Issuing Department: Human Subjects Protection Program
Policy Number: 2015-024.1
Policy Title: Record Retention Formats

Purpose

The purpose of this policy is to set forth acceptable formats for meeting record retention requirements of paper documents.

Definitions

Policy

Policy 2011-024.0, File Requirements & Record Retention Requirements, sets for the documents that must be retained and the minimum time frames for which the files must be maintained. This policy sets forth acceptable formats for the required retention of documents that originated in paper form.

Retention in Paper Format:

Files may be maintained and retained in paper format. If stored off-site the files must be retrievable within a reasonable time frame for inspection and copying. *(Note: Off-site storage must be with an approved UConn Health vendor.)*

Retention of Paper Forms in Electronic Format:

Either during the course of the study, or after study closure, it is acceptable to maintain scanned copies of the original paper documents. The scanned copies must be "Certified Copies" which is defined in FDA Guidance as "a copy of the original information that has been verified, as indicated by a dated signature, as an exact copy having all of the same attributes and information as the original"

For externally funded research the investigator must obtain approval from the funding entity for the electronic storage of the paper forms.

If plans for electronic storage of paper forms were not described in the original submission to the IRB, a request for modification must be submitted. The request, whether submitted at the time of initial review or as a modification, should be inclusive of identification of documents that will be converted to electronic format, a standard operating procedure for verifying that all documents have in fact been scanned completely (e.g. no missing documents, no missing pages within a document, all pages are legible) and saved successfully before any paper versions are destroyed, plans to ensure the confidentiality of the data, plans for secure destruction of the original documents, and if applicable, documentation that the funding entity approves of the electronic storage format.

Prior to scanning, each original paper form must have a written statement similar to the following on the first page "Copy Certified by [insert name] on [insert date]". The scanning must be done by the person certifying the form and on the date the form is certified.

All records stored in electronic format must be available for inspection and copying.

Procedure

As applicable, approval is obtained from funding entity for electronic storage of documents.

Approval is obtained from the IRB, either as part of initial review or through a request for modification, for the electronic storage of certified copies of paper documents. The material to be submitted to the IRB is inclusive of:

- Identification of which documents will be converted to electronic format
- Standard operating procedure for converting paper file to electronic file, including certification process, verification process, and destruction process
- Plans for confidentiality of electronic files
- Approval from the funding entity for the electronic storage, as applicable
- Confirmation that electronic documents will be available for inspection copying.

Related Policies

2011-024.0 – File Requirements & Record Retention Requirements

Basis

Guidance for Industry, Computerized Systems Used in Clinical Investigations, FDA 2007
Replies to Inquires to FDA on Good Clinical Practice, Recordkeeping and Record Retention, March 5, 2014

Document Attributes

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Reviewed and Approved By:

Richard Simon **12/29/2015**

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