UAB Clinical Research Enterprise

Standard Operating Procedure for
Archival of Study Documents and Long Term Storage

SOP #: 4.01
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Approval: **Approved By**

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	1.0	1/1/2019
	1.1	3/6/2020
	1.2	6/11/2024

Purpose

The purpose of this SOP is to explain the process for archiving of study documents and materials

References

- CRE Study Closeout Checklist

Scope

This SOP applies to the following – Study Personnel, Regulatory Affairs, and Industry Sponsors.

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 SOPs and the protocol.

I. Study Closeout Checklist

a. Prior to archival, Study Closeout Checklist must be completed.

   a. The Checklist will be initiated by Study Coordinator upon completion of study closeout visit.

   b. Once SC has completed their assigned section, checklist will be handed off to Regulatory Coordinator.

   c. Once Regulatory Coordinator has completed their assigned section, checklist will be handed off to Financial Manager

   d. Once Financial Manager has completed their assigned section, checklist will be routed back to Regulatory Coordinator for final signoff and archival or study documents, either electronically or on paper.

II. On site storage

a. All study material will remain on site for approximately 15 years

   i. Approximately 6 months after a study has closed the study binders may be filed in long term storage boxes and moved to the appropriate on site storage area.

   ii. Long term storage boxes should be labeled with the appropriate study information indicating its contents.

III. Long storage facility

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