From: OC GCP Questions
To: [redacted]
Subject: Question on documents to keep in a Trial Master File at a sponsor
Date: Thursday, November 02, 2017 11:09:44 AM
Attachments: [redacted]

Good morning --

The only FDA's regulation requiring receipt by the sponsor is for drug accountability (investigational product).

Sec. 312.57 Recordkeeping and record retention.

(a) A sponsor shall maintain adequate records showing the receipt, shipment, or other disposition of the investigational drug. These records are required to include, as appropriate, the name of the investigator to whom the drug is shipped, and the date, quantity, and batch or code mark of each such shipment.

Sec. 312.59 Disposition of unused supply of investigational drug.

The sponsor shall assure the return of all unused supplies of the investigational drug from each individual investigator whose participation in the investigation is discontinued or terminated. The sponsor may authorize alternative disposition of unused supplies of the investigational drug provided this alternative disposition does not expose humans to risks from the drug. The sponsor shall maintain written records of any disposition of the drug in accordance with 312.57.

The CI sites files and the sponsor files do not necessarily have to match. Given the information that you have provided, it appears that the procedures (SOPS) being followed or required by the sponsor appear to be acceptable in keeping with good clinical practice.

Kind regards,

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

From: [redacted]
Sent: Thursday, November 02, 2017 9:16 AM
To: OC GCP Questions <gcp.questions@fda.hhs.gov>
Subject: Re: Question on documents to keep in a Trial Master File at a sponsor

Thank you for your response.

With regards to your information, should the sponsor Trial Master File contain all the documents contained in

the Investigator Site File, such as any receipts kept at the site of some study material (when there is no study requirements to sent it back to the sponsor).

For instance, ICH GCP 8.2.15_Shipping records for Investigational Product(s) and Trial-Related Material_ indicate that documentation on shipment dates, batch and methods of shipment of IP and trial-related material should be at site and sponsor.

Based on this guidelines and referring only to study material received initially at the site (example: PK tubes, CDs to burn CT images...):

I understand that the sponsor will keep track on their end of what material is sent to the site. The site would keep on site the receipt of material received (or keep track of the material). Then if there is no other specific study requirement that instruct for the site to send back to the sponsor a proof that the material was received, in that case, the Study Site File and the Sponsor Trial Master File would not have exactly the same documentation on an activity (Sponsor will have the shipping documentation and the Site will have the receipt documentation).

I hope this example clarifies better a situation where the Site File would be a little different than the Sponsor File for the reason detailed above. Is this situation compliant with the regulation sand the ICH GCP guidelines.

Thank you in advance for your assistance on this questions

[redacted]

From: OC GCP Questions <gcp.questions@fda.hhs.gov>
To: "[redacted]
Sent: Thursday, November 2, 2017 8:08 AM
Subject: Question on documents to keep in a Trial Master File at a sponsor

Good morning –

Recordkeeping is a topic that tends to generate fairly vigorous debate generally driven by personal preferences. In general, our regulations focus on what documentation should be kept rather than how or where it should be maintained. The regulations are deliberately written this way to provide investigators and institutions maximum flexibility in adopting the practices that best suit their specific situations.

There are pros and cons to all recordkeeping practices. Recordkeeping practices that combine trial-related records and the subjects' medical records can minimize record storage problems. In addition, combination records are convenient in that all records and data are maintained in one place. On the other hand, mixing trial related records with treatment records tends to make them more difficult to audit and, (particularly if the subject participates in more than one study) may raise privacy concerns. While a separate file perhaps would be easier to organize and audit, however, data are more likely to be misfiled or missing between the two records; if additional records are generated to duplicate the treatment file, discrepancies can arise which might, in turn, raise a red flag during audit.

So, in answer to your question, our regulations do not dictate how you should maintain your records, and you are free to choose the system that best fits your needs. That said, to avoid recordkeeping problems,

your site should establish expectations on how data will be collected and how records at the site will be maintained. (Those expectations could be documented, for example, through standard operating procedures for your site). As long as the data and records are handled consistently in accordance with those expectations, you should have no problems.

Again, FDA regulations pertaining to recordkeeping practices for clinical trial records are fairly general and do not specifically address your particular question. If the site is following their SOPs, then it would appear to be acceptable and in keeping with good clinical practice.

Kind regards,

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From: [redacted]
Sent: Wednesday, November 01, 2017 9:44 AM
To: OC GCP Questions <gcp.questions@fda.hhs.gov>
Subject: Question on documents to keep in a Trial Master File at a sponsor

Good day,

At the site, in the Study Investigator Binder, the site is keeping receipt of study material received at the site. On the sponsor site, the sponsor is keeping the shipping document of study material sent to the site. Do the sponsor need to have the site (or the CRA) make a copy of any receipt document of study material received from sponsor at the site for the sponsor Trial Master File? or is this not necessary to duplicate this information at the sponsor.

Thank you for your assistance on this question

[redacted]