From: OC GCP Questions
To: [redacted]
Subject: Part 11 Compliance and Electronic IRB Systems
Date: Thursday, August 29, 2019 3:22:32 PM
Attachments: [redacted]

Good afternoon –

I sent your email to the Office of Medical Policy. They are the experts on electronic records in clinical investigations. Please see their response below. Thank you for your patience.

Kind regards,

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

Below is OMP's response.

Hello,

Thank you for your inquiry. Records required for clinical investigations of medical products that are maintained in electronic format in place of paper format, including all records that are necessary for FDA to reconstruct a study must be validated to be compliant with 21 CFR Part 11. Therefore, yes, electronic systems supporting IRB activity should be compliant with 21 CFR Part 11. Please see the guidance document "Use of Electronic Records and Electronic Signatures in Clinical Investigations Under 21 CFR Part 11 – Questions and Answers" for additional information.

The guidance document discusses using a risk-based approach for validation. When using a risk-based approach for validating electronic systems, sponsors and other regulated entities should consider (1) the purpose and significance of the record, including the extent of error that can be tolerated without compromising the reliability and utility of the record for its regulatory purpose and (2) the attributes and intended use of the electronic system used to produce the record.

We hope this information is helpful.

The information provided in response to this inquiry does not address any specific product or trial. Follow-up questions regarding specific products or trials should be directed to the appropriate FDA review division by the sponsor.

From: [redacted]
Sent: Friday, August 16, 2019 3:11 PM
To: OC GCP Questions <gcpquestions@fda.hhs.gov>
Subject: Part 11 Compliance and Electronic IRB Systems

Dear Office of Good Clinical Practice,

An auditor hired by one of our sponsors has noted that our electronic IRB system is used to submit and approve documents and that the system generates protocol data supporting the conduct of the trial and may therefore be subject to 21 CFR Part 11. In addition, the auditor argues that this finding is further supported by the fact that the IRB approval documents are generated, but not signed, by the electronic system. We should note that we have submitted a letter of non-repudiation agreement to the FDA to address our electronic signatures.

In general, do electronic systems that support IRB activity need to be validated to be compliant with 21 CFR Part 11?

Please let me know if you need additional information to provide a response.

Sincerely,