***Archiving Clinical Trial Study Documentation***

1. **PURPOSE**

This Standard Practice Guideline (SPG) describes the processes to ensure clinical trial study-related documentation is stored, retained, and is retrievable for reporting, auditing, and regulatory purposes. **(MANDATORY LANGUAGE)**

1. **SCOPE**

This Standard Practice Guideline (SPG) applies to clinical trial study-related records that include but are not limited to patient research files, regulatory information (essential documents binder/ electronic file, etc.), e-mail, telephone records, and all other correspondence. The process for archival of the electronic research data, related programming, audit trails, and summarization data is not within the scope of this Standard Practice Guideline.

**(MANDATORY LANGUAGE)**

*[Optional: Insert any additional details necessary to further define the scope of this SPG.]*

1. **POLICY**

**Good Clinical Practice (ICH GCP)**

This Standard Practice Guideline aligns with the Good Clinical Practice (GCP) guidelines established by the International Council on Harmonization (ICH), Section 4.9.7:

*Upon request of the monitor, auditor, IRB/IEC, or regulatory authority, the investigator/institution should make available for direct access all requested trial-related records.*

**FDA Regulation(s)** (if applicable)

Per 21 Code of Federal Regulations Part 312.57:

*Record keeping and record retention require that a sponsor shall retain the records and reports required by this part for two years after a marketing application is approved.*

Per 21 Code of Federal Regulations Part 312.62 Investigator recordkeeping and record retention:

*An investigator shall retain records required to be maintained under this part for a period of 2 years following the date a marketing application is approved for the drug for the indication for which it is being investigated; or, if no application is to be filed or if the application is not approved for such indication, until 2 years after the investigation is discontinued and FDA is notified.*

Per 21 Code of Federal Regulations Part 812.140:

*A participating investigator shall maintain the following accurate, complete, and current records relating to the investigator's participation in an investigation: All correspondence with another investigator, an IRB, the sponsor, a monitor, or FDA, including required reports*

**Additional Regulations or Policies  N/A**

**(MANDATORY LANGUAGE)**

*[Optional: Insert any additional project, department, sponsor, institution, state, or federal policies that apply]*

1. **DEFINITIONS**

ARCHIVE: To place or store in an archive

ARCHIVES: The documents or records relating to the activities of an organization; a place where historical records are kept

ARCHIVIST: A person who has the job of collecting and storing the materials in an archive

AUDITOR: An individual responsible for the systematic and independent examination of trial-related activities and documents to determine whether the trial-related activities being evaluated were conducted and the data were recorded, analyzed, and accurately reported according to the protocol, the sponsor’s standard operating procedures, Good Clinical Practice, and the applicable regulatory requirement(s). (ICH-GCP R2 definition)

GOOD CLINICAL PRACTICE: A standard for the design, conduct, performance, monitoring, auditing, recording, analysis, and reporting of clinical trials that provides assurance that the data and reported results are credible and accurate, and that the rights, integrity, and confidentiality of trial subjects are protected

INDEPENDENT ETHICS COMMITTEE (IEC):

An independent body (a review board or a committee, institutional, regional, national, or supranational), constituted of medical professionals and non-medical members, whose responsibility it is to ensure the protection of the rights, safety and well-being of human subjects involved in a trial and to provide public assurance of that protection, by, among other things, reviewing and approving/providing favourable opinion on, the trial protocol, the suitability of the investigator(s), facilities, and the methods and material to be used in obtaining and documenting informed consent of the trial subjects.

The legal status, composition, function, operations, and regulatory requirements pertaining to Independent Ethics Committees may differ among countries, but should allow the Independent Ethics Committee to act in agreement with GCP as described in this guideline

(ICH-GCP R2 definition)

INSTITUTIONAL REVIEW BOARD (IRB):

An independent body constituted of medical, scientific, and non-scientific members that is responsible for ensuring the protection of the rights, safety, and well-being of human subjects involved in a trial by, among other things, reviewing, approving, and providing continuing review of trial protocol and amendments and of the methods and material to be used in obtaining and documenting informed consent of the trial subjects (ICH-GCP R2 definition)

HUM/IRB NUMBER: A unique number assigned to project applications through eResearch

INTERNATIONAL COUNCIL ON HARMONISATION (ICH): A joint initiative involving both regulators and research-based industry representatives of the European Union, Japan, and the USA in scientific and technical discussions of the testing procedures required to assess and ensure the safety, quality, and efficacy of medicines

MONITOR: An individual who acts as a liaison between the sponsor and the investigator of a clinical study, and who oversees the progress and conduct of the trial; may also be referred to as a Clinical Research Associate (CRA)

NCT NUMBER: A unique number called the ClinicalTrials.gov Identifier assigned to every study on ClinicalTrials.gov

PRINCIPAL INVESTIGATOR (PI):

A Principal Investigator is a doctor who leads the clinical research team and, along with the other members of the research team, regularly monitors study participants’ health to determine the study’s safety and effectiveness

STUDY DOCUMENTATION: All records, in any form (including, but not limited to, written, electronic, magnetic, and optical records; and scans, x-rays, and electrocardiograms) that describe or record the methods, conduct, and/or results of a trial, the factors affecting a trial, and the actions taken

WORK AID (WA)/WORK INSTRUCTION (WIN): A supporting document containing detailed instructions for performing a task to meet the requirements of the SPG

Note: Some of the definitions above were obtained from the IRBMed Glossary. These definitions were current as of 01-Oct-2022 and are subject to change. Please see the [IRBMed Glossary](https://research.medicine.umich.edu/office-research/institutional-review-boards-irbmed/guidance/glossary) for the most current definitions and additional guidance.

