From: OC GCP Questions
To: [redacted]
Subject: Question about 21 CFR Part 11 Applicability for 3rd Party Entity in Clinical Trial
Date: Monday, June 11, 2018 8:30:00 AM
Attachments: [redacted]

Good morning --

The best guidances available that explain FDA's opinions on the use of electronic records and computerized systems used in clinical trials include "Guidance for Industry: Part 11 Electronic Records and Electronic Signatures Scope and Application Guidance" https://www.fda.gov/downloads/RegulatoryInformation/Guidances/ucm125125.pdf and the "Guidance for Industry Computerized Systems Used in Clinical Trials" https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm070266.pdf

If you intend for the electronic copies to substitute for the paper copies (i.e. destroy or dispose of the originals) then 21 CFR 11 applies CFR - Code of Federal Regulations Title 21 . This regulation covers the use of electronic records and signatures used to meet an FDA record-keeping requirement. If you propose to maintain electronic copies of study records in lieu of the paper copy, your system for doing so would have to comply with the requirements of Part 11. For example, your process for copying and retrieval would have to meet expectations for availability and being able to generate electronic copies suitable for FDA review and further copying. There are a couple of points to consider. First, Part 11 applies only to the records that are required to be maintained by regulations. For clinical trials in general, sponsor record keeping and retention requirements are found in 21 CFR 312.57 and clinical investigator record keeping requirements are found in 21 CFR 312.62. Second, please note that retention periods are specified in the regulations. Records only have to be retained for the period of time indicated. You are free to decide how records are to be copied, stored or otherwise disposed of, if the records you propose to copy and archive are no longer required by FDA to be retained. That said, you do not have to keep the paper copies if your electronic system complies with Part 11. If you are unsure if you can comply with Part 11, it would be wise to retain the paper.

To meet regulatory requirements, records relating to the conduct of a clinical trial need to contain all of the information that was contained on the original records. If patient information and sponsor information were on the original research records, this information must be preserved.

Part 11 regulations may apply to your system depending on whether your actual business practices make use of electronic records instead of paper records under § 11.2(a). For example, if a record is required to be maintained under a predicate rule and you use a computer to generate a paper printout of the electronic records, but you nonetheless rely on the electronic record to perform regulated activities (in your case statistical analysis), the Agency may consider you to be using the electronic record instead of the paper record. That is, the Agency may take your business practices into account in determining whether part 11 applies.

Part 11 requirements are not intended to apply to electronic systems that are used just to create paper printouts that are subsequently maintained in traditional paper-based systems. In such cases, the electronic systems would function essentially the same way that manual typewriters or pens would function, and any signatures would be traditional handwritten signatures

The relevant US FDA regulations on record retention for clinical trials are as follows:

For drug and biologic studies, 21 CFR 312.62(c) states: "Record retention. An investigator shall retain records required to be maintained under this part for a period of 2 years following the date a marketing application is approved for the drug for the indication for which it is being investigated; or, if no application is to be filed or if the application is not approved for such indication, until 2 years after the investigation is discontinued and FDA is notified."

For device studies, 21 CFR 812.140(d) states: "Retention period. An investigator or sponsor shall maintain the records required by this subpart during the investigation and for a period of 2 years after the latter of the following two dates: The date on which the investigation is terminated or completed, or the date that the

records are no longer required for purposes of supporting a premarket approval application or a notice of completion of a product development protocol."

As you will note, the retention period is dependent on whether the data will be used to support a marketing application with FDA. The sponsor is usually the only party totally knowledgeable about the status of its investigational product (e.g., whether it has been approved for marketing, whether the sponsor no longer intends to seek marketing approval, etc.). Therefore, it is best to check with the study sponsor regarding the status of the investigational product and the need to retain the study records. You should check with each of the study sponsors before discarding any study files.

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 They are the experts on electronic records and computer systems.

I hope this information is helpful. Please contact us again at gcp.questions@fda.hhs.gov should you have additional questions.

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: Thursday, June 07, 2018 2:09 PM
To: OC GCP Questions <gcpquestions@fda.hhs.gov>
Subject: Question about 21 CFR Part 11 Applicability for 3rd Party Entity in Clinical Trial

To Whom It May Concern:

I have a client that downloads reports maintained electronically for clinical trials. After downloading these reports they often provide statistical analysis. I cannot locate any information as to whether those downloaded electronic copies are subject to the regulation and if the client is thereby a regulated entity with requirements to keep those reports valid and whole as well as having retention and deletion standards.

Your timely reply would be much appreciated.

Sincerely,

[redacted]