

Office of Clinical Research (OCR)

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Responsibility: OCR		Page 1 of 3
Policy 1.3.4		

GUIDELINES FOR CERTIFIED COPY CREATION FOR ELECTRONIC BINDERS SOP

- Purpose** The purpose of this standard operating procedure (SOP) is to provide guidance to research personnel relating to certified copies. This SOP also serves to ensure data quality by establishing verification checkpoints to confirm that data are present, complete, and accurate.
- Scope** This SOP applies to the activities involved in creating a certified copy of an original source document or data. A certified copy is defined as a copy of original information that has been verified as an exact copy having all of the same attributes and information as the original. A certified copy (irrespective of the type of media used) of the original record has been verified (i.e., by a dated signature or by generation through a validated process) to have the same information, including data that describe the context, content, and structure, as the original. Original source data may be captured on paper or as a part of an electronic record. An electronic record is any combination of text, graphics, data, audio, pictorial, or other information representation in digital form that is created, modified, maintained, archived, retrieved, or distributed by a computer system.

Procedure

A. Preface

- a. When a copy is used to replace an original document (e.g., source documents, CRF), the copy should fulfill the requirements for certified copies.
- b. All data must be verifiable, and all documentation needs an audit trail. ALCOA should be utilized in all cases to achieve data quality. (Attributable, Legible, Contemporaneous, Original, Accurate).
- c. If the original document or data (paper or electronic) is retained elsewhere, the copy does NOT need to be certified (e.g., original e- signature on Protocol Signature Page is maintained in a 21CFR11 compliant system).
- d. Copies received from an outside institution will be considered an unaltered copy as received.
- e. Monitors and FDA auditors may request to see the original documents or certified copies to verify validity of data for trial related monitoring.
- f. Items that are defined as copies and NOT originals include:
 - i. Documentation received via fax
 - ii. Printouts retrieved from a computer system

B. Paper Source to Paper Copies

Certification of a paper copy may be indicated by any of the following methods:

1. A signed/initialed and dated statement on the copy that indicates it is an exact copy of the original information.
 - a. This is to be done by the individual making the copy, or the individual verifying that the copy is the same as the original.
 - b. The statement may be in the form of a stamp as long as it is accompanied by an original signature/initials and date.
2. Signature/initials and date without a statement
 - a. The dated signature/initials indicate that the signer has verified that the copy is an exact copy of the original as per this SOP.
3. Documents consisting of multiple pages may be verified as a packet if the packet is to remain intact in the paper file and clarification of the copy may be indicated by any of the following methods:
 - a. The first page of the copy must have a signed and dated statement that indicates that the package consisting of a specific number of pages is an exact copy of the original information.
 - b. Each page must be initialed and dated to verify that it is part of the package.

C. Paper Source to Electronic Copies

Certification of a paper source to electronic copy may be indicated by any of the following methods:

1. A electronically signed/initialed and dated **copy** that indicates it has been reviewed and is an exact copy of the original information.
 - a. This is to be done by the individual making the **scan**, or the individual verifying that the **copy** is an exact copy of the original document.
 - b. At the time the electronic **scan** is created, the individual making the scan should verify that the electronic copy is an exact copy of the original document.
 - c. The electronic copy of the original will be uploaded and stored on Complion and electronically signed to indicate that it has been reviewed.
2. An electronic copy of the original is uploaded into Complion in the following manner:
 - a. The individual making the **scan** or the individual verifying that the **copy** is an exact copy will upload the electronic copy
 - b. No additional documentation will be required since the electronic copy will contain the audit trail with name, date, and time the action was completed (auto-generated by Complion).
3. Documents consisting of multiple pages may be verified as a packet if the packet of copies is to remain intact in the electronic file. Certification of the copy may be indicated by any of the following methods:
 - a. At the time the electronic scan is created, the individual making the scan must verify that the electronic copy is an exact copy of the original and contains all the pages. The electronic copy of the original document is uploaded and stored in Complion and electronically signed by that same individual.
 - b. If the person who verifies that the scan is an exact copy is not the same individual uploading the document into Complion, the person uploading the document will verify that the exact copy that is being uploaded has been verified (signed, dated and initialed) by the originator

of the exact electronic copy. Complion will automatically establish an audit trail with name, date and time that the action of uploading was completed.

D. Electronic Source to Electronic Copy

Certification of an electronic copy may be indicated by the following method:

1. An electronically signed and dated copy that indicates that it has been reviewed to be an exact copy of the original information.
 - a. Completed by the individual making the electronic copy, or the individual verifying that the copy has been verified as an exact copy prior to being uploaded into Complion.
 - b. When a copy of the original is uploaded and stored directly in Complion, the individual completing that task should verify that the copy is the exact copy of the original using an electronic signature applied directly in Complion which documents the verification.
2. An electronic exact copy of the original is stored in Complion
 - a. The individual who created or verified the exact signed electronic copy uploads the document into Complion. No additional documentation is required, since the system creates an audit trail with the name, date, and time that the action was completed.
3. Validated process of an electronic copy of the original is stored in Complion.
 - a. Validation of this process has been completed by the site, prior to users being granted permission to use the site.
 - b. When the electronic copy is created or obtained (downloaded from portals, received via email) the individual making the copy verifies that the electronic copy an exact copy of the original (source document).
 - c. Copies of emails and any corresponding attachments uploaded directly into Complion via the Outlook integration have been validated to be the same as the original.
 - d. The copy of the original is with name of verifying individual, date and time is uploaded into Complion and that action is recorded as an audit trail with name, date, and time by Complion.
4. Documents consisting of multiple (more than (1)) pages may be verified as a packet if the packet of copies is to remain intact in the electronic file and certification of the copy may be indicated by any of the following methods:
 - a. At creation of the electronic copy, the individual making the **scan** must verify the electronic copy is an exact copy of the original and contains all the pages. The exact copy of the original is stored in Complion and electronically signed to create an audit trail.
 - b. At creation of the electronic copy, the individual making the **copy** must verify that the electronic copy is an exact copy of the original and contains all the pages. The exact copy (with signature of person attesting to the content) is placed in Complion after the individual has confirmed that the verification has occurred. The action of uploading is documented with an audit trail in Complion.

Applicable References to Regulations

21 CFR 11

FDA Guidance: E6 (R2) GCP