From: OC GCP Questions
To: [redacted]
Subject: PI"s Long-term storage of documents question
Date: Friday, March 08, 2019 11:09:37 AM
Attachments: [redacted]

Good morning –

For drug and biologic studies, 21 CFR 312.62(c) states: "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."

A study sponsor can request, often as part of the investigational plan, that sites maintain records for a longer period of time. If retention of study records has become burdensome/costly for your site, the sponsor may offer to assume responsibility for the site's records, if longer retention is necessary to allow them to use the study to support future applications/submissions.

In writing SOPs regarding record retention, as you have indicated you have, it would be best to cite the regulations noted above and include the caution that the site should contact the specific study sponsor prior to any destruction of study records, even if the regulation-required retention period and/or sponsor requested timeframe has expired.

It is best to continue to communicate with the sponsor and your institutional officials to resolve this situation. FDA regulations do not mention the 15-year requirement. It might be best to ask the sponsor to assume responsibility of the study records at their site to lessen your burden.

As you state, the sponsor should give a site permission to destroy the records. I again suggest that you work the sponsor and your institutional officials to resolve this situation.

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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Office of Good Clinical Practice
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From: [redacted]
Sent: Thursday, March 07, 2019 5:28 PM

To: OC GCP Questions <gcpquestions@fda.hhs.gov>
Subject: PI's Long-term storage of documents question

I have a question regarding long-term storage of documents after a trial is completed at our site. I have run into a couple situations where sponsors are asking us to store documents longer than that what I feel is stated in contract. For example, we have a contract that states that our site needs to store documents according to "applicable regulations". I have interpreted this to mean FDA regulations.

In the case of the study in question, the study has met FDA regulation for length of storage – the last study of the investigational drug was more than 2 years ago, there have been no newer studies, nor does the sponsor state that they are going to be doing studies in the future, etc.

However, the sponsor is not agreeing to the destruction of the documents, and is stating that we need to store documents for a minimum of 15 years after study end (which would mean an additional 10 years of storage). The sponsor states that it is now their policy to require all sites to store documents for at least 15 years. This new policy was not communicated to our site during the study, or the policy was changed after the study was completed. The sponsor is stating that "applicable regulations" would also mean their own policies and procedures, not just FDA regulations. As a side note, when I asked for a copy of that policy / procedure, it was stated that the sponsor cannot provide it since we are not part of the sponsor company.

Do you feel that sponsor's internal policies and procedures be considered "applicable regulations" and require our site to store documents for as long as sponsors want? If this would not be considered "applicable regulations" what would our next steps be?

The second situation that I am seeking advice on is if you can give any advice on what we should do when a sponsor will not agree that documents can be destroyed? I have had several instances where sponsors either will not respond to inquiries about destruction or their response is to state that they will not ever agree that documents can be destroyed and state that documents need to be stored on site indefinitely. Another response that I have received is that we cannot destroy documents as the sponsor cannot predict whether their company (or others) may decide to research in the future (even if there are no plans to continue research at this time).

These situations are very burdensome and expensive for sites. However, I have read in many different places (Q&A documents from FDA / ICH, etc) that say the sponsors are the ones that can truly determine when documents are no longer needed and can be destroyed, so I am hesitant to destroy without sponsor approval, but I fear in some cases we will never receive sponsor approval.

Just a note, we do have a storage policy at our institution that states documents will be held for the longer of:

1. FDA regulations
2. Contractual language
3. 3-year minimum (our institutional minimum)

By having this policy in place, would that cover our site if sponsors would not agree to destruction, and we determine that all three storage lengths have been met?

Thank you for your time to review and respond to these questions.

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