From: OC GCP Questions
To: [redacted]
Subject: Question on Good Clinical Practice regarding Record retention for DMF
Date: Tuesday, December 23, 2014 11:08:46 AM

Good morning –

While I cannot specifically speak to clinical investigator e-signatures on Clinical Study Agreements, electronic signatures are allowed under FDA regulations.
FDA's regulations for electronic records and electronic signature can be found at 21 CFR Part 11 (http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=11). Part 11 applies to records in electronic form that are created, modified, maintained, archived, retrieved, or transmitted under any records requirements set forth in Agency regulations, as well as electronic records submitted to the Agency under the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act, even if such records are not specifically identified in Agency regulations. That said, electronic signatures may not conflict with FDA regulatory requirements Such transcription 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:
Part 11, Electronic Records; Electronic Signatures — Scope and Application
http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm072322.pdf

For general information on the use of computer systems in clinical trials in FDA regulated clinical trials, please reference the following guidance:

http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM070266.pdf

Electronic Source Data in Clinical Investigations:

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

I hope this information is helpful. Please contact us again at gcp.quesstions@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: Monday, December 22, 2014 12:52 PM
To: OC GCP Questions

Subject: RE: Question on Good Clinical Practice regarding Record retention for DMF

Good afternoon,

Dear FDA,

I would like to know if a Principal investigator can use their electronic signature for a Clinical Study Agreement with a pharmaceutical? Is there any additionals information you can provide to me?

Kindly regards,

[redacted]