

SOP#: ADCR-8

Certifying Scanned Paper Documents

Version #: 2.0

Next Review Date: 01/2026

Approved Date: 01/2024

Review Interval Period: Biennial

**NCI Clinical Director Signature/
Effective Date:**

POLICY

Research source documents originally collected in paper form at NIH (e.g., drug diaries) must be maintained for the duration of the research study. Paper research records can be scanned into an electronic version, verified and certified identical to the paper version. The person certifying the scanned copy must have the original paper document for comparison. Once the scanned electronic version is certified, the paper version can be destroyed via appropriate method. The certified scanned copy is locked and cannot be changed.

Only certified copies should be uploaded to CRIS. If not a certified scanned version, then the original paper document needs to be maintained.

As paper research source records will typically contain Personally Identifiable Information (PII), the transmission of the scanned version must be in a secure manner (e.g., encrypted email, directly to a team network shared folder). PII cannot be redacted as the scan must be identical to the original paper version.

This process may also be used for other paper documents (e.g., Delegation Log, monitoring visit log).

NOTE: Scanned outside medical records are not considered source documents and are not required to be certified since the original source is maintained at the outside facility.

DEFINITION

Certified Copy is a copy of 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, per FDA guidance document [Use of Electronic Records and Electronic Signatures in Clinical Investigations Under 21 CFR Part 11 – Questions and Answers.](#)

PURPOSE

To describe the procedure for certifying copies of original paper source documents and maintaining certified electronic copies in a secure electronic system (e.g., shared folders, CRIS, or electronic database).

RESPONSIBILITIES

- Principal Investigator: The Principal Investigator is responsible for ensuring the paper source document is appropriately scanned and verified as a certified copy of the original document, prior to destruction of the paper source document. These responsibilities include, but are not limited to:
 - Identifying which original source documents will be scanned
 - Identifying the individual who will perform the quality control review and scan of the source document
 - Identifying the individual who will verify and certify the scanned document
 - Determine the management of the certified electronic copy and the original source document. Once an electronic copy is certified as complete and accurate (Step 6), the original paper version may be shredded.
 - Determine the time frame for completing these procedures
- PI may delegate the role of scanning the paper source document as well as verifying the scanned copy, to an appropriately trained staff person. This delegation must be documented (e.g., on the Delegation Log, Data Management Plan, or team meeting minutes).

PROCEDURES

STEP 1: Secure Appropriate Scanner

- The scanner must be attached directly to a computer or to a computer docking station to ensure that a secure connection is maintained for scanning paper records that contain PII.
- If a docking station with an attached scanner is used, the computer must have the scanner software loaded to be able to use the scanner. Contact the [NCI At Your Service](#) to load required software onto computer.
 - A scanner can be obtained from your Branch Administrative Officer

STEP 2: Identify Protocol Document Types for Scanning

- Any research documents that are originally maintained/collected in paper format may be scanned and stored electronically.
- Examples of document types:
 - Patient questionnaires
 - Participant drug diaries, seizure charts, symptom log, temperature recordings
 - Delegation of tasks logs/signature logs
- Other paper documents where source data are collected

STEP 3: Identify Permanent Location of Electronic Certified Copies of Source Document

- Identify a secure location to maintain electronic certified copy of source document (e.g., CRIS and/or team specific shared folder in the subject's electronic research record)
- The PI or designee will determine who is allowed to access the secure location

STEP 4: Perform Quality Control Review of Paper Document

- Completed by the delegated research staff to ensure the documents are compliant with ALCOA-C (See Appendix A), i.e., source documents should be attributable, legible, contemporaneous, original, accurate and complete.
 - Consult with team member(s) who generated the paper source document if document is incomplete.
 - If the paper source document can be appropriately corrected or completed, by the author, this should be done prior to scanning.
- Prepare all documents for scanning by removing paper clips, staples, sticky notes (which are not part of the source document), and other extraneous materials.

STEP 5: Scan Paper Document

- Once the quality control review has been completed, the original paper source document will be scanned by the individual who performed the quality control review into a pdf document.
- The scanned electronic copy must be saved in a secure folder on a password protected location. This version is not yet certified.

STEP 6: Verify and Certify Scanned Copy as an Exact Copy

- The individual who verifies and certifies the scanned copy as an exact copy of the original paper form should be a different person than the individual that performed the QC review and scan if possible. This person must also be able to access the secure folder.
- The individual that certifies the scanned copy **MUST** have the original paper document for comparison. Staff that do not have access to the actual paper documents cannot certify the scanned copy.
- The verification process entails:
 - Each page of the scanned document is clear, readable and complete compared to the original paper source document
 - All pages are present
 - No extraneous marks are noted on the copy relative to the source
- Once the verification process is complete, the reviewer must certify the scanned copy and lock the pdf document (see Appendix B). This will validate that the document is scanned accurately and is a true duplication of the original paper document.
- Once the scanned documents are archived electronically, they are available for review for auditing, monitoring, and inspection by any regulatory authority.

