Clinical Research Enterprise (CRE)
Standard Operating Procedure for CRE Master Binders

SOP #: 2.02

Version: 1.0

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Revision History:	**Version**	**Effective Date**	**Description**
	1.0		

Purpose
The purpose of this SOP is to define the term Regulatory Master Binders and their usage.

References
- 21 CFR 50

Scope
This SOP applies to the following – Study Personnel, Regulatory Affairs, Industry Sponsors and the FDA (if applicable).

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. Master Binders
a. Regulatory master binders will be maintained to provide a uniform location and system for specific program related material.
b. Information will be clearly labeled and organized for easy referencing.
c. Information will be updated in a timely manner.

II. Binders
a. Standard 3 ring binders will be used.
b. Binders will be labeled indicating materials included. Reference the Regulatory Master Binder Template for more information.

III. Information
a. The following list includes the minimum information required to be maintained:
   i. Protocol and Amendments
   ii. IB (if indicated)
   iii. 1572 (if indicated)

iv. CV/Resumes
v. Medical Licenses
vi. IRB training
vii. UAB Hospital Laboratory: CAP/CLIA, Lab Normals
viii. Informed Consent Forms
ix. Completed Pharmacy Documents (maintained in the IDS pharmacy until study closure)
x. Release of Pharmacy Form
xi. Financial Disclosure Forms
xii. Site Visit Materials
xiii. Correspondence
xiv. Applicable logs: DOA, training, screening/enrollment

IV. Other

a. Master Binder provided by Sponsor is acceptable to use, provided that the information above is included.
b. Master Binders will be added and updated as necessary.

Training