From: OC GCP Questions
To: [redacted]
Subject: Has there been any changes since we contacted you last year?
Date: Wednesday, June 04, 2014 11:51:42 AM

Good morning –

Thank you for your inquiry. There have been no changes in the policy. Regarding your e-mail below, based on the limited information provided, it appears that scanning copies of original consent documents to electronic format may not conflict with FDA regulatory requirements; such scanned copies may be considered "Certified Copies" as mentioned in my original email.

Kind regards,

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

From: [Redacted]
Sent: Tuesday, June 03, 2014 4:13 PM
To: OC GCP Questions
Subject: Has there been any changes since we contacted you last year?

Hello, Ms. Kezer,

I am a research nurse working for the transplant surgery department of the [redacted].
I am taking over a project started last year to revise an institutional policy. Below, I pasted in the original email question and reply. I am now wondering if there have been any substantial changes since the project was shelved. Thank you for your time.

[redacted]

GCP,

One of the responsibilities of investigators is to keep study records, including consent forms.

What are the FDA's written policies in regards to whether an '*electronic copy'* of the *'original signed hard-copy consent'* can be stored with the research records rather than the *'original signed hard-copy consent'*? Specifically, can the *'original signed hard-copy consent'* be disposed of and replaced when an

'electronic copy' has been made?

Thank you,

Good morning:

You may be helpful to review this guidance document -- Computerized Systems Used in Clinical Investigations - Link below --
http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM070266.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 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.)
Hope this information is helpful.
Kind regards,
Doreen M. Kezer, MSN
Senior Health Policy Analyst
Office of Good Clinical Practice
Office of the Commissioner, FDA