Note: Appendix B specifies the use of “Certify (Invisible Signature)” because this process has less steps than “Certify (Visible Signature).” It is acceptable to use “Certify (Visible Signature)” as well to certify scanned copies.

STEP 7: Destroy Paper Records

Once there is a certified electronic version, paper documents may be destroyed by shredding or placing in a secure shred box.

Appendix A: ALCOA-C

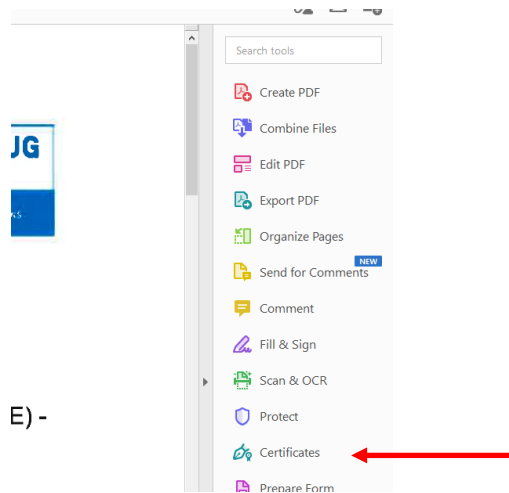
The investigator/institution should maintain adequate and accurate source documents and trial records that include all pertinent observations on each of the site's trial subjects. Source data should be attributable, legible, contemporaneous, original, accurate, and complete. Changes to source data should be traceable, should not obscure the original entry, and should be explained if necessary (e.g., via an audit trail). (ICH GCP E6R2 4.9.0 and ICH GCP E6R2 4.9.1)

- **Attributable:** The person who completed the form should be indicated on the document, e.g., study team member, participant, other staff member
 - It should be clear who the data refers to, when the data was observed and recorded, and who made the observation and recorded the data. Each page or electronic source document should include the subject code, the signature of the investigator collecting the data and the date the data was obtained.
- **Legible:** All data elements are clear and readable, and signatures are identifiable.
- **Contemporaneous:** The data should be recorded in a timely manner in relation to when the data was collected.
- **Original:** The source document should be in original form
- **Accurate:** Data should be accurate and made without error. If errors are discovered, they should be corrected per GCP guidelines, i.e., single line through error, correction clearly written, initialed and dated.

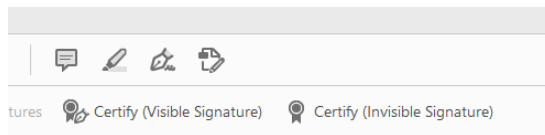
Complete: All required fields should be completed. If data are missing, the reason for missing data should be documented.

Appendix B: Certifying Scanned Copy

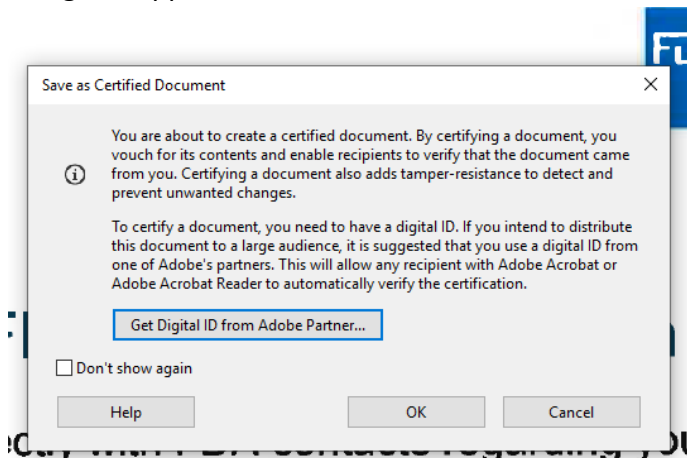
1. Open pdf document in network drive.
2. Under Tools, Select “Certificates” on right side of pdf. If you don’t have certificates listed, use search box at top right.