**(MANDATORY LANGUAGE)**

*[Optional: Insert any additional definitions for technical or special terms used within the Standard Practice Guideline that may not be familiar to the lay reader]*

1. **ROLES AND RESPONSIBILITIES**

**Lead Archivist(s)/Designee**

An individual filling the role of Lead Archivist is *accountable* for the storage, retention, and retrieval of archived records. The Lead Archivist or Designee shall be responsible for the following activities: **(MANDATORY LANGUAGE)**

* Determines record retention requirements (duration) based on applicable government, industry and/or institutional regulations and policies for a specific project
* Ensures relevant project-specific contractual and/or industry sponsor requirements are included in the archive process
* Ensures appropriate authorization is obtained prior to the destruction of archived records
* Determines the time point at which clinical trial study records will be archived based on project completion
* Notifies relevant staff to begin the archive process
* Notifies relevant staff, including the Principal Investigator, when archive activities have been completed

**(MANDATORY LANGUAGE)**

*[Optional: Insert any additional details regarding the responsibilities of the Lead Archivist(s)/Designee*]

**Archivist(s)/ Designee**

An individual filling the role of Archivist is *responsible* for the storage, retention, and retrieval of archived records. The Archivist or Designee shall be responsible for the following activities: **(MANDATORY LANGUAGE)**

* Records, tracks, and files clinical trial study records based on work aids/work instructions
* Monitors and controls access to archived documents

**(MANDATORY LANGUAGE)**

*[Optional: Insert any additional details regarding the responsibilities of the Archivist(s)/Designee]*

**Principal Investigator/Designee**

The Principal Investigator is responsible for the planning, oversight, and approval of the archive process. The Principal Investigator shall be responsible for the following activities:

* Reviews and approves the record retention requirements of the archival process including record destruction
* Approves the initiation of the archive process
* Approves the completion of the archive process
* Delegates responsibilities as appropriate

**(MANDATORY LANGUAGE)**

*[Optional: Insert any additional details regarding the responsibilities of the Principal Investigator/Designee]*

**Additional Roles and Responsibilities**  **N/A**

**(MANDATORY LANGUAGE)**

*[Optional: Insert any additional role(s) and responsibilities that apply to this SPG]*

1. **PROCEDURE**

**Archival Communication Plan**

*[Describe the process that is used to confirm a project is ready for archival/transfer, how that information is communicated and to whom (e.g. research team, sponsor, IRB, etc.)]*

**Archived Record Format(s)**

*[Describe the format (paper, electronic, etc.) in which the records will be archived/transferred]*

**Archived Record Naming Conventions**

*[Describe document naming and labeling conventions for each archived/transferred document type]*

**Archived Record Storage Location(s)**

*[Describe the location(s) where archived/transferred documentation will be stored (i.e. locked rooms and file cabinets with limited access etc.). If there is more than one location, indicate which types of documents are stored in which location(s)]*

**Archived Record Tracking and Retrieval**

*[Describe the process for tracking and retrieving archived/transferred records]*

**Archived Record Destruction**

*[Describe the process for destroying records. Obtain sponsor approval where applicable.]*

**Additional Procedures**  **N/A**

*[Optional: Insert any additional relevant procedures. Provide enough detail to ensure the procedure is consistently carried out, without providing so much detail that violations occur due to normal or expected variations in the work.]*

1. **REFERENCES**

Clinicaltrials.gov NCT Number:

<http://www.clinicaltrials.gov/ct2/manage-recs>

FDA Title 21 CFR 312.57 - Recordkeeping and record retention:

<http://www.ecfr.gov/cgi-bin/retrieveECFR?gp=&SID=3b751866ac374d96e405d93a091c2b9c&mc=true&n=pt21.5.312&r=PART&ty=HTML#se21.5.312_157>

FDA Title 21 CFR 312.62 - Investigator recordkeeping and record retention:

<http://www.ecfr.gov/cgi-bin/retrieveECFR?gp=&SID=3b751866ac374d96e405d93a091c2b9c&mc=true&n=pt21.5.312&r=PART&ty=HTML#se21.5.312_162>

FDA Title 21 CFR 812.140 - Records

<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=812&showFR=1&subpartNode=21:8.0.1.1.9.7>

Good Clinical Data Management Practices, Society for Clinical Data Management

<http://www.scdm.org/>

International Council on Harmonisation:

<http://www.ich.org/>

<https://database.ich.org/sites/default/files/E6_R2_Addendum.pdf>

University of Michigan IRBMed Record Keeping Guidance:

<https://research.medicine.umich.edu/office-research/institutional-review-boards-irbmed/guidance/record-keeping-guidelines>

**(MANDATORY LANGUAGE)**

*[Optional: Insert any additional SPG references]*

1. **APPENDICES**

**Appendix A:** Disposition of Clinical Trial Study Documentation  N/A **Appendix B:** Authorization to Destroy Clinical Trial Study Documentation N/A

**(MANDATORY LANGUAGE)**

*[Optional: Insert any additional SPG appendices]*