From: OC GCP Questions
To: [redacted]
Subject: Record retention and archival for IRB
Date: Tuesday, May 13, 2014 11:05:21 AM

Good morning –

Below is the link to a new guidance entitled Electronic Source Data in Clinical Investiga ions issued in September 2013.

http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM328691.pdf

Additionally you can sign up for new guidance release updates on our GCP website. Please see the link below. Please see the middle of the page .."Sign up for Good Clinical Practice/Human Subject Protection e-mail updates".

http://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/default.htm

Kind regards,

Doreen M. Kezer, MSN
Senior Health Policy Analyst
Office of Good Clinical Practice
Office of the Commissioner, FDA

From: [Redacted]
Sent: Monday, May 12, 2014 3:32 PM
To: OC GCP Questions
Subject: RE: Record retention and archival for IRB

It has been a little over a year since I last contacted the FDA. I wanted to see if there have been any updates or guidances from the FDA regarding archiving paper records into electronic formats.

Thanks,
[redacted]

>>> OC GCP Questions <gcp.questions@fda.hhs.gov> 2/1/2013 4:43 PM >>>
Dear [redacted]-

Thank you for your question. You are correct that FDA's IRB regulations address requirements for IRB record retention [21 CFR 56.115(b)] but do not address specific methods of archiving IRB records. When the regulations are silent, IRBs and institutions are free to develop their own procedures and practices as long as the applicable regulatory requirements for record retention are met.

FDA does not have specific guidance to address your question about IRB records, but you may find it helpful to review FDA's guidance called "Computerized Systems Used in Clinical Investigations" found at http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM070266.pdf. The introduction states:

> *This document provides to sponsors, contract research organizations (CROs), data management centers, clinical investigators, and institutional review boards (IRBs), recommendations regarding the use of computerized systems in clinical investigations. The computerized system applies to records in electronic form that are used to create, modify, maintain, archive, retrieve, or transmit clinical data required to be maintained, or submitted to the FDA.*

We are frequently asked if sites may archive records by converting paper documents into an electronic format - in essence, creating certified copies of source documents. Again, neither FDA's regulations nor the ICH GCP E6 Good Clinical Practice: Consolidated Guidance, (which is recognized as official FDA guidance - http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm073122.pdf) defines "certified copy" however the term is mentioned in the ICH E6 definitions for "source data" and "source document":

> 1.51 **Source Data**: All information in original records and certified copies of original records of clinical findings, observations, or other activities in a clinical trial necessary for the reconstruction and evaluation of the trial. Source data are contained in source documents (original records or certified copies).

1.52 **Source Documents**: Original documents, data, and records (e.g., hospital records, clinical and office charts, laboratory notes, memoranda, subjects' diaries or evaluation checklists, pharmacy dispensing records, recorded data from automated instruments, copies or transcriptions certified after verification as being accurate and complete, microfiches, photographic negatives, microfilm or magnetic media, x-rays, subject files, and records kept at the pharmacy, at the laboratories, and at medico-technical departments involved in the clinical trial).

Although the term "certified copy" is not specifically defined in the ICH E6 guidance, FDA attempted to define this term in the computerized systems guidance document referenced above as follows (see Definitions section):

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.

The use of certified copies as described above generally applies to situations where original records are copied to a different media for archiving purposes and the originals are destroyed. If it is decided to have a certified copy substitute for the original, it would be desirable to have a Standard Operating Procedure (SOP) describing how such copies would be made, verified, and documented. The person who certifies the copy as an accurate and complete representation of the original, having all of the same attributes and information should be the same person who actually made the copy from the original. Certification should be accomplished by having the person who makes the copy, sign or initial and date the copy to indicate it meets the requirements of a certified copy as described above. This should be described in the SOP and can be accomplished by initialing and dating each copy or by initialing and dating a document certifying copies in bulk. Whichever method is used the SOP should describe the procedure and ensure that the integrity of the original records is preserved. (There are many ways to accomplish this, and the procedures described above are only suggested examples.)

So, in summary, IRBs are required to retain IRB records for at least 3 years after completion of the research. How the IRB and institution choose to archive the required records (e.g., paper or electronic) is up to the IRB and the institution. If you choose to archive records electronically, you should consider developing an SOP to address the method used to convert paper records to electronic records (e.g., scanning), when you convert the paper records to electronic records (e.g., when the study is completed and IRB oversight is closed out), and how you ensure that the integrity of the original records is preserved (e.g., how you create certified copies of the original paper records).

IRBs records must be maintained for at least 3 years after completion of the research. Whether the IRB or institution chooses to retain such records for a longer period of time is up to the IRB and the institution. We are aware that some IRBs choose to maintain their IRB records, or certain IRB records (e.g., meeting minutes) longer than the required 3 year period after study completion, but you should discuss all issues and questions surrounding IRB record retention with the appropriate institutional officials.

Lastly, you will also want to keep in mind that the regulations require that IRB records be accessible for inspection and copying by authorized representatives of the FDA at reasonable times and in a reasonable manner. So you should think through the process you will use to give an FDA inspector access to your records during an inspection if the records are archived electronically.

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 the Commissioner, Food and Drug Administration

From: [Redacted]
Sent: Tuesday, January 29, 2013 10:05 AM
To: OC GCP Questions
Subject: Record retention and archival for IRB

Our organization would like to archive all of our study files that have closed, meaning all participants have completed the study and no participants are in follow up. We understand that files should be kept for 3 years after study closure. We keep these in the original paper format. We would like to scan them and store them electronically. Once we have the originals scanned and backed-up, we would destroy the paper originals, thus making it a paperless record retention system. I understand that the FDA regulations do not specifically address archiving but instead speak to record retention times.

Sec. 56.115 IRB records.
b) The records required by this regulation shall be retained for at least 3 years after completion of the research, and the records shall

be accessible for inspection and copying by authorized representatives of the Food and Drug Administration at reasonable times and in a reasonable manner.

This does not state how the records should be retained whether in hard copy or electronic copy.

Our questions are:

1. Do we need to keep records in hard copy for 3 years after study completion *or* can we archive them electronically as soon as the study is completed?
2. At what time can records completely be destroyed? Ex: a study that has been completed greater than 3 years, what is the retention time they need to be kept?
3. Are there any rules as how to archive them?

Kind regards,
[redacted]