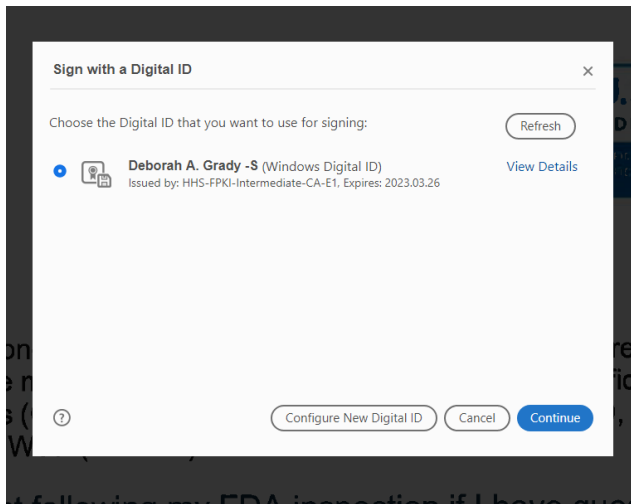
3. Click on “Certify (Invisible Signature)” top center of screen.



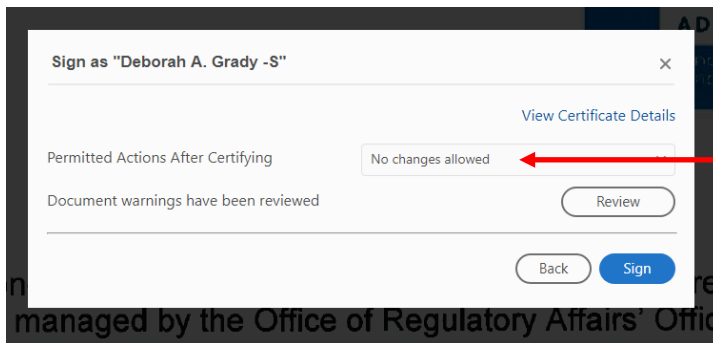
4. The following will appear, select “OK.”



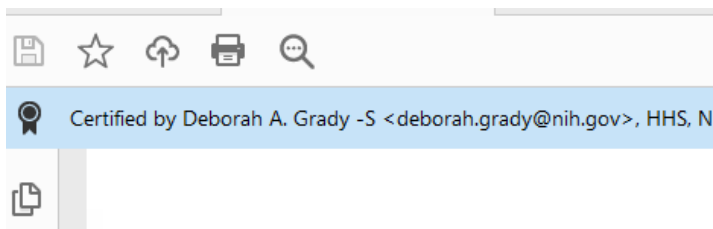
5. The following will appear with the digital ID associates with your account. Select “Continue.”



6. The following will appear. For Permitted Actions After Certifying, select “No changes allowed” then click on “Sign”



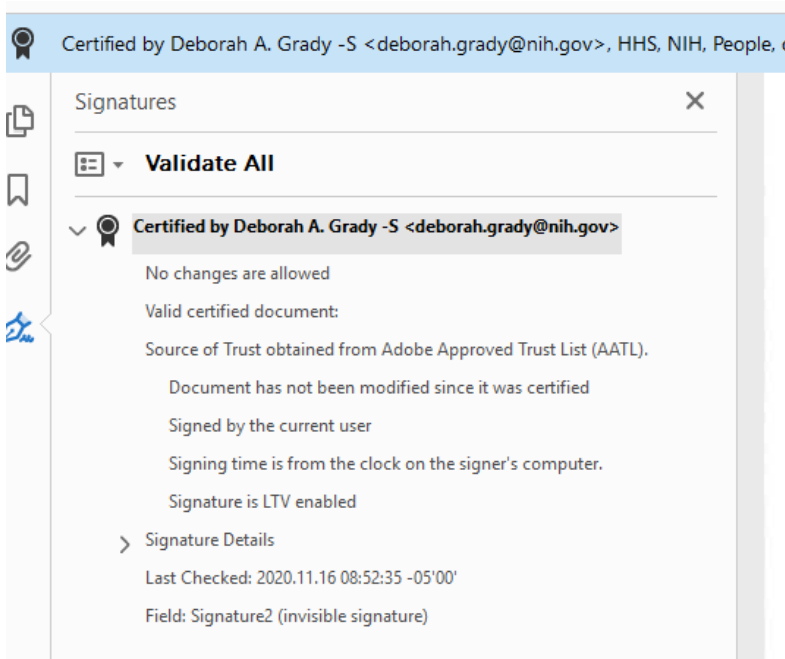
7. On the upper left of the document, the following will appear “Certified by . . .”



8. To get details of when the certificate was applied, click on "Signature Panel" on right side.



9. Information about when the signature was applied will appear:



10. When the pdf is next opened and any attempt is made to edit it, the following will appear:

