From: OC GCP Questions
To: [redacted]
Subject: Question Regarding Study Records
Date: Tuesday, August 04, 2015 1:14:05 PM

Good morning –

Yes the records can be converted to a PDF format while the trial is still ongoing. Please see the information bellow. The records can be retained in either hardcopy, electronic or other media. 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: Monday, August 03, 2015 10:07 AM
To: OC GCP Questions
Subject: Question Regarding Study Records

I am aware that FDA has noted that it is acceptable to create pdf files (i.e. certified originals) for the retention of records when a trial is complete. Can paper originals be converted to pdf files, and the paper version destroyed, while the trial is still running?

From: [redacted]
Sent: Friday, July 31, 2015 3:54 PM
To: [redacted]
Subject: RE: Two Questions -follow up

Hi [redacted]

I apologize for the delay. I've been out of the office for a family emergency and am just now getting my footing back.

Regarding your first question (scanning consents and destroying the originals), HHS regulations do not preclude this process. However, I strongly recommend you to verify that this would be acceptable to FDA, ORI, NIH, the funding institution, and reflected in your SOPs.

Regarding your second queston and based on the limited information about the research, I cannot comment as to whether the research is expeditable; but texting could be consider both a "digital recording" and a survey procedure.

Thanks,
[redacted]

From: [redacted]
[redacted] July 22, 2015 2:22 PM
To: [redacted]
Subject: Two Questions

Hi [redacted]: Two hopefully quick questions for you.

Is it acceptable to OHRP for investigators to scan consent forms and other study related documents and save them as pdf files and shred the paper originals? We have received a request for modification for this to occur because of an issue with space allocation. I know that it is acceptable to have faxed version of the consent form so this seems reasonable too (e.g. having a pdf of the original); but want to check. The investigator has noted provisions for security of the pdf file.

A study will employ the use of text messaging. For example, in a depression study a text would be sent asking the subject how s/he feels today and subject would respond. Does OHRP view texts as a "digital recording" under category 6 or is this viewed as use of survey procedures? (or both)

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Collection of data from voice, video, digital, or image recordings made for research purposes.

Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies. (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b)(2) and (b)(3). This listing refers only to research that is not exempt.)

[redacted]