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

2.13.19

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
a. Primary Study Coordinator should print out any correspondence from study sponsor or CRO to be filed.
b. This should include any pertinent correspondence including but not limited to, newsletters, enrollment updates, and any site specific information.
c. 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
a. Study specific bins will be located in BDB 813 and labeled according to study.

III. Regulatory Coordinator
a. The Regulatory Coordinator should review all correspondence for appropriate action items.
b. The Regulatory Coordinator or Student Assistant should then file all correspondence under the "Correspondence" tab of regulatory master binder for appropriate study.