From: OC GCP Questions
To: [redacted]
Subject: RE: Patient changing investigators and their electronic archives
Date: Tuesday, January 24, 2017 3:43:00 PM

Dear [redacted]

Your email doesn't mention whether the study is for drugs or devices. FDA's regulations in 21 CFR 312 do not specifically address the transfer of study subjects or their records from one study site to another for INDs, however, 21 CFR 812.140(e) does permit an investigator or sponsor to transfer record custody for device studies, provided certain requirements are met. When the regulations are silent, sponsors, investigators, IRBs, and institutions are free to develop their own procedures and practices as long as applicable regulatory requirements are met.

Ideally, the complete eCOA for subject 1 would reside at both site A and site B. At a minimum, Site A should maintain original source records of the subject up to the time of transfer and should note in their site's records that the subject transferred to site B, and the date this occurred. If the complete eCOA records, or eCOA records for this time period are not made available to site A, a notation regarding the location of these records should be kept in site A's records for patient 1.

Site B should receive copies of the patient's records from site A and document in their records that the subject transferred from site A and the date the transfer occurred. Site B should have a complete eCOA record of all visits, as you note in in your email.

For data analysis and recordkeeping purposes, you should ensure that a subject is consistently identified in a way that allows all data regarding a single subject to be attributable to that subject. The data used in the analyses must be traceable back to the records maintained at both the sites and complete transparency is important. Good communication is going to be very important between all parties involved.

Beyond that, there may be other criteria that you need to address. For this reason, you should discuss your question with the sponsor and appropriate management, including resources such as legal and clinical data management staff at your company, to develop and document an acceptable plan for transferring a subject and their records from one site to another.

I hope this information is helpful to you. If you need further assistance, please feel free to contact the GCP mailbox at gcp.questions@fda.hhs.gov .

Best regards,

Sheila

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-----Original Message-----

From: [redacted]
Sent: Friday, January 20, 2017 10:27 AM
To: OC GCP Questions
Subject: Patient changing investigators and their electronic archives

GCP,
Our company collects eCOA source patient data on behalf of each investigator and kept live and available during the length of the study. Once completed, the study database is shut down and certified Source patient data is provided to both the Sponsor (full copy) and Investigators (site specific copy) for their GCP record keeping.

This issue is when a Patient 1 moves from Clinical Site A to Clinical Site B during their active enrollment. Our TrialMax system process is to then associate the patient data with the new invitational site. The eCOA patient data is then viewable by Clinical Site B so they can continue with Patient 1 for the remainder of the trial. Our continued process is to provide the full specific patient 1 archive to Clinical Site B as the patient 1 responsibility was moved to them. We do not send a duplicate copy of the patient 1 archive to the original Clinical Site A as they are no longer responsible.

I have reviewed your Replies to Inquiries to FDA on GCP under Recordkeeping and Record Retention. I did not find anything specific on this subject.

ICH E6 section 8.3.13 does not address who retains the archive data for a moved patient. I am assuming that our process of providing the eSource patient 1 archive only to Clinical site B is in keeping with regulations.

Confirmation of our interpretation would be helpful.

[redacted]