From: OC GCP Questions
To: [redacted]
Subject: FW: Message from Unknown sende[redacted] - Investigator Record Retention
Date: Thursday, September 03, 2015 5:32:00 PM

Dear [redacted] -

It was a pleasure to speak with you on the telephone today. Thank you for your question about the FDA regulations on record retention requirements for investigational drug studies.

As we discussed, the FDA has regulations for investigator recordkeeping and record retention for drug and biologic studies that can be found at 21 CFR 312.62 (see http://www.ecfr.gov/cgi-bin/text-idx?SID=83c688c4e46e2c3581047e2204dfcc51&mc=true&node=se21.5.312_162&rgn=div8). The regulations specifically found at 312.62(c) address investigator record retention and I've copied this section here for your reference:

> (*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.*

If I understood your question correctly, you retired from conducting research in [Redacted] and you have clinical study records in off-site storage for hundreds of studies you participated in over [Redacted] years of your career. Your specific question appears to have been related to FDA record retention requirements for study records where no marketing application may have ever been filed (e.g., product development stopped and the IND was withdrawn) and for which the retention period is well beyond the required timelines addressed in the regulations. The regulations noted above should assist you in assessing your record retention responsibilities for such studies.

As we discussed, and if applicable, you may also want to be aware of any state laws, institutional requirements, and contractual agreements that you may have had for retaining specific study records. As you will note, the retention period is dependent on whether the data will be used to support a marketing application with FDA. In most cases, 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, whether the sponsor no longer intends to seek marketing approval, etc.). Therefore, if you have any questions about your record retention responsibilities related to a particular study in question, you may consider checking with that study sponsor if necessary.

FDA does not have regulations or guidelines on destruction of records once the record retention requirements have been met. When FDA regulations are silent, investigators, sites, sponsors, IRBs and institutions are free to develop their own standard operating procedures to handle specific situations. Maintaining confidentiality of subject identities and records is important when considering how records are destroyed. You may consider documenting the process you decide to follow.

Should you have any additional questions, please don't hesitate to respond to this email and we will be happy to assist you.

I hope this information is useful. If you need further information and/or have additional questions, please feel free to contact us at the official GCP mailbox, gcp.questions@fda.hhs.gov. You may also find it useful to access the set of redacted GCP e-mails found at http://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/RepliestoInquiriestoFDAonGoodClinicalPractice/default.htm since we find that many questions and concerns are repeated over time.

Best Regards,

Janet

Janet Donnelly, RAC, CIP

Policy Analyst, Office of Good Clinical Practice

Office of Special Medical Programs, Food and Drug Administration