From: OC GCP Questions
To: [redacted]
Subject: 21 CFR Part 11 Compliance
Date: Thursday, March 08, 2018 9:44:00 AM
Attachments: [redacted]

Good morning –

Please see the Office of Medical Policy (OMP's) cleared response:

Response:

Can you tell us why you are applying parts 50 and 56 to your study?

The regulations under 21 CFR 50 and 56 apply only to clinical investigations regulated by the Food and Drug Administration as well as clinical investigations that support applications for research or marketing permits for products regulated by the Food and Drug Administration. If your study is not being conducted under an IND and otherwise not under Title 21, then regulations under Title 21, including 21 CFR parts 11, 50, and 56 would not apply.

Kind regards,

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

U.S. FOOD & DRUG ADMINISTRATION

From: [redacted]
Sent: Thursday, March 01, 2018 4:34 PM
To: OC GCP Questions <gcp.questions@fda.hhs.gov>
Subject: 21 CFR Part 11 Compliance

If we are doing a study in which we are applying 21 CFR 50 and 56 and we are using an FDA approved drug for it's approved use (we are not filing an IND) are we required to use a 21 CFR Part 11 compliant data capture system?

Thanks. [redacted]

[redacted]