From: OC GCP Questions
To: [redacted]
Subject: Investigator / Sponsor Communication - Wet Signature
Date: Wednesday, January 10, 2018 9:33:00 AM
Attachments: [redacted]

Good morning –

This is what we have stated in the past regarding study-related emails.

The requirements for retaining your e-mail correspondence depends in large part on whether or not the content of these e-mails include records that are required to be kept under our regulations. For example, if [a CRO, has assumed responsibility for keeping records of the distribution of the drug to clinical investigators (21 CFR 312.57 (a)) and you use e-mail records as part of the record keeping system to meet this requirement, those e-mails would have to be retained and such electronic records would fall under the requirements of 21 CFR 11 (part 11).

Regarding storage of study-related e-mails, as electronic study data they would be covered by 21 CFR Part 11. If it can be certified that the information on the disc or in the zip file is an accurate copy of the e-mails exchanged, there would seem to be no reason they could not be stored in this manner. If a bioresearch monitoring (BIMO) inspection of the site were to occur, all that would be required is that the FDA investigator be able to read these e-mails and make copies of those he/she finds relevant.

As you probably know already, a final guidance issued re: the scope and application of Part 11. You can find this document on our GCP web site at www.fda.gov/oc/gcp/guidance.html. The guidance does address that record keeping practices will be influenced by the way in which a company uses computerized and paper-based systems. The definition of Part 11 records has been streamlined and the agency now uses a "narrow" interpretation of what constitutes a Part 11 record. As you can read on page 5 of the final guidance, records that must be maintained under predicate rule requirements that are maintained in electronic form in addition to paper format, and are relied on to perform regulated activities will be considered Part 11 records. The guidance continues that actual business practices may dictate whether a company is using electronic records instead of paper records. A company, therefore, needs to decide whether it is going to rely on the paper record exclusively or a combination of the electronic and paper record (which is fairly common).

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 as they are the experts on Part 11 compliance.

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: Tuesday, January 09, 2018 2:22 PM
To: OC GCP Questions <gcp.questions@fda.hhs.gov>
Subject: RE: Investigator / Sponsor Communication - Wet Signature

Hello,

Thank you for your quick reply. One last question, what is the FDA's stance on email correspondence? Do they consider email to be CFR Part 11 compliant?

Best regards,

[redacted]

From: OC GCP Questions [mailto:gcp.questions@fda.hhs.gov]
Sent: Monday, January 08, 2018 11:49 AM
To: [redacted]
Subject: Investigator / Sponsor Communication - Wet Signature

Good afternoon -

FDA regulations do not specifically mention sponsor signatures, therefore, scanning copies of original documents does not conflict with FDA regulatory requirements. If records are to be stored electronically, your computer system would have to comply with part 11 (www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=11)

That said, it is always good to be able to ascribe a report to someone as these will likely be important study data. When FDA regulations on silent on a specific topic, we suggest developing standard operating procedures (SOP). These procedures will assist you in determining how to maintain records and, for those that could depend on the opinion/expertise of a particular person, how best to ensure they will always know who made the diagnosis/decision. Sites therefore have flexibility in how they handle documents at their sites and signatures because FDA's regulations do not specify how this must be done. The SOP that you develop might include instructions that documents how the original document with the wet signature if you chose to use a wet signature.

I've listed below a few FDA guidance documents that you may find helpful in answering your question:

FDA's Guidance for Industry - Part 11, Electronic Records; Electronic Signatures - Scope and Application found at
www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM072322.pdf

FDA's Guidance for Industry - Computerized Systems Used in Clinical Investigations found at

www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM070266.pdf

FDA's Draft Guidance for Industry - Electronic Source Data in Clinical Investigations found at

www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM328691.pdf

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: Monday, January 08, 2018 11:50 AM
To: OC GCP Questions <gcp.questions@fda.hhs.gov>
Subject: Investigator / Sponsor Communication - Wet Signature

Hello,

This question relates to correspondence generated by a sponsor to a clinical study site. It has been suggested that the sponsor is not required to apply a wet signature to a site visit confirmation letter or site visit follow-up letter **IF** that letter is sent to the site via email by the author of the letter. It is suggested that sending it via email meets the CFR 11 requirement for biometrics. The types of letters given as examples would of course be filed in the TMF (both the site and the sponsor) as critical correspondence. Additionally, it is important to note that this company is a paper based company.

Can you confirm if this is correct?

Best regards,

[redacted]