From: OC GCP Questions
To: [redacted]
Subject: Question on transfer of study records
Date: Friday, April 03, 2015 12:41:23 PM

Good afternoon –

You should check with your reviewing IRB and your institutional officials regarding the transfer of records from one PI (clinical investigator) to another PI both from the same practice. The informed consent might need to be changed as the new PI would need to be listed as a contact in case the subject experiences an adverse event from the investigational product. I would also think that the subjects should be informed that the other PI will be taking over. This communication can be review and approved by the IRB. Additionally, the sponsor should notify FDA that the one of the PIs is retiring. They can consult FDA regulatory practice manager (RPM) for the IND. Below is some general information regarding transfer of study records.

GCP requires that documentation of study data be accurate, complete, legible, and timely. Any changes or corrections should be dated, initialed, and explained and should be made in a manner that does not obscure the original entry (that is, an audit trail should be maintained). The study records should be adequate to demonstrate how the study was actually conducted.

Data used in any analyses must be traceable back to the records maintained at the clinical sites. Complete transparency is important. Please note that site 1 needs to maintain records of the patient up to the time of transfer and should note in the site's records that the patient transferred to site 2 and when this occurred. Site 2 should receive copies of the patient's records from site 1 and document in their records that the patient transferred from site 1 and when the transfer occurred. The sponsor records should also reflect this transfer.

Also it is not clear to me even if the study is from one practice (two PIs) that a close out needs to be completed for the PI who is retiring. Again you should consult your RPM for the IND. FDA does not have a guidance document that provides details about how to close out a study. However, the following information is found in the "Guidance for Industry, E6 Good Clinical Practice: Consolidated Guidance" (April 1996 ICH)
http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM073122.pdf
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Trial master files should be established at the beginning of the trial, both at the investigator/institution's site and at the sponsor's office. A final close-out of a trial can only be done when the monitor has reviewed both investigator/institution and sponsor files and confirmed that all necessary documents are in the appropriate files.

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

From: [redacted]
Sent: Wednesday, April 01, 2015 4:17 PM
To: OC GCP Questions
Subject: Question on transfer of study records

Hi,
I have a question on a situation where a study has finished and all patient study activities are complete (only data cleaning and close out activities to occur), but the PI (MD) is retiring and closing his research facility. The PI is a part of a large multi site practice and has a partner(MD) within the overarching practice who is conducting the same study as a PI a few miles down the road at one of the other clinics. All patients recruited came from their practice where both MDs have access to the medical records. The retiring PI sent a letter to the subjects stating he is closing his practice and the remaining study activities would be finished out by the partner who is also conducting the study. Would the retiring PI have to get subject consent to transfer each subject's study record to the new PI? Or would that typically be covered in the study consent document? I have confirmed that the data privacy statement signed by each of the patients as a part of them being a patient of the practice covers the transfer of the medical records.
Thanks for your insight.

Kind Regards,

[redacted]