The Site Council
Healthy Relationships with Healthy Sites

Let's Destroy Our Obsolete Paper Study Records: Reader Comments and Questions

By Norman M. Goldfarb

The article, "Let's Destroy Our Obsolete Paper Study Records," addresses issues related to the destruction by study sites of obsolete paper study records. Several readers responded with comments and questions, as discussed below.

What happens to a site's study records if the site or principal investigator (PI) leaves the stage?

Study sites and PIs are separate entities, each with different obligations for the retention of study records:

- Study sponsors contract with study sites (not PIs) to conduct studies and retain study records. Study sites rely on PIs to supervise proper creation of study records for storage. If a PI retires or otherwise leaves the stage, the study site is still responsible to the study sponsor for records storage.
- The FDA generally requires PIs (not sites) to retain study records. PIs rely on their sites to perform the actual record retention, although that obligation is probably not spelled out in a contract. If a PI is also an owner or officer of the study site, they share the site's responsibilities for records storage. In some cases, the PI is a party to the CTA agreement and may also have site responsibilities for that reason. If a study site closes its doors or otherwise leaves the stage, the PI is still responsible to the for records storage.

The FDA permits PIs to delegate their records storage obligation to another person, e.g., a representative of the study site or maybe the site itself:

> An investigator or sponsor may withdraw from the responsibility to maintain records … and transfer custody of the records to any other person who will accept responsibility for them under this part, including the requirements of § 812.145: Records inspection. Notice of a transfer shall be given to FDA not later than 10 working days after transfer occurs. (CFR 812.140(e))

If the PI leaves the stage and has transferred custodianship of the records to the site, the site's regulatory obligation to the FDA survives. The study site's contractual obligation to the study sponsor would also survive.

Similarly, unless explicitly forbidden in the CTA, study sites may contract with other entities to perform certain duties, e.g., records storage. Such an entity may be the PI, a records storage business, or any other suitable person or entity. The site should notify the study sponsor of the new custodian of the records.

If a site leaves the stage, the PI's records storage obligation to the FDA would survive, since the PI's obligation is to the FDA, not the study sponsor. However, if the PI is also an owner or officer of the study site, their personal records storage obligation to the study sponsor may survive.

The "Information Sheet Guidance for IRBs, Clinical Investigators, and Sponsors: FDA Inspections of Clinical Investigators" (June 2010) does not exclude site records from the study sponsor's responsibilities for record retention:

> Sponsors, IRBs and investigators are required to permit authorized FDA employees (for an FDA inspection) reasonable access at reasonable times to inspect and copy all records of an investigation.

The study site or PI may thus able to pass the records storage obligation to the study sponsor.

If the study sponsor closes its doors or otherwise leaves the stage (without transferring its contractual rights to a third party), the site's records storage obligation to the study sponsor expires. The PI never had such an obligation but their obligation to the FDA would survive.

While the FDA generally does not inform investigators when their obligation to store study records has expired, that obligation does expire when records become obsolete.

Other Issues

In addition to FDA rules, study sites may have policies or be subject to state medical liability regulations pertaining to records-retention.

The FDA may inspect records of overseas study sites conducted under a U.S. IND or IDE. If the study sponsor is based outside the United States, sites should check their clinical trial agreement (CTA) for records storage requirements. They should also ask the study sponsor for a copy of that country's pertinent regulations.

If a study site changes its name, moves, terminates its clinical research program, merges, is acquired, or closes, its doors, the study sponsor may not know how to contact the site about study records, patient safety, or other matters. In such cases, study sites may want to update study sponsors with new contact information.

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Caveats

The author is not an attorney and this document does not constitute legal advice. Laws and regulations can be subject to interpretation and, depending on the circumstances, may or may not be stringently enforced.

About the Author

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