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 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

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

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)

History

N/A

Next Review Date

July 2027

Responsible Party

Director, Clinical Trials