Certified Copies of Clinical Research Records	CR-407
Clinical Research Standard Practices	**Effective Date:** September 2024

SCOPE AND PURPOSE The document is applicable to the following people of Penn State College of Medicine and all Penn State Health entities engaged in clinical research:

X	Principal Investigators	X	Regulatory Specialists
X	Sub-Investigators	X	Key Study Ancillary Personnel
X	Study Coordinators/Associates	X	Financial Analyst/Research Accountants
X	Data Specialists	X	Central Research Office Personnel

This standard operating procedure (SOP) describes the procedure for the creation of certified copies of research documents, whether regulatory documents or participant documents. A certified copy is a reproduction of an original document that has been verified, as indicated by a dated signature, as an exact copy having all the same attributes and information as the original. This SOP also serves to ensure data quality by establishing verification checkpoints to confirm that data are present, complete, and accurate. This SOP does not apply to copies and non-originals such as documentation received via fax or printouts retrieved from a computer system (e.g., patient charts or health/medical records, IXRS confirmations, etc.).

When conducting human subjects research, investigative site personnel may be required to retain research records in compliance with applicable laws, regulations, institutional policies, and agreements. Investigative site personnel may maintain electronic copies of the research records to:

- Increase accessibility of the documents amongst the appropriate study team members.
- Reduce physical storage needs.
- Reduced risk of loss or damage: Paper documents are susceptible to loss, damage, or deterioration over time. Electronic copies are less vulnerable to these risks, and backups can be easily maintained to prevent data loss.
- Enhanced security due to storage on one of the investigative site's HIPAA-compliant solutions.
- Searchability and indexing allows for efficient retrieval and management of records.
- Compatibility with digital workflows in the hybrid and remote work-environments of the investigative site and can be access remotely by Sponsors and CROs when used with the investigative site's eRegulatory system.
- Enhanced auditability as the electronic documents can be tracked, timestamped, and logged more effectively, making it easier to monitor the history and usage of certified copies.

As study and Sponsor requirements will vary, it is the responsibility of the Principal Investigator (PI) to ensure there is documentation of Sponsor's approval for the electronic storage of certified copies of source documents prior to implementation.

POLICY AND PROCEDURE STATEMENTS

1. General principals
    a. When a copy is used to replace an original document (e.g., source documents, etc.), the copy should fulfill the requirements for certified copies.
    b. All data must be verifiable, and all documentation needs an audit trail. ALCOA-C should be utilized in all cases to achieve data quality. (ALCOA-C = Attributable, Legible, Contemporaneous, Original, Accurate, Complete).
    c. All consent forms, assent forms, and HIPAA authorizations that include originals signatures must be maintained. Certified and copies are not permitted for these documents.
    d. 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). A certified copy is typically intended to replace an original source document (e.g., electronically store a paper document, copy of a paper document that has been lost/misplaced, etc.).
    e. Copies received from an outside institution will be considered an unaltered copy as received and no certification is required.
    f. Original paper documents should be retained for as long as feasible while the study is open to enrollment through participant follow-up and data analysis.
        i. When destroying the original documents, all documents should be treated as if they contain confidential and protected health information thus should be shredded or otherwise obliterated.
    g. Once original documents stored on electronic media (including but not limited to USB drives, CDs, DVDs, etc.) have been transferred off, the electronic media should be handled per institutional policies and procedures. Reusable media may be reused once it has been properly erased.
    h. Monitors and FDA auditors may request to see the original documents or certified copies to verify validity of data for trial related monitoring.
    i. If the research is FDA regulated, the systems and procedures must be FDA compliant (including 21 CFR 11)
    j. The individual certifying a copy should be the individual making the copy/scan of the original document(s); however, it must be the individual who verifies that copy is true and accurate copy that contains all the same attributes and information as the original.
        i. The PI does not need to be one to certify the copy; however, the integrity and compliance of the certification process is the responsibility of the PI.
    k. The certified copy shall contain the following elements:
        i. The statement “I hereby certify that the attached digital copy is an accurate and complete representation of the original, having all of the same attributes and information.”
            - The above statement can be on a cover page or placed on the first page of copy.
            - If the copy is also a paper document, the statement can be printed on a label that is then placed on the first page of the document or handwritten on the first of the page of the document.
            - If the above statement is placed on a cover page, a description of the brief document being copied should be included.

