***TITLE: PI Oversight***

***SOP Version #*** CL XX.XX

***Author(s):***

***Approved by Date***

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***Approval:***

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***Renewed 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 provide guidance on critical activities that a principal investigator must adhere to in order to provide protocol oversight.

**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**

21 CFR subpart D (312.55 --.70) ; ICH-GCP 4. Investigator

**IV. DEFINITIONS/ACRONYMS**

PI – Principal Investigators

ICH – International Conference on Harmonization

CFR – Code of Federal Regulations

**V. RESPONSIBLE PERSONNEL**

This SOP applies primarily to the principal investigators (PI) but also the entire research team.

**VI. DETAILS**

Oversight of a study and the research team is the exclusive responsibility of the principal investigators. He/she may delegate the tasks, but per the 1572, (Appendix A - http://www.fda.gov/aboutfda/reportsmanualsforms/forms/default.htm) or the IOR (appendix B) for non-FDA supported studies, the PI retains all responsibility. In order to do this, communications is paramount and understanding how to conduct research within CFR and ICH guidance. In addition to each research trial’s requirements and protocol specific responsibilities. The following are activities required of the PI for all studies:

1. Monthly meetings with research staff for each protocol
2. Documented assurance of proper subject consenting
3. Quarterly contact with the sponsor related to protocol implementation
4. Presence at all monitor visits
5. Review all safety labs, initialing and dating appropriate review
6. Document and assure documented all training for research staff
7. Review and document attestation, grade and resolution of all AEs and SAEs.
8. Review at least every 6 months deviations that have occurred during the implementation of a study.

**VII. QA**

Tracking and monitoring meetings will take place as required and will be QC’d twice a year to assure compliance and to document non-compliance with justification.

**VIII. APPENDICES / RESOURCES**

Appendix A…FDA Form 1572

Appendix B Investigator of Record

**IX. RELATED SOPS**

N

Appendix A (copy of 1572)

Appendix B

**STATEMENT OF INVESTIGATOR FOR**

**INVESTIGATIONAL DEVICES**

**21 Code of Federal Regulations (CFR) 812.43**

To participate in a study involving Investigational Devices; an investigator must complete this statement and submit it to the University of Alabama at Birmingham (“UAB”) Office of Sponsored Programs (“OSP”).

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| Study name and protocol number (if applicable):  **1.** |
| Name and address of investigator:  **2.** |
| Education, training, and experience that qualifies the investigator to conduct this study, including dates, location, extent and type of experience. Please indicate by checking below that curriculum vitae is attached and also if any other statement of qualifications is attached.  **3.**  Curriculum Vitae  Other Statement of Qualifications |
| 4 Name(s) of sub-investigator(s) who will assist the investigator in the conduct of this study (Mark *none* if no sub-investigators will be involved in this study.):  None  **4.** |
| Terminated investigation or research: If the investigator has been involved in an investigation or other research that was terminated, please list the terminated investigation or other research below and attach an explanation of the circumstances that led to the termination for each terminated investigation or research (Mark *none* if no investigation or research has been terminated\*.):  None  **5.**  \*Per the FDA, the definition of ‘terminated’ is the stopping of a study prior to complete enrollment. The study may be terminated by the FDA, the IRB or the sponsor. |
| Commitments:  **6.**  I agree to conduct the study in accordance with the agreement with the sponsor, the investigational plan, 21 CFR Part 812 and other applicable Food and Drug Administration (“FDA”) regulations and conditions of approval imposed by the reviewing institutional review board (“IRB”) or FDA.  I agree to supervise all testing of the device involving human subjects.  I agree to ensure that the requirements for obtaining informed consent are met.  I agree that I will promptly update the financial disclosure information that I provide to the sponsor to allow it to submit a complete and accurate certification or disclosure statement as required under 21 CFR part 54 in the event that any relevant changes occur during the course of the investigation and for 1 year following completion of the study. |
| Investigator signature and date:  Date: |