
Clinical Research Enterprise (CRE)

Standard Operating Procedure for Initial Study Regulatory Documents

SOP #: 2.01

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Approval: Approved By

Date

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| Revision History: | Version | Effective Date | Description |
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Purpose

The purpose of this SOP is to explain the process that occurs after the receipt of study regulatory/start up documents, including their processing and returning to the study Sponsor.

References

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Scope

This SOP applies to all members of CRE staff

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. Definition

- Study start up documents are usually sponsor-generated documents, including the study Protocol, Investigator's Brochure, 1572, Financial Disclosure Form, Informed Consent Template, and other study-related materials needed for the initial approval process.

II. Receipt of Study Start up Documents

- Once received, copies should be saved on the CRE folder in the applicable labeled folders and sub-folders.
- If documents are not received electronically, they should be scanned on to the CRE folder as soon as possible.
- All documents should be completed according to specific Sponsor instructions, in accordance with UAB policies.
- Documents should be submitted to the appropriate study personnel (i.e. Investigator or Sub-Investigator) for signature.

III. Return of Study Start up Documents

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- a. Copies of all documents should be retained for site records.
 - i. All forms that are not required for further submission (i.e. protocol signature page, Sponsor specific Financial Disclosure Forms) should be filed in the study binder, immediately.
 - ii. Additional copies of documents that are required for further submission should be made at this time.
 - b. The original signed and completed documents should be returned to their sponsor per their preferred (and provided) method of courier (i.e. FedEx UPS, etc.)
 - i. If using an electronic submission hosting service (Intralinks, etc), the documents should be posted according to specific instructions.
 - c. Original documents maintained on site should be filed in the study binders immediately.
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Training