From: OC GCP Questions
To: [redacted]
Subject: Informed Consent retention question
Date: Friday, February 26, 2016 10:16:09 AM

Good morning –

Scanned informed consent documents do not conflict with FDA regulations.

That said, FDA issued a draft guidance on electronic informed consent. While still out for public comment and not for implementation, this guidance will give you a good overview on FDA current thinking on eIC.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

Q. 14 - 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.

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

This communication does not constitute a written advisory opinion under 21 CFR 10.85, but rather is an informal communication under 21 CFR 10.85(k) which represents the best judgment of the employee providing it. This information does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the views expressed.

From: [redacted]
Sent: Thursday, February 25, 2016 4:22 PM
To: OC GCP Questions
Subject: Informed Consent retention question

I am the Quality Assurance Manager at a clinical research laboratory in [redacted] We generally test cosmetics and toiletries on the skin of human subjects using Repeated Insult Patch testing, Photoallergy and Phototoxicity Testing among other types of tests.

Is it acceptable to retain a copy of each informed consent by scanning the original and saving it to our internal network? We would be returning the original signed copy to the subject after scanning. We would not be obtaining consent electronically. The subject will be signing a paper copy of the consent.

Thank you for your reply.
[redacted]