From: OC GCP Questions
To: [redacted]
Subject: E-signatures, eICF
Date: Wednesday, December 07, 2016 6:43:00 AM
Attachments: [redacted]

Good morning –

Please see FDA's guidance document on eICF.
http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM436811.pdf

For questions regarding this document and eICFs, please contact the Center for Drugs (CDER) Office of Medical Policy (OMP) at
301-796-2500
CDEROMP@fda.hhs.gov

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: Monday, December 05, 2016 5:25 PM
To: OC GCP Questions
Subject: E-signatures, eICF

Could you please provide me with a working phone number and email address for Regulatory Affairs and Regional Operation office.

I have been trying to contact them to
+1 301-796.5320 → Not working
+1 301-827.3101 → Not working

We as company want to move forward with e-signatures and eICF but even though according to CFR21 part 11 this is allowed. We would like to know what kind of requirements (policy documents, SOPs, e-signature verification, and ICH-GCP requirements) we have to fulfill in order to be lawful compliant

On the other hand, Do you have templates of these policy documents for our revision and guidance. If so, could you please provide digital copy of them. Thanks

Kind Regards

[redacted]