***TITLE: Record Storage***

***SOP Version #*** RM XX.XX

***Author(s):***

***Approved by Date***

***\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_***

***\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_***

***Approval:***

***Approved by Date***

***\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_***

***\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_***

***Annual Review of current version Review date Description***

***\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_***

***\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_***

***\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_***

|  |
| --- |
| **Instructions for modifying this template:**   1. This is a template and should be used as such. Please use this in the manner most appropriate for your research unit. 2. Text in blue is language you may want to modify as most applicable for your area. However, anything in this template can and may be modified as appropriate for your area while accounting for your interpretation of the most current FDA Guidance. 3. After you have modified this SOP template, do not forget to remove the “Instructions for modifying this template” table. |

**I. SCOPE/PURPOSE**

The purpose of this SOP is to explain the process for record storage. All trial data must be kept so that the data can be accessed after the trial is finished. The Sponsor for the clinical trial has the responsibility of informing the Investigator/Institution when essential documents no longer need to be retained.

All documentation as defined in ICH GCP guidelines must be retained until notification from the sponsor. Archived materials should include all related paperwork such as:

- Trial site files, including ‘regulatory and financial documentation’

- Source documents

- Consent forms

- Patient logs and details

- Case report forms (CRFs)

Staff will ensure all relevant clinical trial documentation is properly maintained and is accessible for as long as required in accordance with ICH GCP guidelines.

**II. ALLOWABLE EXCEPTIONS**

This SOP is meant to be followed without deviation. However, it is an allowable exception to follow procedures specified in a protocol or by the sponsor. If a deviation from this SOP occurs, a description of this event will be written and filed with this list of SOP’s and the protocol.

**III. RELEVANT REGULATIONS/GCPS**

ICH GCP (International Conference on Harmonisation Good Clinical Practice Guidelines)

FDA (Food and Drug Administration) requirements

**IV. DEFINITIONS/ACRONYMS**

**V. RESPONSIBLE PERSONNEL**

This SOP applies to the following – Study Investigators, Study Coordinators, Regulatory Affairs, and Sponsors.

**VI. DETAILS**

## I. Labeling and recording of archived essential documents

* 1. Long term storage boxes must be labeled with the study protocol title, trial site number (if applicable) name of sponsor, name of principle investigator, research group assigned section and study number (if applicable), date archived, date to be destroyed (if available) and total number of boxes used for study archiving.
  2. The department administrator (or equivalent) will maintain a record of archived essential documents. The record will include the study protocol title, trial site number (if applicable) name of sponsor, name of principle investigator, research group assigned section and study number (if applicable), total number of boxes used for study archiving, date archived onsite, date archived off-site, archiving site locations and date to be destroyed (if available).

## Long term storage

* 1. Approximately (6) months after the study site for the trial has been closed, the essential study documents may be filed in long term storage boxes and moved to the appropriately designated onsite storage location, located at 703 19th Street South ZRB 533, Birmingham, AL 35294-0007.
  2. Approximately (2) years, after the CCTU study site for the trial has been closed, the essential study document storage boxes may be moved from the onsite storage location to the off-site contracted storage facility, located at Iron Mountain at 3000 2nd Avenue South, Birmingham, Alabama 35294.

**VII. QA**

Annually review stored documents to determine if any are able to be destroyed.

**VIII. APPENDICES/RESOURCES**

none

**IX. RELATED SOPS**

none