
Clinical Research Enterprise (CRE)

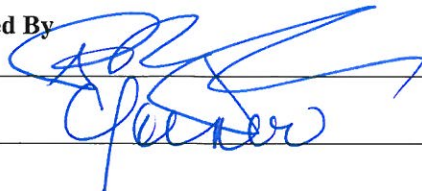
Standard Operating Procedure for Filing of Sponsor Correspondence

SOP #: 3.00

Version: 1.0

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Approval: Approved By



Date

1.1.19

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Revision History:	Version	Effective Date	Description
	1.0		

Purpose

The purpose of this SOP is to define the process for filing Sponsor and CRO correspondence.

References

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Scope

This SOP applies to the following – Study Personnel and Regulatory Affairs

Allowable Exceptions

This SOP is to be followed without deviation.

I. Study Coordinator Role

- Primary Study Coordinator should print out any correspondence from study sponsor or CRO to be filed.
- This should include any pertinent correspondence including but not limited to, newsletters, enrollment updates, and any site specific information.
- Coordinator should label all correspondence with short name of study and either file in appropriate study bin or place in outbox for student assistant to file.

II. Bins

- Study specific bins will be located in BDB 813 and labeled according to study.

III. Regulatory Coordinator

- The Regulatory Coordinator should review all correspondence for appropriate action items.
 - The Regulatory Coordinator or Student Assistant should then file all correspondence under the “Correspondence” tab of regulatory master binder for appropriate study.
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