Investigator's Documents and Transfer of Responsibility

October 15, 2020

**Question 1:**

I’m working for a sponsor, and we were recently contacted by an Investigator that needed to close his site (in 2020). He has conducted 2 studies with us in the past:

1st study: The site was owned by the investigator. Now 2 years elapsed since marketing approval in US (which was in 2017), but not in other ICH regions in which submissions are still in review. Documents are to be kept (not destroyed).

2nd study: The site was bought by another organization during the study (in 2019) and a new contract was signed with this organization. No marketing application has been submitted yet nor formal discontinuation of clinical program. Documents are to be kept (not destroyed). The PI told us he also sold all current and previous study records to that organization in 2019.

1st question: Can an Investigator sell the study documents along with his clinical practice while he continues to do clinical research? Who has the ultimate responsibility of the investigator’s documents after the transaction: the Investigator or the new organization?

He now contacted us in 2020 to mention the clinical site needed to close and the organization cannot store the study documents anymore because the organization is dissolving (no more fund to archive). As sponsor, we decided to take charge of archiving all study documents on his behalf. However, we consider the documents still relies under his responsibility.

2nd question: Are we right to say that the study documents remain under the Investigator’s responsibility even if we provide the storage facility?

**Answer 1:**

Based on the information in your email, generally the responsibility of storing the records would be the sponsor’s responsibility.

As you will note, the retention period is dependent on whether the data will be used to support a marketing application with FDA. The sponsor is usually the only party totally knowledgeable about the status of its investigational product (e.g., whether it has been approved for marketing, whether the sponsor no longer intends to seek marketing approval, etc.). Therefore, it is best to check with the study sponsor regarding the status of the investigational product and the need to retain the study records. You should check with each of the study sponsors before discarding any study files.

If investigational records are transferred off-site to a third party (i.e., Contract Research Organization (CRO), sponsor etc.), the sponsor and FDA should be notified by the associated clinical investigator in the form of a final report. A sponsor of an investigational drug study shall retain the records and reports for two years after an approved marketing application or until two years after shipment and delivery of the drug for investigational use is discontinued and FDA has been so notified [21 CFR 312.57(c)].

If a sponsor closed the study the sponsor should have notified FDA. Therefore no future correspondence to FDA is necessary. The notification of the study close should have been sent to the FDA review division overseeing the study.

We strongly recommend that the sponsor contact the appropriate review division within the Center where the IND application was filed to discuss the appropriate IND reporting and closeout requirements.

Additionally, FDA's regulations do not prohibit the off-site storage of study records. If an FDA Bioresearch Monitoring (BIMO) inspection of the research site were to occur, however, FDA investigators would expect to see the original records or certified copies of such. Therefore, the only requirement would be that stored records be made available for inspection when needed for studies involving investigational drugs and/or biologics and 21 CFR 812.145 for studies involving investigational devices. Specifics for storage of study records, and delivery when needed, would be the subject of written legal contracts between the research site and the storage facility. It may also be helpful to establish written standard operating procedures (SOPs) for storage of the records and for tracking who is able to access them, so that the Agency can be assured that the records have not been tampered with or altered and that confidentiality of information has been maintained throughout the duration of the transfer and storage. Any change in location of the study records should be communicated to the study sponsor.

Either method of record keeping is permitted by the regulations and our GCP guidance does not offer any stated preference for one method over the other. In general, our regulatory expectations regarding record keeping focus only on what documentation should be kept and not how or even where, necessarily, it should be maintained. This is deliberate to afford investigators and institutions maximum flexibility in adopting those practices they feel best suit their specific situation.

Your first question - is a legal question. You will have to consult your legal team at your institution or company.

Your second question - Generally if the clinical investigator cannot store the documents, they are returned to the sponsor.

Please see the website. https://www.fda.gov/drugs/investigational-new-drug-ind-application/federal-regulations-clinical-investigators#312.62 It cites the regulations on Investigator recordkeeping and record retention.

**Question 2:**

As previously mentioned, I work for a sponsor and many investigators’ records have been returned to us in the past years for several reasons (e.g., investigator retirement, site closure, inability to store documents, etc.). I have read many Q&A on the FDA website and haven’t found the exact answers to the below questions.

1. According to the regulation, when the investigator’s documents are returned to the sponsor, who remains responsible of the study documents? The Sponsor who is archiving the documents or the Investigator who conducted the clinical trial?

2. As per our interpretation of the regulations, is it correct to mention that “The investigator remains the owner of the material stored in archiving location provided by the sponsor”? Or is it more a legal question?

3. I know that: If an FDA Bioresearch Monitoring (BIMO) inspection of the research site were to occur, however, FDA investigators would expect to see the original records or certified copies of such. In case of site closure or investigator retirement, is the FDA expecting to only see the original records/certified copies OR they are also expecting to meet with some site staff and the Investigator (which could be a difficult task)? The reason why I am asking this question is because as per our SOP, we request the Investigator’s contact information for such situation when the transfer of the study documents is related to a retirement or site closure.

4. If the regulations are silent on my above questions. Does it mean that we need to define these points in our SOPs and agreement?

**Answer 2:**

1. Once the documents are returned to the sponsor, it is the sponsor’s responsibility.

2. See first answer.

3. It depends. Details of the inspection location site can be worked out with the FDA investigator.

4. The more detailed the SOP is, the better. As long as others on staff can follow the SOP as written.