***TITLE: Eligibility Confirmation***

***SOP*** /CL XX.XX

***Author(s):***

 ***Developed by Date***

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***Approval:***

 ***Approved by Date***

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***Annual review of current version Review date Comment***

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**I. SCOPE/PURPOSE**

The scope of this SOP is to describe how subject eligibility confirmation will be 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. Eligibility Confirmation must be determined before a subject can be enrolled into a clinical trial. To determine eligibility always refer to the current version of the protocol, including any protocol Clarification Memos and Letters of Amendment.

**II. ALLOWABLE EXCEPTIONS**

This SOP will be adhered unless exceptions/waivers are obtained. Waivers/Exceptions will be noted in a formal note to file (see relevant SOP). Written verification from the Sponsor will be required.

**III. RELEVANT REGULATIONS/GCPS**

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

SOPs GCP FDA Guidance: E6 GCP, Sections 4, 5.18.4, 6.5

21 CFR 50 – Protection of Human Research Subjects

21 CFR 54 – Financial Disclosure by Clinical Investigators

21 CFR 56 – Institutional Review Boards

21 CFR 312.70 – General Responsibilities of the Investigator

21 CFR 812 - Investigational Device Exemptions

45 CFR 46 – Protection of Human Subjects

FDA Industry Guidelines and Information Sheets

FDA Compliance Policy Guidance Programs: 7348.809, 7348.810, and 7348.811

**IV. DEFINITIONS/ACRONYMS**

SOP Standard Operating Procedures

GCP Good Clinical Practices

**V. RESPONSIBLE PERSONNEL**

Principal Investigator (PI)

Subinvestigator

Research Nurse

Study Coordinator

Research Support Staff (Research Assistant/Specialist)

Other applicable Research Staff associated in the clinical trial involved with subject enrollment

**VI. DETAILS**

 It is the responsibility of designated study staff to perform all assessments required to

 determine eligibility. These assessments may include reviewing available medical records;

 collecting and reviewing medical/medications history information; performing physical

 examinations and reviewing the findings thereof; and performing laboratory evaluations and

 reviewing the results thereof. In addition, documentation of written informed consent must

 also be reviewed.

1. Documentation to address each of the protocol’s inclusion and exclusion criteria must be present in the research record. This documentation will be determined and signed by the PI or as delegated by PI confirming subject’s eligibility. Documentation can be noted in the following ways:
2. Chart notes to address the entry criteria.

2. Eligibility checklists used as source documentation as long as the criteria included corresponds with the protocol and each inclusion/exclusion criterion is addressed.

3. Original documents or certified copies of protocol required diagnostic results and/or history (e.g., laboratory results, radiology report, medication history, etc.) are placed in the subjects source document.

1. Documentation to address pertinent negatives must also be present in the research record. For example, exclusion criteria may require that the subject not be using any concomitant medications, or has not been diagnosed with another disease. Appropriate documentation includes but is not limited to, the following:
2. Chart notes to address each negative criterion. For example, “None of the concomitant medications excluded by the protocol are being used by the subject” is an acceptable way to document that the criterion has been met.
3. Eligibility checklists used as source documentation as long as the criteria included

corresponds with the protocol and each inclusion/exclusion criterion is addressed.

NOTE: A blanket statement regarding all such exclusion criteria, such as “The subject does not meet any of the exclusion criteria outlined in the protocol” is NOT considered adequate.

If a site is unclear regarding eligibility, clarification will be made with the sponsor in writing. This clarification will be filed with the eligibility criteria in the subject’s source or in the regulatory documents.

 Eligibility criteria must be strictly followed to ensure that ineligible participants are not enrolled and exposed to unnecessary risk and so that the final data points can be analyzed without compounding variables. All information provided by the potential participant and source documents must be reviewed to identify all important elements that may or may not make the patient eligible for the research study.

Enrolling ineligible subjects is considered to be a compliance violation of the currently approved IRB protocol (investigational plan), GCP guidance, federal regulations, and the Statement of the Investigator (FDA Form 1572). If specific eligibility criteria are negatively impacting recruitment and enrollment of participants, it is recommended that the study team evaluate the possibility of amending the protocol to allow for more flexible eligibility criteria. Accepting waivers for eligibility from sponsors for anything other than eliminating the apparent and immediate hazard to research participants is also considered to be a compliance violation.

Review checklist before a Monitor Visit for Completeness.

**VII. QA**

A QA/QC process will occur before a monitor visit to review inclusion/exclusion checklist for completeness.

**VIII. APPENDICES**

**Appendix A CL xx.xx Sample of Inclusion/Exclusion Checklist**

**IX. RELATED SOPS**

none

**APPENDIX A CL xx.xx**

**Sample Inclusion/Exclusion Checklist**

**Inclusion Criteria**

**(PI Initials) 1.xxxxx**

**\_\_\_\_\_\_ 2.xxxxx**

**\_\_\_\_\_\_ 3.xxxxx**

**\_\_\_\_\_\_ 4.xxxxx**

**\_\_\_\_\_\_ 5.xxxxx**

**\_\_\_\_\_\_ 6.xxxxx**

**\_\_\_\_\_\_ 7.xxxxx**

**\_\_\_\_\_\_ 8.xxxxx**

**\_\_\_\_\_\_ 9.xxxxx**

**Exclusion Criteria**

**\_\_\_\_\_\_ 1.xxxxx**

**\_\_\_\_\_\_ 2.xxxxx**

**\_\_\_\_\_\_ 3.xxxxx**

**\_\_\_\_\_\_ 4.xxxxx**

**\_\_\_\_\_\_ 5.xxxxx**

**\_\_\_\_\_\_ 6.xxxxx**

**\_\_\_\_\_\_ 7.xxxxx**

**\_\_\_\_\_\_ 8.xxxxx**

**\_\_\_\_\_\_ 9.xxxxx**

**I have reviewed the Inclusion /Exclusion Criteria and the subject meets the required criteria to enroll in the study.**

**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**PI Signature Date**