From: OC GCP Questions
To: [redacted]
Subject: eSignatures versus signatures collected electronically
Date: Monday, January 28, 2019 9:55:34 AM
Attachments: [redacted]

Good morning –

Thank you for your patience. This is our first day open after the Government shutdown.

Please see FDA guidance on Electronic Informed Consent - https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM436811.pdf It does not specifically mention a signature line, however, Qs 6 and 7 should be helpful to you regarding electronic signature on a eIC.

Please also see this guidance on electronic records and electronic signatures - https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM563785.pdf

Please see the link below to past GCP queries. The 2018 queries have not been posted as of yet.
Replies to Inquiries to FDA on Good Clinical Practice

If I have not adequately answered your question, please contact the Center for Drugs (CDER), Office of Medical Policy (OMP) at CDEROMP@fda.hhs.gov as this office has the expertise on electronic records in clinical investigations.

Kind regards,

Doreen M. Kezer, MSN
Senior Health Policy Analyst
Office of Good Clinical Practice
Office of the Commissioner, FDA

FDA U.S. FOOD & DRUG ADMINISTRATION

From: [redacted]
Sent: Friday, January 25, 2019 3:08 PM
To: OC GCP Questions <gcpquestions@fda.hhs.gov>
Subject: eSignatures versus signatures collected electronically

Hi Office of GCP,
I have been thinking of you often during this terrible government shutdown. You provide such a valuable service to the industry—I wanted you to know that we appreciate you and hope you are doing OK.

Now to my questions:
I have been evaluating eConsent systems and am seeing several that have a signature line on the informed consent that does not meet the criteria for an eSignature. I am

wondering about the validity of a signature captured digitally for informed consent. Can you please give me some guidance on the requirement for a true eSignature for eConsent.

Also, I know in the past you had a web page with de-identified responses you have previously provided. Do you still provide that and if so, please send me the link. I had hoped to check there before reaching out to you, but could not find that resource.

Thank you,

[redacted]