***TITLE: SOP Development***

***SOP Version # RM 01.01***

***Author(s):***

 ***Approved by Date***

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**I. SCOPE/PURPOSE** The scope of this SOP is to describe how SOPs will be developed and managed by UAB research sites The purpose of SOPs is to assure consistency and rigor with the design, conduct and implementation of clinical trials at UAB by providing standards and guidelines for the staff. This SOP will describe the development and implementation of SOPs by the CTO Research Group SOP Committee.

**II. ALLOWABLE EXCEPTIONS**

This SOP will be adhered unless exceptions are required. Exceptions will be noted in a formal note to file (see relevant SOP).

**III. RELEVANT REGULATIONS/GCPS**

ICH-GCP: 5.1 Quality Assurance and Quality Control, 1.38 Monitoring, 5.18.2 SOPs GCP

**IV. DEFINITIONS/ACRONYMS**

SOP Standard Operating Procedures

CTO Clinical Trials Office

**V. RESPONSIBLE PERSONNEL**

**VI. DETAILS**

The following is a description of how SOPs will be developed

1. Develop SOPs
2. Develop a list of SOPs to meet the needs of the UAB researchers (see appendix A)
3. Assign the development of an SOP to one of three workgroups: Regulatory Management, Fiscal Management, or Clinical Implementation.
4. From Appendix A, each workgroup will develop assigned SOPs using the SOP template (Appendix B). Approximately 6 weeks or an agreed upon timeline will be allowed for the development of each SOP.
5. As each workgroup finishes their SOP, it will be presented to the SOP Committee. This can be done in a SOP Committee meeting, or via email; all reviewers will be asked to comment as applicable. All reviewers will have 5 business days to provide comments.
6. All comments will be incorporated by the workgroup leader or designee into the SOP. The workgroup leader or designee will obtain review and comment from his/her workgroup on the edits/changes to the SOP.
7. The SOP will be sent to the members of the SOP Committee for final approval. A quorum of members must approve the SOP for it to be final.
8. After the SOP Committee approves the SOP one of several things might happen:
	1. SOP will be made available to the UAB research community via posting on the CTO website.(password protected site)
	2. If the SOP is required for the research community, an institutional officer will approve the SOP (this will be a PDF version of the SOP)
	3. If the SOP is not required but a guideline or recommendation, and could be modified by each research area/unit, the signature block will be left blank. This version will be posted as a word document.
9. The SOP will be retained centrally in the CTO office.
10. Maintaining and amending SOPs
11. The SOP will be reviewed annually by the SOP Committee.
12. An annual review date will be noted in the footer of the SOP.
13. If changes are implemented, the SOP will be re-issued with a new version date and steps V.I will be repeated
14. Archive SOPs
15. All SOPs will be retained for an indefinite period of time
16. SOPs will be tracked with identification of previous version of the SOP in the footer.
17. SOPs will be archived electronically.

**VII. QA**

 NA

**VIII. APPENDICES/RESOURCES**

Appendix A – SOP listing

Appendix B - SOP Template

**IX. RELATED SOPS**

NA

**Appendix A**

***SOP List***

***Clinical Management (CM)***

|  |
| --- |
| Adverse Event and Serious Adverse Event Reporting |
| Subject Screening and Recruitment |
| Informed Consent Process and Documentation  |
| Eligibility Confirmation |
| Monitor Visits (SAV, IMV, COV) |
| Reconciliation of outstanding issues (PDs, SAEs, etc.) |
| Record Organization/Retention |
| Satellite site management |
| PI Oversight |
| Source Document development |
| SAE Reporting process |
| Data Management : CRF completion and query resolution |
| Protocol Deviations |
| FDA Audits |
| Sample Processing and Shipping  |
| Shadow charts |
| Study Coordinator Checklist |
| Reporting to subject at close of study |
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***Regulatory Management (RM)***

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| SOP Management |
| Confidentiality of Information |
| Regulatory Document Submission Process (Initial and continuous Submissions) |
| Sponsor, CRO and Internal Audits |
| Required training |
| Site activation: investigator meeting |
| IND/IDE Development and Management  |
| Drug/Device Storage, Accountability and Management |
| Site responsibility log (Authority and Delegations of Responsibilities of Research Staff) |
| Note to file |
| 1572  |
| Site Specific Informed Consent Form |
| Financial Disclosures |
| Multisite trial management (pending) |
| Clinical Trials.gov registration and reporting |
| Quality Management plans |
| IND Safety Letters |
| Administrative Hold |
| Closing a study (include remote close out; record retention; notifying the IRB) |
| Record Organization/Retention |
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***Financial Management (FM)***

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| Budget Standards: building a study budget within UAB required parameters [pending] |
| Reviewing the protocol: for financial impact |
| Study Feasibility |
| Budget and Contract Process |
| CIRB reporting |
| Effort reporting [pending] |
| Multisite trial budgets [pending] |
| Budget management standards (monthly reconciliation) |
| Subject compensation [pending] |
| Billing compliance (CTBN, CBR, etc.) |
| Closing a study budget |
| Obtaining final payment from sponsor (OSP) |

**Appendix B**

***TITLE: XXXXXXXXXXXXXXXXX***

***SOP RM/FM/RM XX.XX***

***Author(s):***

 ***Approved by Date***

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