**Regulatory Policy**

**Record Retention and Archiving**

**Version 1.0**

**1.0 Introduction**

This SOP establishes a standardized mechanism for study record retention and archiving for all studies.

**2.0 Scope**

This SOP applies to all personnel who are involved in the conduct of clinical studies.

**3.0 Record Retention**

The essential documents listed below must be retained by the Investigator for as long as needed to comply with national and international regulations, usually for two (2) years after the date a marketing application is approved for the drug indication for which it is being investigated. If no application is to be filed or if the application is not approved for such indication, then the essential documents must be retained until two (2) years after the investigation is discontinued and the FDA is notified. Essential documents include:

• IRB approvals for the study protocol and all amendments

• All source documentation

• CRF copies (NCR or paper copies printed from electronic records provided by the sponsor)

• Participants’ original, signed informed consent forms

• FDA Form 1572 (as required)

• All other regulatory and protocol-specific study documents

These documents must be retained for a longer period if mandated by the applicable regulatory requirements or as required by the sponsor on a study-specific basis. It is the responsibility of the sponsor to inform the regulatory monitor or study coordinator when these documents no longer need to be retained.

**4.0 Process for Record Archiving**

If a study closes and there is no further data collection or further contact with study patients, records are archived:

• All documents are removed from the closed study binders, kept together and placed in a Banker’s box.

• Central archiving, vendor-specific tracking paperwork is prepared for documents to be archived (See Appendix A). This includes an inventory of all study documents.

• A copy of every completed tracking and inventory form is made. The original form is filed centrally and the copy is given to the archiving vendor.

**5.0 Process for Record Retention**

The research team is responsible for the maintenance and retention of study documents for their assigned studies until they are notified that the records will be archived centrally. The following documents will be archived:

• Patient CRF copies

• Patient research chart

• Drug accountability records and copies of pharmacy dispensing logs

• Study regulatory binder

• All other regulatory and protocol-specific study documents

**6.0 Archiving Vendor Requirements**

The archiving vendor is able to provide the following services for the study team:

• Record and information management

• Control and access to records and information

• Security and safety for all records and information

• Reliable record tracking system

• Door-to-door delivery service

• Timely record retrieval

• Inventory reports

**7.0 Retrieval of Stored Documents**

If required, research records in long-term storage may be requested for retrieval. Records should be requested at least two (2) weeks in advance. In circumstances where advanced notice is not provided, records from long-term storage will be available as soon as possible, keeping in mind that it might take up to seventy-two (72) hours. In the circumstance where this is required by a sponsor, a “rush” request can be made, but the sponsor should be aware of a possible additional charge that will be billed to the study. For those that are requested by regulatory agencies without prior notice, the Director of Research will notify the auditor that it may take up to seventy-two (72) hours to retrieve the requested records.

**8.0 Disaster Recovery Plan**

In the case of a disaster, destroyed documents are reconstructed using existing, surviving records located at UCLA.

**Appendix A**

**IRON MOUNTAIN STORAGE FORM**

***BOX NO. \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_***

***STUDY TITLE:***

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