From: OC GCP Questions
To: [redacted]
Subject: question re: original (wet ink) ICFs
Date: Thursday, March 19, 2015 1:06:56 PM

Good afternoon –

The scenario you describe may not conflict with FDA regulations. Many institutions and sites are going to a fully electronic record system. Your EMR can be your source record which would include the informed consent document.

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You may also want to look at FDA's Compliance Program Guidance Manual (CPGM) for the FDA inspection of clinical investigators during a bioresearch monitoring (BIMO) inspection of a clinical study site, available at: http://www.fda.gov/ICECI/EnforcementActions/BioresearchMonitoring/ucm133562.htm In particular, you may want to review Part III, Inspectional, which identifies some of the things an FDA investigator will look for during a clinical investigator site inspection.

ICH E-6 Good Clinical Practice: Consolidated Guidance
http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM073122.pdf
Please see this guidance for 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)."

That said, FDA just issued a draft guidance on electronic informed consent. While still out for public comment and not for implementation, this guidance will give you a good overview on FDA current thinking on eIC.

http://www.fda.gov/ucm/groups/fdagov-public/@fdagov-drugs-gen/documents/document/ucm436811.pdf

Q14. What materials or documents will FDA require during an inspection?

During inspections of clinical study sites, FDA requires access to records and reports made by the investigator, including site-specific versions of eIC, materials submitted to IRBs for review and approval, all amendments to the site-specific eICs, and all subject-specific signed eICs. These should be available at the site either in electronic or paper form. FDA reserves the right to review the content of the informed consent program or document and the corresponding consent of the subject, the subject's LAR, and a witness, where applicable, along with the date that the eIC was signed. Any updates to the documentation should also be available for review.

Additionally FDA also issued a new information sheet on informed consent. Again this document is still in draft form and out for public comment and not for implementation however you might find some of this information helpful. Please see the link below.

http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM405006.pdf It states --

When written informed consent is required, the use of electronic, including digital, signatures is permitted under FDA's regulations, provided it is in compliance with applicable regulations.

Also, please see page 17 of the guidance.

I hope this information is helpful. Please contact us again at gcp.questions@fda.hhs.gov should you have 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: Thursday, March 19, 2015 8:13 AM
To: OC GCP Questions
Cc: [redacted]
Subject: question re: original (wet ink) ICFs

Good day.

We have recently encountered a large institution in the US where we have been informed that we can review scanned copies of the original ICFs used for research protocols, however, the original (wet ink) copy is **not** made available to the monitor at monitoring visits. We have requested the site's SOP for this (which states that the EMR is considered the original source document), but we have been told that we cannot view the original wet ink copy. The site insists that wet ink copies are stored off-site but cannot provide the address or location, nor can they provide the wet ink copy when requested.

My question to you is: Is this acceptable?

[redacted]