Retention of Clinical Research Records	CR-404
Clinical Research Standard Practices	**Effective Date:** September 2024

SCOPE AND PURPOSE This document is applicable to the following roles within Penn State College of Medicine and 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 policy describes the minimum retention period for clinical research records, the process for securing records for long-term storage, and destroying records as the end of the retention period.

This SOP may be shared with Sponsors and/or CROs upon request.

POLICY AND PROCEDURE STATEMENTS

1. Store in a secure location for a **minimum** retention period of six years from the date of study closure with the IRB as all studies conducted at the College of Medicine and Penn State Health involve obtaining an authorization or a waiver of health information under Health Insurance Portability and Accountability (HIPAA).
    a. Due to evolving technologies, electronic records should be stored on Penn State Health Information Services (PSH IS)/College of Medicine Information Technology (COM-IT) approved platforms.
        i. As PSH IS/ COM-IT approved platforms and solutions changes, notification of a Sponsor is not required.
    b. Electronic records should not be stored on portable electronic media (e.g., CD, USB jump drive, etc.) as the primary method of long-term storage as these media can become obsolete and records can no longer be reproducible and/or easily lost.
    c. If electronic records are to be stored on portable electronic media, regular checks (at least annually) are to be performed to ensure the records remain accessible and readable.

2. Records may be destroyed once the longest retention requirement has been met of the following applicable standards:
    a. Clinical Trial Agreement (CTA) or Subaward agreement
    b. For FDA-regulated products: two years after the study is completed/terminated or the date that the records are no longer required for purposes of (whichever is later):
        i. supporting a premarket approval application,
        ii. a notice of completion of a product development protocol,
        iii. a humanitarian device exemption application,
        iv. a premarket notification submission,

v. a request for De Novo classification

c. For NIH-funded studies: as required by the NIH Grants Policy Statement in effect at the time of the award.

3. Any records not being stored in departmental spaces are to be managed and maintained by the College of Medicine Clinical Trials Office (CTO). Any records being stored off-site must be managed by the CTO, unless written approval is received from the CTO Director.
    a. For this policy, off-site means any location where College of Medicine or Penn State Health operations do not occur regularly on business days.

4. Once the retention period has lapsed, the records may be destroyed. When applicable, the Sponsor will be notified prior to destruction as indicated in the CTA.
    a. If a Sponsor/CRO requires the investigative site to receive approval prior to destroying, Sponsor agrees to respond within 30 days of receipt of Institution's request to destroy the records. If after 90 days of the first of three attempts (no sooner than three weeks apart) to contact Sponsor in writing. Institution has not received a response. Institution shall be permitted to destroy the any records after meeting all commitments.
    b. If Sponsor/CRO will not agree to the above, Sponsor must maintain contact with the investigative site, via the CTO, after the termination of the Study to ensure the Institution is able to contact Sponsor at such time that Institution should request destruction of study records as the retention period has lapsed. Sponsor shall notify the investigative site annually of their current business address and name under which they do business.
        i. If the investigative site is unable to establish contact with Sponsor, the Institution should not be required to retain records indefinitely, at the investigative site's expense.
    c. The proposed sets of language offer the investigative site the ability to destroy study records once all legal obligations to federal and local statutes have been met, and contractual obligations cannot be met for whatever reason.

RELATED POLICIES AND REFERENCES

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

Code of Federal Regulations: Investigational New Drug Application (21 CFR 312.60, 62, & 68)

Code of Federal Regulations: Investigational Device Exemption (21 CFR 812.140)

Code of Federal Regulations: Investigational Device Exemption (45 CFR 164.514 & 530)

International Conference on Harmonization Good Clinical Practice E6(R2)

NIH Grants Policy Statement: Record Retention and Access

APPROVALS

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DATE OF ORIGIN AND REVIES

Date of origin: November 2023 (previously included in CR-211: Regulatory Files and Participant Records)

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CONTENT REVIEWERS AND CONTRIBUTORS

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HISTORY OF REVIEWS AND REVISIONS

August 2024	
Policy and Procedure Statements	Information regarding the storage of records by electronic means added.
Approvals	“Authorized” and “Approved” switched to align with CR-101.
History of Reviews and Revisions	Section added.