From: OC GCP Questions
To: [redacted]
Subject: 21 CFR part 11
Date: Tuesday, December 17, 2019 11:01:03 AM

Good morning –

Thank you for your email. The Clinical Trial Agreement (CTA) is a negotiated contract between the sponsor and the clinical investigator or research institution. The contract should ensure compliance with all applicable laws and regulations relating to the conduct of the study, good clinical practice, health information privacy, etc.

Additionally, FDA would generally not review clinical trial agreements or contracts during an inspection.

Since CTA's are not mentioned in FDA regulations, I don't believe that they need to be Part 11 compliant. However, it might be best to ask the Center for Drugs (CDER), Office of Medical Policy (OMP) at CDEROMP@fda.hhs.gov as they are the experts on Part 11 compliance in clinical trials.

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 16, 2019 12:46 PM
To: OC GCP Questions <gcpquestions@fda.hhs.gov>
Subject: 21 CFR part 11

Hello,

I am hoping for some clarity. Does 21 CFR part 11 apply to electronic signature on the Clinical Trial Agreement (CTA) between a sponsor company and the site?

Thank you,