We are a testing laboratory performing testing for clinical trial specimens only, Phase 1 to Phase III. Is there any requirement for the length of time clinical trial specimens must be maintained?

Thank you