***TITLE: Regulatory Management***

***SOP*** RM XX.XX

***Author(s):***

***Approved by Date***

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***Annual review of current version Effective date Description***

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**Instructions for modifying this template:**

1. This is a template and should be used as such. Please use this in the manner most appropriate for your research unit.
2. Anything in this template can and may be modified as appropriate for your area while accounting for your interpretation of the most current FDA Guidance.
3. After you have modified this SOP template, do not forget to remove the “Instructions for modifying this template” table.

**I. SCOPE/PURPOSE**

The purpose of this SOP is to describe the management for regulatory documents.

**II. ALLOWABLE EXCEPTIONS**

This SOP is meant to be followed without deviation. 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.

**III. RELEVANT REGULATIONS/GCPS**

ICH /GCP ([www.ichgcp.org](http://www.ichgcp.org))

21 CRF 11, 50 ([www.fda.gov](http://www.fda.gov))

45 CRF 46 (<http://ohrp.osops.dhhs.gov>)

**IV. DEFINITIONS/ACRONYMS**

Essential Documents: “Essential Documents are those documents which individually and collectively permit evaluation of the conduct of a trial and the quality of the data produced. These documents serve to demonstrate the compliance of the investigator, sponsor and monitor with the standards of Good Clinical Practice and with all applicable regulatory requirements.”

**V. RESPONSIBLE PERSONNEL**

This SOP applies to the following – Study Investigators, Study Coordinators, Regulatory Affairs and sponsors.

**VI. DETAILS**

Regulatory documents are submitted to track and evaluate the ethical and procedural conduct of a trial and the quality of the data that is produced

Regulatory documents demonstrate the compliance of the Investigator, Sponsor and IRB/IEC with the standards of Good Clinical Practice and with all applicable regulatory requirement

Investigators must maintain 1 file for each study, and all essential documents must be in the file.

Must be established at beginning of each study.

Updated throughout life of study.

All required regulatory documents must remain at the study site, be accurately maintained and verified during monitoring visits. Except for the financial disclosure form, all original regulatory documents remain in the Project Notebook.

WHERE to keep my regulatory documents?

PROJECT / REGULATORY /ESSENTIAL DOCUMENT NOTEBOOK

The purpose of the Project Notebook is to provide a place for the site to maintain an accurate and current record of all required regulatory documents. These regulatory documents must be maintained in the Project Notebook.

The monitor/clinical administrator will review the documents that the investigator maintains in the Project Notebook for accuracy and completeness. Monitors will audit to confirm that required regulatory documents are being maintained.

It is strongly recommended that the Project Notebook be maintained in the order listed in the Table of Contents so that the notebook can be easily monitored and required documents are readily found.

SECURE LOCATIONS ARE NEEDED FOR CERTAIN DOCUMENTS…..

*Subject Contact Information* and *Financial Disclosures* should be kept in secure and separate location; place a Note to File in the corresponding section to identify where the documents are located and in whose custody. Additionally, if any required documents are kept in another location, place a Note to File in the corresponding section to identify where the documents are located and in whose custody.

HOW LONG should regulatory documents be maintained?.

According to 21 CRF 312.57:

“Two years after a marketing application is approved for the drug, or if an application is not approved for the drug, until two years after shipment and delivery of the drug for investigational use is discontinued and the FDA has been notified.”

**VII. QA**

N/A

**VIII. APPENDICES/RESOURCES**

N/A

**IX. RELATED SOPS**

N/A