From: OC GCP Questions
To: [redacted]
Subject: Site filing of electronic images
Date: Monday, May 18, 2015 10:51:38 AM

Good morning [redacted] –

Please see the message below from ORA. Your email was discussed with ORA staff as well as staff in the Center for Drugs (CDER). It appears your processes are acceptable. Thank you for your patience.

My BIMO colleagues and me agree that the firm's process described below for filing of electronic images is acceptable. We will make sure to reinforce at BIMO classroom courses that this or similar approaches are acceptable and not uncommon during an inspection.

Kind regards,

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

From: OC GCP Questions
Sent: Friday, May 15, 2015 3:31 PM
To: [redacted]
Subject: Site filing of electronic images

Hi [redacted] –

Please see the preliminary response below. SMEs means "Subject matter experts". I thought your processes looked correct but wanted a second opinion from ORA. Once I hear back from Hector I will respond again.

Have a great weekend.

Doreen

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

From: Colon, Hector J.
Sent: Friday, May 15, 2015 2:27 PM
To: OC GCP Questions
Subject: RE: Site filing of electronic images

Hi Doreen,

The process described below looks appropriate to me. I will seek for the opinion of other SMEs and will get back to you.

Thanks,
Hector

From: OC GCP Questions
Sent: Thursday, May 14, 2015 3:20 PM
To: Colon, Hector J.
Subject: FW: Site filing of electronic images

Hi Hector ---

I don't know if I missed this email or what. I think what she describes appears acceptable but I am hesitant to say so until you weigh in as she stated otherwise from an FDA inspection. Can you give me your take on this? I will respond directly back to the inquirer. As always, I thank you for your guidance.

Kind regards, Doreen

From: [redacted]
Sent: Tuesday, May 12, 2015 3:14 PM
To: OC GCP Questions
Subject: FW: Site filing of electronic images

Good morning-
I am following up to my email from 4 months ago. I have not yet seen a response. Can you kindly let me know if I can expect one?
Thank you
[redacted]

From: [redacted]
Sent: Friday, January 30, 2015 11:34 AM
To: FDA GCP Questions
Subject: Site filing of electronic images

Good morning-
During a recent Clinical Investigator site audit, the FDA inspector stated that he expected to see electronic images filed in each individual subject binder and a central location was not acceptable. I re-read both the attached guidance documents for any insight and would appreciate your comments on the following process:

Digital images are captured for each subject at multiple visits as part of the study protocol

A central tracking log is completed in order to track image by subject, visit etc. The log is kept in the Clinical Study Binder
All images for all subjects are stored in a central location
Digital images are transferred from the central location to a reading center for interpretation
The transfer process is validated and tracked on the central tracking log
The clinical interpretation of the image is entered on a CRF by the reading center for each subject
As the clinical interpretation requires analysis of images throughout the course of the subject's participation, the CRF with the complete info is not provided to the site for filing with the subject's medical/study record until the end of the study.
At the end of the study a certified copy of ALL subjects images is made and filed with the Clinical Study materials.

I cannot find any regulation or guidance document that would require images to be filed individually in a subjects medical record/chart. Could you please comment on whether centralized storage with appropriate documentation of the location of the storage is acceptable and if not please provide regulations to reference.

Thank you in advance,
[redacted]