- A template cover page can be found on the CTO website.

ii. "COPY" on each page

iii. Page number in the format "X of Y" where X is the current page and Y is the total number of pages in the document.

- If a cover page is used, the cover page should NOT be included in the count of total pages.

l. For documents containing more than 20 pages, certified copies should be verified by a second person.

m. For certified copies in an electronic format:

i. In general, source documents should be scanned under parameters that would generate the best replication of the original document.

ii. Source documents should be scanned and saved as PDF files.

iii. Scanning procedures should consider source type (e.g., hand-written notes, photographs, or print), resolution quality, and file size (e.g., documents scanned in color render larger file sizes).

iv. Documents stored on electronic media should be maintained in compliance with institutional polic**y** *Retention of Clinical Research Records* (CR-211)

2. Paper Source to Paper Copies

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

i. A signed and dated statement on the copy that indicates it is an exact copy of the original information. The printed name of the person verifying the copy should appear with the signature.

- This is to be done by the individual making the copy, or the individual verifying that the copy is the same as the original.
- The statement may be in the form of a stamp if it is accompanied by an original signature/initials and date.

ii. 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:

- 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.
- Each page must be signed/initialed and dated to verify that it is part of the package.
- A signature stamp is prohibited from being used.

b. Copies shall contain the elements listed in 1.k above.

3. Paper Source to Electronic Copies

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

i. An electronically signed and dated copy that indicates it has been reviewed and is an exact copy of the original information.

- 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.

- 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.
- The electronic scan shall be merged with a cover page containing the following certification statement listed in section 1.k above, as well as the other required elements
- The electronic copy of the original will be electronically signed according to institutional policy *Electronic Signatures* (CR-402). The electronic copy is to then be uploaded and stored in accordance with institutional policies/SOPs *Regulatory Files and Subject Records* (CR-211) and *Use of Florence eBinders* (CR-406).

ii. An electronic copy of the original is uploaded into Florence eBinders using ePrinter function in the following manner:
- The individual making the copy or the individual verifying that the copy is an exact copy will upload the electronic copy.
- Copies shall contain the elements listed in 1.k above.
- 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 Florence eBinders).
- The individual making the copy will mark the document as containing PHI, if applicable.

4. Electronic Source to Electronic Copy
   a. Certification of an electronic copy may be indicated by the following method:
      i. An electronically signed and dated copy that indicates it has been reviewed and is an exact copy of the original information.
         - This is to be done by the individual making the copy, or the individual verifying that the copy is an exact copy of the original document.
         - At the time the electronic copy is created, the individual making the scan should verify that the copy is an exact copy of the original document.
         - The electronic copy shall be merged with a cover page containing the following statement listed in section 1.k as well as the documents elements listed.
         - The electronic copy of the original will be electronically signed according to institutional policy *Electronic Signatures* (CR-402). The electronic copy is to then be uploaded and stored in accordance with institutional policies/SOPs *Regulatory Files and Subject Records* (CR-211) and *Use of Florence eBinders* (CR-406).

      ii. An electronic copy of the original is uploaded into Florence eBinders using ePrinter function in the following manner:
         - The individual making the copy or the individual verifying that the copy is an exact copy will upload the electronic copy.
         - Copies shall contain the elements listed in 1.k above.

- 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 Florence eBinders).
- The individual making the copy will mark the document as containing PHI, if applicable.

iii. An electronic copy of the original is uploaded into Florence eBinders using Duplicate function in the following manner:
- The individual making the copy or the individual verifying that the copy is an exact copy will upload the electronic copy.
- Copies shall contain the elements listed in 1.k. above.
- 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 Florence eBinders).

RELATED POLICIES AND REFERENCES

Clinical Research Guidebook (https://research.med.psu.edu/research-support/guidebook/)

Clinical Trials Office website (https://research.med.psu.edu/cto/)

Code of Federal Regulations: Electronic signatures (21 CFR 11)

FDA Guidance "Part 11, Electronic Records; Electronic signature – Scope and Application. September 2003

International Conference on Harmonization Good Clinical Practice E6(R2)

Responsibilities of the Research Team (CR-103)

Regulatory Files and Subject Records (CR-211)

Data Management (CR-401)

Electronic Signatures (CR-402)

Retention of Clinical Research Records (CR-404)

Use of Florence eBinders (CR-406).

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