

From: OC GCP Questions
To: [REDACTED]
Subject: Record keeping and record retention
Date: Thursday, May 25, 2017 10:15:00 AM

Good morning -

The regulations for drugs (21 CFR 312.62(c)) state that "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."

The retention period is dependent on whether the data will be used to support a marketing application with FDA. It may take several years after a study is closed at an individual site for the sponsor to submit the data in a marketing application to FDA for approval of their product. The sponsor is usually the only party totally knowledgeable about the status of its investigational product (e.g., whether it has been approved for marketing, or whether the sponsor no longer intends to seek marketing approval, etc.).

You will need to ask the sponsor if they intend to submit the data in a marketing application to FDA. If so you would need to retain the documents as listed above.

I hope this information is helpful.

Kind regards,

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This communication does not constitute a written advisory opinion under 21 CFR 10.85, but rather is an informal communication under 21 CFR 10.85(k) which represents the best judgment of the employee providing it. This information does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the views expressed.

-----Original Message-----

From: [REDACTED]
Sent: Thursday, May 25, 2017 9:11 AM
To: OC GCP Questions
Subject: Record keeping and record retention

Hello,

If a site has screened no subjects but has received and returned IP, does the investigator need to retain the documents. The sponsor has copies of all site documents.

Thank you for your assistance.

[REDACTED]