From: OC GCP Questions
To: [redacted]
Subject: Typed Dates
Date: Friday, June 26, 2015 11:49:53 AM

Dear [redacted] -

I see that you sent two questions in so I will answer both in one email.

Question 1 -- Do you have a prior query answer on the use of typed dates for signatures on documents required by the regulations and predicate rules (example protocol, monitoring reports, etc.). The entity is signing with wet ink, but the date is typed.

We believe this is not in compliance with the principals of ALCOA, but could use the FDA interpretation.

Answer 1 – It depends as typed dates may not conflict with FDA regulations. If you are using an electronic system for entering data, dates can be typed. The two guidances links below should help you.

http://www.fda.gov/OHRMS/DOCKETS/98fr/04d-0440-gdl0002.pdf -- Computerized Systems Used in Clinical Trails

3. Date/Time Stamps

Controls should be established to ensure that the system's date and time are correct. The ability to change the date or time should be limited to authorized personnel, and such personnel should be notified if a system date or time discrepancy is detected. Any changes to date or time should always be documented. We do not expect documentation of time changes that systems make automatically to adjust to daylight savings time conventions. We recommend that dates and times include the year, month, day, hour, and minute and

encourage synchronization of systems to the date and time provided by international standardsetting agencies (e.g., U.S. National Institute of Standards and Technology provides information about universal time, coordinated (UTC)). Computerized systems are likely to be used in multi-center clinical trials and may be located in different time zones. For systems that span different time zones, it is better to implement time stamps with a clear understanding of the time zone reference used. We recommend that system documentation explain time zone references as well as zone acronyms or other naming conventions.

http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm328691.pdf -- Electronic Source Data in Clinical Investigations

While in the past FDA used to think of written dates as the only appropriate way to document a date, current thinking is moving away from that. There is a new draft guidance document on electronic informed consent http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM436811.pdf . While still in draft the information is this guidance should be helpful to you.

Since FDA regulations do not specifically address how a date should be transcribed. When the regulations are silent, sponsors, sites and institutions are free to develop their own standard operating procedure (SOP) for handling a specific situation. SOPs assure consistency from all study staff when entering data in a clinical trial.

Question # 2 - Recently I ran into an issue with a signature that we could use guidance on.

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> This entity is applying a JPEG image of a handwritten signature to Word documents and then typing in the date and creating a PDF for retention. This JPEG image is stored in a encrypted vault that they enter a password to get the image. After the image is available it is applied to the electronic Word document via a insert image in the Word application. The final document is only maintained electronically in the eTMF. The document contains no information as to the time of the image being applied and the date is manually typed, not computer generated.

The image from the final PDF can easily be copied and applied to other documents. The image in the document cannot be readily deleted from the PDF, but can be redacted. Was tested by the external auditor.

We are familiar with the definitions in 21 CFR Part 11 and do not feel this meets the definition for a valid electronic signature.

What is not entirely clear is whether this could be classified as a digital signature or if it is none of the above.

The entity is stating this is a handwritten signature and not bound by 21 CFR Part 11.

We do not consider the signature valid as you can not prove who applied the image and typed the date in. We consider the signature not to be attributable.

Answer – Per the guidance on Electronic Records and Electronic Signatures
http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm072322.pdf

From scenario you describe it appears that the JPEG electronic signature cannot be validated and may not be compliant with FDA regulations under Part 11.

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