

Good Clinical Practice Q&A: Focus on Study Documents

What procedures are necessary to ensure that copies of source documents can be considered certified?

Copies of source documents are usually considered as valid as originals as long as they are certified copies. A certified copy is a document that has been certified by a qualified person to be an exact copy of the original record and to have all the same attributes and information as the original.

This means that an individual, typically a medical records specialist, ensures that the copies represent the totality of the original source documents. Certification means that this individual has verified the integrity of the photocopying process and that no portion of the original has been altered or deleted (e.g., that handwritten notes in the margins and back pages of the original records are accurately captured). The verification process should be documented in a standard operating procedure or operations manual and, of course, should include the dated signature of the individual ensuring the integrity of the process.

In its April 1999 draft industry guidance entitled, "Computerized Systems Used in Clinical Trials," the FDA defines certified copy as "a copy of original information that has been verified, as indicated by dated signature, as an exact copy having all of the same attributes and information as the original." The same definition appears in the agency's September 2004 draft revisions to the April 1999 guidance. While the April 1999 guidance addresses certified copies in the context of electronic records, FDA officials maintain that this definition is just as relevant to paper-based records.

Certified copies are typically used in source data verification when original documents are unavailable due to litigation proceedings, or less commonly, when original records are transported from one healthcare facility to another. The key issue in the use of certified copies is the robustness of the verification process as demonstrated by written documentation of both the process and the individual copies.¹

What is the recommended course of action for an investigator if he/she retires and no longer has the ability to store source data and essential documents from a clinical trial? How is this addressed if an institution has a policy of destroying records after a period of time that is shorter than the time period mandated by the FDA?

According to 21 CFR 312.62, "An investigator shall retain records required to be maintained under this part for a period of 2 years following the date a marketing application is approved for the drug for the indication for which it is being investigated, or, if no application is to be filed or if the application is not approved for such indication, until 2 years after the investigation is discontinued and FDA is notified."

If an investigator retires and is unable to store the study data, he/she must transfer custody to another person who will accept responsibility for them. The investigator should provide a written notice of this transfer to the sponsor. This notification should be maintained in the investigator file.

If an investigator is conducting a study in an institution that will otherwise destroy records before the FDA-mandated record-retention period, then the investigator must request that

the institution make an exception to its policy to honor the requisite record-maintenance period. In other cases, the sponsor might provide for off-site storage of the study records. In all cases, an investigator should be reminded not to destroy any study records without first checking with the sponsor, and record retention requirements should be specified in the protocol.²

References

1. "Good Clinical Practice: A Question & Answer Reference Guide", Barnett International, 2005, pgs. 138-139
2. Ibid, pg. 142

Source

"Good Clinical Practice: A Question & Answer Reference Guide 2005," is available for \$39.95 at <http://www.barnettinternational.com/>