UNIVERSITY OF SOUTH ALABAMA

CT 312 RECORD ARCHIVING & RETENTION

EFFECTIVE DATE: July 2024

Purpose

This policy and procedure describes the proper retention and storage of research records for studies that are initiated and/or coordinated through the University of South Alabama Clinical Trials Office and/or any affiliates. This policy is intended to ensure compliance with all applicable Food and Drug Administration (FDA) Code of Federal Regulations, the International Conference on Harmonization (ICH) Guidelines (E6) for Good Clinical Practices (GCPs), Department of Health and Human Services (DHHS), Office for Human Research Protections (OHRP) regulations, USA Institutional Review Board's Policies, and Procedures for HIPAA Privacy in Research and Confidentiality for clinical studies, where applicable.

Scope

This policy and procedures apply to all clinical trials that are conducted through the University of South Alabama (USA) Clinical Trials Office (CTO).

Definitions

Medical Record- The Medical Record may be either a hospital or affiliate office record and is a file that is created and maintained for every individual and each clinical event of being evaluated and/or treated as either an inpatient, outpatient, ambulatory or emergency patient. The Medical Record contains patient specific information, as appropriate, to the care, treatment, and services provided, and it may be paper-based, in an electronic format, or a combination of both. The Medical Record is the property of the University of South Alabama and/or its affiliates as stated above and shall not be removed except by subpoena, court order, or applicable State of Alabama statute. Medical records relating to study subjects that are not submitted to the sponsor may include some of the same information as is included in the Research Records; however the sponsor has no claim of ownership to those documents or the information they contain.

Research Record- The Research Record includes all data recorded, collected, and/or results arrived at per the requirements of a research study protocol or scientific inquiry. The Research Record may include but is not limited to: research proposals, research protocol, laboratory records, both physical

and electronic, progress reports, abstracts, theses, case report forms or their equivalent, electronic data records, regulatory files, pharmacy records, IRB communications, signed informed consent forms, as well as any other documents or materials created for the Study and required to be submitted to a Sponsor or its agent, such as protocol required X-rays, MRIs, or other types of medical images, ECGs, EEGs, or other types of tracings or printouts, or data summaries, oral presentations, internal reports, journal articles, thesis dissertations and any documents or materials provided to a governmental agency such as the Department of Health and Human Services (DHHS), or an institutional official by a respondent.

Policy

Investigators are responsible for maintaining study documents in accordance with applicable federal regulations, International Conference on Harmonization (ICH) Good Clinical Practice (GCP) Guidelines, Health Insurance Portability and Accountability Act (HIPAA) requirements and departmental procedures. Study documents must be readily accessible for audit by the Food and Drug Administration (FDA), approving Institutional Review Board (IRB), and/or departmental personnel as appointed by the Department Chair.

The Principal Investigator is the custodian of the research records and is the responsible party for research record preservation, retention, and storage.

The Principal Investigator is responsible for ensuring all study documentation is maintained in a complete, presentable and organized fashion. The Principal Investigator or designee must maintain and retain documents in adherence with this policy and procedure.

Study records must be retained for a specific amount of time depending on the regulations and policies that apply to the specific research study. For studies where multiple regulations and/or policies apply, the records must be maintained for the period which is longest. Furthermore, a fully executed contract involving a specific research study and any research record ownership, storage, and/or retention requirements agreed upon within the contract, may supersede the requirements of this policy.

Retention Periods:

HIPAA: 6 years after the study completes participation
NIH: 3 years after the completion of the study
FDA- IND: 2 years following the date a marketing application is approved or abandoned (or as required by sponsor)
FDA- IDE: 2 years following the date a product receives premarket approval or is abandoned (or as required by sponsor)
DHHS: 3 years after the completion of the study

Procedure

1. Storage Conditions and Security of the storage area or facility
    a. The storage area or facility should be conducive to the stability and protection of the records, preventing accidental or premature destruction of the records.
    b. The storage area must be secure, and have limited physical and/or electronic access to research records in order to protect them from accidental or un-intentional release to unauthorized persons, to prevent the alteration, destruction, or loss of research records, and ensure the protection of confidential or proprietary information.
    c. If research records are stored off-site (not on USA property or within the affiliated PI's place of business), then an arrangement that protects the confidentiality of the research records must be in place, such as a Business Associate Agreement (BAA) between USA and the off-site storage facility prior to placing any records there for storage.

2. Labeling and tracking stored records
    a. All study documents (regulatory, pharmacy, patient files, lab manual, temperature logs, etc.) should be packaged together in a banker's box.
    b. The storage box should be clearly and accurately labeled on the outside with protocol number, PI, and sponsor name.
    c. A barcode should be placed on the outside of the storage box.
    d. A list of the box contents should be made. A label with the same barcode number as the outside should be placed on the contents list.
    e. The list of contents with barcode should be retained on-site for quick reference.
    f. The storage box should be entered into the archiving facility's database with corresponding barcode number.

3. Destruction of Research Records
    Refer to the storage guidelines included in this policy in addition to the sponsor contract, as applicable. When the proper storage period for the Research Records has been fulfilled, the destruction of the research records may be considered as follows:
    a. Request permission to destroy- The Investigator should obtain written notification or permission from the Sponsor prior to any record destruction. If the sponsor grants permission for research records destruction, follow their guidelines for destroying the records.
    b. If the sponsor does not have any specific guidelines for destroying research records, or if the study is an Investigator Initiated study, and is not funded by a sponsor, the below process should be followed:

1. Record all paper and electronic documents being destroyed in a log kept within the CTO. The log should include the study name, sponsor, date of destruction, list of documents being destroyed or deleted, and name of person destroying the documents.
2. Shred all paper documents in a confidential shred bin

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Additional Resources

21 CFR Part 11 Electronic Records
21 CFR Part 312.57 Recordkeeping and record retention
21 CFR Part 312.68 Inspection of Investigator's Records and Reports
21 CFR Part 812.140 Records
21 CFR Part 812.145 Inspections
ICH E6, 5.5 Trial Management, Data Handling and Record Keeping
Health Insurance Portability and Accountability Act (HIPAA)

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History

N/A

Next Review Date

July 2027

Responsible Party

Director, Clinical Trials