From: OC GCP Questions
Sent: Tuesday, April 22, 2014 2:52 PM
To: [redacted]
Subject: RE: Records Retention

Dear [Redacted],

Thank you for your inquiry. If the study is conducted under an investigational new drug application (IND), the IND regulations pertaining to investigator and sponsor recordkeeping and record retention apply.

The regulations pertaining to investigator recordkeeping and record retention under an IND are found in 21 Code of Federal Regulations (CFR), Part 312, Subpart D, § 312.62. The following is the provision in § 312.62(c):

> Record retention. An investigator shall retain records required to be maintained under this part for a period of 2 years following the date a marketing application is approved for the drug for the indication for which it is being investigated; or, if no application is to be filed or if the application is not approved for such indication, until 2 years after the investigation is discontinued and FDA is notified.

Also, for your reference, you may access this provision through the following link: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=312.62.

The regulations pertaining to sponsor recordkeeping and record retention under an IND are found in 21 CFR § 312.57. The following is the provision in § 312.57(c):

> A sponsor shall retain the records and reports required by this part for 2 years after a marketing application is approved for the drug; or, if an application is not approved for the drug, until 2 years after shipment and delivery of the drug for investigational use is discontinued and FDA has been so notified.

(Link to § 312.57(c): http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=312.57).

For investigational device studies, the relevant provision is 21 CFR § 812.140(d). The following is that provision:

> Retention period. An investigator or sponsor shall maintain the records required by this subpart [21 CFR Part 812, Subpart G – Records and Reports] during the investigation and for a period of 2 years after the latter of the following two dates: The date on which the investigation is terminated or completed, or the date that the records are no longer required for purposes of supporting a premarket approval application or a notice of completion of a product development protocol.

(Link to § 812.140(d): http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm).

I hope this information is helpful to you. If further assistance is needed, please contact us once again at the official GCP mailbox, gcp.questions@fda.hhs.gov.

Best regards,
Kathleen Pfaender, RN, JD
Senior Health Policy Analyst
Office of Good Clinical Practice
Office of Medical Products and Tobacco
Federal Food and Drug Administration
WO32/5129
301-796-8346

From: [Redacted]
Sent: Monday, April 21, 2014 12:43 PM
To: OC GCP Questions
Subject: Records Retention

Hello,

How long should an institution retain study records if it is not specified in the contract? Contract states to follow GCP rules and regulations.

Regards,
[Redacted]