From: OC GCP Questions
To: [redacted]
Subject: How should investigators maintain case histories
Date: Monday, May 04, 2015 10:48:05 AM

Good morning –

The records can be retained in either hardcopy, electronic or other media. Please see the information below. This is an earlier email responding to record retention in electronic format.

Scanning copies of original documents do not conflict with FDA regulatory requirements; such scanned copies may be considered "Certified Copies." The term "Certified Copy" is defined in FDA's Final Guidance Computerized Systems Used in Clinical Investigations (the one you referenced) as: "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." See: http://www.fda.gov/OHRMS/DOCKETS/98fr/04d-0440-gdl0002.pdf

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. Neither FDA's regulations nor the ICH E-6 Good Clinical Practice: Consolidated Guidance http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM073122.pdf defines "certified copy", however, the term is mentioned in the 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 defined in the ICH E6 guidance, we attempted to define this term in the CCT Guidance referenced above:

"Certified Copy means a copy of original information that has been verified, as indicated by 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. However, 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. (There are many ways to accomplish this, and the procedures described above are only suggested examples.)

Burning a CD at the end of the study, converting e-mails into a PDF format or adopting a procedure to make certified copies are all acceptable methods to achieve study related documents. (FDA does not have any regulatory requirements as to the type of CD or DVD that might be used to preserve information

(presumably to meet the regulatory requirements concerning clinical data/records). A company just needs to make certain that whatever media it uses does so in a manner that preserves the integrity of the original data/information.

As you will note, the retention period is dependent on whether the data will be used to support a marketing application with FDA. 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, it is best to check with the study sponsor regarding the need to retain the study records.

FDA does not object to off-site storage of study records. If the study records are going to be transferred off-site, it is best to document this transfer and keep the documentation for your records. Additionally, FDA does not have guidelines on how records should be destroyed. When FDA regulations are silent, sites are free to develop their own standard operating procedures to handle specific situations. Maintaining confidentiality of subject identities and records is important.

Please also see guidance on Part 11 –Electronic Records --
http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM126953.pdf

Or draft e-Source Guidance:
http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM239052.pdf

I hope this information is helpful. Please contact us again at gcp.questions@fda.hhs.gov for additional questions.

Kind regards

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

From: [redacted]
Sent: Friday, May 01, 2015 4:15 PM
To: OC GCP Questions
Subject: How should investigators maintain case histories

Dear Sir or Madame:

As you are aware, the following record keeping requirements are outlined in 21 CFR 312.62.

> *(b) Case histories. An investigator is required to prepare and maintain adequate and accurate case histories that record all observations and other data pertinent to the investigation on each individual administered the investigational drug or employed as a control in the investigation. Case histories include the case report forms and supporting data including, for example, signed and dated consent forms and medical records including, for example, progress notes of the physician, the individual's hospital chart(s), and the nurses' notes. The case history for each individual shall document that informed consent was obtained prior to participation in the study.*

(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.

However, I have a question with regard to how such records should be maintained, e.g. hardcopy, electronic copy or other media form. Thank you in advance for your response.

Best regards,

[redacted]