From: OC GCP Questions
To: [redacted]
Subject: econsent and email in lieu of print
Date: Thursday, June 19, 2014 3:02:50 PM

Good afternoon –

This is what our IT experts in the Center for Drugs (CDER) have said in the past regarding electronic informed consents.

The FDA regulatory requirements for Informed Consent, found in 21 CFR Part 50, do not explicitly prohibit having: "…the subject "sign" electronically and then have the option to print out a scanned version of the signature…" Further, as outline in FDA's Final Guidance for Industry on Part 11, Electronic Records; Electronic Signatures — Scope and Application, FDA does not intend to exercise enforcement on Electronic signatures.

Additionally, it appears that scanning copies of original consent documents may 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 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

Please see the link below to your Informed Consent Guidance
Guidances > A Guide to Informed Consent - Information Sheet

A few guidance document links that might be helpful to you are listed below.

http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM328691.pdf

http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM126953.pdf

I hope this information is helpful to you. 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: Wednesday, June 18, 2014 3:30 PM
To: OC GCP Questions
Subject: econsent and email in lieu of print

We provide an electronic informed consent system for clinical trials. Many patients and other trial participants would like to have their signed consent form emailed. At this time we read the

regs/guidance to be printed copy only and that emails are not acceptable.

Thank you,
[redacted]