

From: OC GCP Questions
To: [REDACTED]
Subject: Email Correspondence
Date: Thursday, January 26, 2017 7:18:00 AM
Attachments: [REDACTED]

Good morning –

In discussing this issue in the past with others in the agency, we believe that e-mail is a reasonable and reliable method to send information because e-mail systems inherently meet part 11 requirements. E-mail systems, when used properly, have controls that ensure: 1) limited system access through individual user accounts/passwords, 2) the confidentiality of information contained in messages/attachments; and 3) user authentication (i.e., by using e-mail, one is generating an electronic signature and making a statement that, in essence, makes the statement "this is my account and I've prepared this message." Further, the records created are generally not "high risk" documents that would require all of the part 11 controls.

The use of e-mail in place of correspondence is common place and efficient and has adequate controls for the types of documents. The more efficient a site or sponsor is in dealing with its documentation requirements, the more time it will have to address issues that impact on human subject protection-- which is really their basic focus and responsibility.

FDA's Part 11 regulations address electronic records. You may want to look at those if you haven't. They are available on the web at:

<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=11>

Computerized Systems Used in Clinical Investigations -

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

Electronic Source Data in Clinical Investigations -

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

If an email communication would have an impact upon the respective study, then it would be appropriate to maintain a record of that communication and/or decision. A dated signature would only be needed if the document is a certified copy, which is probably not likely for an email. (See below).

Certified Copy: A certified copy is a copy of original information that has been verified, as indicated by a dated signature, as an exact copy having all of the same attributes and information as the original.

Returning the emails by burning them to a disk in PDF format does not go against FDA regulations.

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

Kind regards,

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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: Wednesday, January 25, 2017 3:02 PM
To: OC GCP Questions
Subject: Email Correspondence

What is the best practice when dealing with emails between the CRA and the site?

I would like to be able to train our CRAs to make sure that what we store in the TMF are actually relevant communications to the study.

Is there a decision making tree that could be followed in order to make sure that we are not filing meaningless communications.

Another question is after the study is over what are the best practices for storing and returning these correspondences back to the site?

Currently we have been burning them all to a disk in PDF format and sending to the site. Is this compliant in the event of an audit?

If not what are some safeguards we could use to make sure that it is.

Kind Regards

[REDACTED]