**From:** OC GCP Questions
**To:** [redacted]
**Subject:** RE: Destruction of Archived Clinical Trial Records
**Date:** Friday, March 17, 2017 10:57:00 AM
**Attachments:** [redacted]

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Dear [redacted],
Your question was forwarded to the Office of Good Clinical Practice.

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.).

FDA's official guidance, ICH E6 "Good Clinical Practice: Consolidated Guidance," contains a similar time period for record retention:

4.9.5 Essential documents should be retained until at least 2 years after the last approval of a marketing application in an ICH region and until there are no pending or contemplated marketing applications in an ICH region or at least 2 years have elapsed since the formal discontinuation of clinical development of the investigational product. These documents should be retained for a longer period, however, if required by the applicable regulatory requirements or by an agreement with the sponsor. It is the responsibility of the sponsor to inform the investigator/institution as to when these documents no longer need to be retained (see section 5.5.12).

Although not required, you may want to consider electronically archiving the study records for those companies that have failed to respond to your certified letters, before destroying the paper copies. FDA believes that study documents captured on paper can be archived as electronic copies, if the electronic copies are "certified copies." FDA defines certified copies in the guidance regarding the use of computerized systems in clinical investigations. This guidance is accessible at www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM070266.pdf and the definition of certified copies it includes reads as follows:

"Certified Copy: A certified copy is a copy of original information that has been verified, as indicated by a dated signature, as an exact copy having all of the same attributes and information as the original."

You may also want to consider sending one more certified letter to those companies, including a statement that you plan to destroy the paper documents as of [date greater than 30 days from letter date], unless they contact you and indicate that the study documents are still needed for submission or review by [date 30 days from letter date].

As a last thought, you may wish to consider consulting the appropriate institutional officials for these studies and your legal counsel on how to handle this situation.

I hope this information is helpful to you. If you need further assistance, please feel free to contact the

GCP mailbox at gcp.questions@fda.hhs.gov .

Best regards,

Sheila

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**From:** [redacted]
**Sent:** Thursday, March 16, 2017 11:21 AM
**To:** CDER DRUG INFO
**Subject:** Destruction of Archived Clinical Trial Records

My company has contacted pharmaceutical sponsors regarding the confidential shredding of archived data for clinical trials conducted at our site over the past 20 years. I have sent certified letters -- in some cases multiple certified letters -- but some sponsors have not responded to our notification that we're closing the archive location and shredding documents that have met state, federal, and contractual requirements.

In cases, in which sponsors/compounds were bought by another company, I have contacted both the original sponsor and the company that purchased the original sponsor.

**Question: When a sponsor ignores certified letters (for which we have a return receipt showing their signature), or when certified letters are returned as undeliverable, or when multiple unsuccessful attempts have been made to contact the sponsor, may we shred records that have met archival requirements?**

Thank you.

[redacted]