From:	OC GCP Questions
To:	[redacted]
Subject:	Source Documents for Clinical Trials
Date:	Monday, June 18, 2018 8:39:00 AM
Attachments:	[redacted]
Importance:	High

Good morning –

The regulations pertaining to investigator recordkeeping and record retention under an IND (both electronic and paper) 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.

You may access this provision through the following link: 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): 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.

It is best to check with the study sponsor regarding the status of the investigational product and the need to retain the study records.

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
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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.

From: [redacted]
Sent: Thursday, June 14, 2018 3:35 PM
To: OC GCP Questions <gcpquestions@fda.hhs.gov>
Subject: Source Documents for Clinical Trials
Importance: High

Hello:

I am inquiring about the length of time that source documents have to be maintained by clinical research sites, when they are utilizing an Electronic Medical Records (EMR) that is compliant with 21 CFR Part 11 requirements.

NEXT Oncology ***source documents*** consist of original documents and records ("wet ink" signature or data written with a pen) including, but not limited to:

- Medical records
- Clinical and office charts
- Informed consent forms
- Laboratory notes
- Memoranda
- Subjects' diaries or evaluation checklists
- Pharmacy dispensing records
- Records kept at the pharmacy
- Records kept at the laboratories, and
- Records kept at medical/technical departments involved in a clinical trial

<u>Our current process for filing of original "wet ink" source documents consists of the following:</u>

1. Paper source documents are utilized to consent study subjects and capture study related activities as per clinical trial protocol (i.e., serial vital signs, serial EKGs, pharmacokinetics sample draw times, and etc.)
2. Original "wet ink" paper source documents are scanned in the Electronic Medical Records (EMR) system
3. Original "wet ink" paper source documents are filed in the patient's medical record chart

Can you please verify what the FDA requires for a set period of time before a clinical trial site can destroy the above original documents and records ("wet ink" signature or data written

with a pen)?

Kind Regards,

[redacted]