From: OC GCP Questions
To: [redacted]
Subject: Question Regarding Certified Copies
Date: Wednesday, April 18, 2018 11:43:00 AM
Attachments: [redacted]

Good morning –

From the scenario you describe, it appears that the secondary facility's clinical record is your source document and therefore would not need to be certified. The information received would be transcribed on the CRF for the study.

FDA regulations do not specifically state that all copies of study documents need to be signed as certified copies. SOPs are recommended and documentation of training for study staff on newly developed SOPs is also recommended. Clarifying your current SOP might assist your staff in understanding why you want them to certify certain study documents.

FDA's regulations require that the investigator "...establish and maintain adequate and accurate case histories that record all observations and other data pertinent to the investigation on each individual administered the investigational drug or employed as a control in the investigation. Case histories include the case report forms and supporting data including, for example, signed and dated consent forms and medical records including progress notes of the physician, the individual's hospital chart(s), and the nurses' notes...." [See 21 CFR 312.62(b).]

"Source data" is all the information contained in original records and certified copies of original records of clinical findings, observations, or other activities in a clinical trial necessary for the reconstruction and evaluation of the trial. Source data are contained in source documents. Whether a CRF or other form is a "source document" depends on whether it is the place where the data or information is captured, for the first time, on a durable medium.

The customary practice for a site may be to record observations and data in a subject's medical records first, and then to transcribe the information onto a CRF. If a question subsequently arises about information that was entered onto the CRF, the answer to the question would be resolved by going back to the source data contained in source documents (e.g., medical records, progress notes of the physician, hospital chart(s), lab results, x-ray films, EKGs) to determine what the correct information is. The CRFs should report what is contained in the original source documents.

FDA's investigators routinely compare the source data with the information reported on the CRFs. This is how they reconstruct the study and determine if the clinical investigator properly conducted it (i.e., followed the protocol; appropriately included or excluded subjects; accurately and completely reported his observations, any concomitant medications used by the subjects, and adverse events; appropriately supervised his staff in the conduct of the study; etc.).

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

U.S. FOOD & DRUG ADMINISTRATION

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: Tuesday, April 17, 2018 5:07 PM
To: OC GCP Questions <gcpquestions@fda.hhs.gov>
Subject: Question Regarding Certified Copies

Hi
I have had a question from a site (and it is a common issue) about certified copies when the site is receiving faxed information from another institution for example if someone is admitted to another hospital for an SAE or information is required to confirm eligibility. In this case the secondary institution is not a site and is essentially providing the information to assist the trial site. It can often be challenging to get this information and to try and get this certified by the secondary institution will be very difficult if not impossible. What do you advise in this case? I have copied the original site question here and would be grateful for any advice you can provide.

Situation:
When the clinical trial patient is admitted to a secondary hospital / facility and the Study Coordinator is seeking information with respect to the admission (SAE reporting – admission notes, medication charts etc.), or when a patient is first referred to the clinical trial site for participation in a clinical trial and they need previous treatment history for the patient the secondary facility usually faxes pages of admission notes, tests, medication charts, correspondence etc. to the clinical trials site.

Question:
How can the clinical trials site verify that what has been sent is a true and accurate reflection of the secondary facility's clinical record (the source) if the secondary facility does not verify the accuracy of the copy – i.e. they put the original document through a fax machine, so they don't even see the copy? Also, it is very difficult to get a secondary facility to each page as it is already significant additional work for them to send these to us in the first place.

In terms of normal patient care (outside of clinical trials) the above scenario would be treated as a true and accurate reflection of the record and is used to treat the patient (sometimes in life-threatening situations). No confirmation is sought on the accuracy of the record, it is just treated as fact.

Many thanks for your advice.

With best wishes

[redacted]

[redacted]