From: OC GCP Questions
To: [redacted]
Subject: Registry study ICF via Phone process
Date: Tuesday, November 18, 2014 11:11:31 AM

Good morning –

The scenario that you describe in your email does not appear to conflict with FDA regulations.

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

FDA recently issued a *draft* guidance on informed consent. Please see the link below. It discusses electronic ICDs.
http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM405006.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: Tuesday, November 18, 2014 5:49 AM
To: OC GCP Questions
Subject: Registry study ICF via Phone process

Good morning,

I would like to gather some information regarding the consenting process for patients that are agreeing to participate in a registry study. The protocol does not outline for any procedures to be completed as part of the study nor is an IP being investigated. Patients may be identified at a different location (i.e., physician's office out of state) rather than at the participating registry site.

My question is if patients are located at a different location, may the informed consent be completed via the phone? The site would send (email) the ICF to the patient prior to obtaining the patient's consent and the patient would follow up with sending their signed document to the site. If this is acceptable, is there anything other then documenting the ICF process in the source need to be recorded. I am assuming that the IRB/EC is fully aware that the ICF will be obtained via the phone.

Thank you for your time and assisting me in clarify this process.

Kind regards,
[redacted]