GA-101 REVISION HISTORY

Date of Revision	Page(s)/Section(s) Revised	Revision Explanation
01AUG2011		
15MAY2017		
31OCT2017	All	Cosmetic Only
26MAR2019	All	Minor corrections and updates.

GA-101 STANDARD OPERATING PROCEDURE ON SOP'S: PREPARING, MAINTAINING AND TRAINING

I. INTRODUCTION AND PURPOSE

This standard operating procedure (SOP) describes the preparation and maintenance of the written procedures that this research team follows to ensure compliance with all FDA regulations and guidelines (and the policies and procedures of this institution, if appropriate) for all clinical trials conducted at this investigative site. This SOP also describes procedures for training on SOPs and documentation of training.

2. SCOPE

This SOP applies to the written procedures followed by this research team as it conducts all clinical studies subject to investigational new drug and device regulations for drugs and biologics during all investigational phases of development.

3. APPLICABLE REGULATIONS AND GUIDELINES

21 CFR 312.60	General responsibilities of investigators

4. REFERENCES TO OTHER APPLICABLE SOP'S

All SOPs are applicable to this SOP

5. RESPONSIBILITY

It is the responsibility of the Clinical Research Director/Manager at this investigative site to approve all SOPs. It is the responsibility of all members of the clinical research team involved in supervising, managing, or conducting study-related activities to follow the SOPs. This includes the following:

- Principal Investigator
- Sub-Investigator
- Research Director/Manager
- Research Coordinator
- Support Staff

6. DEFINITIONS

The following definitions, from the International Conference on Harmonization, Good Clinical Practice: Consolidated Guideline, apply to this SOP.

Clinical Trial/Study: Any investigation in human subjects intended to discover or verify the clinical, pharmacological and/or other pharmacodynamic effects of an investigational product(s), and/or to identify any adverse reactions to an investigational product(s), and/or to study absorption, distribution, metabolism, and excretion of an investigational product(s) with the object of ascertaining its safety and/or efficacy.

Standard Operating Procedures (SOPs): Detailed, written instructions to achieve uniformity of the performance of a specific function.

7. PROCESS OVERVIEW

A. Procedure for preparing new SOPs or revising previously issued SOPs
B. Procedure for reviewing SOPs
C. Procedure for providing training on implementing SOPs

8. PROCEDURES

A. PROCEDURE FOR PREPARING NEW SOPS OR REVISING PREVIOUSLY ISSUED SOP'S

RESPONSIBILITY	DESCRIPTION OF PROCEDURE
Research Director/Manager Research Coordinator	Based upon changes to the FDA regulations, guidelines, or research practice (or the policies and procedures of this institution, if appropriate), write a new SOP or revise a previously issued SOP that describes the new or revised procedures. Each SOP includes the following in the header: • The title • The number for that SOP • The date of the current version • The date of the previous version
Research Director/Manager	Write the SOP, using the following format: • Introduction and Purpose • Scope • Applicable Regulations and Guidelines • References to Other Applicable SOPs • Attachments • Responsibility • Definitions • Process Overview • Procedures • Maintain a Table of Contents by number and title of the SOPs.
Research Director/Manager Research Coordinator Support Staff	Review draft SOP to ensure accuracy and completeness.
Research Director/Manager	Approve (sign and date, if appropriate) each new SOP after it is finalized.
Research Director/Manager	Distribute the new SOP to all team members. Collect the superseded SOP, if appropriate. Maintain a distribution list.

Research Coordinator	Maintain an historical archive of copies of all previous versions of SOPs to be available in the event of an audit.

B. PROCEDURE FOR REVIEWING SOP'S

RESPONSIBILITY	DESCRIPTION OF PROCEDURE
Designated PI Research Director/Manager Research Coordinator	At least annually, review all SOPs. If revisions or additions are required, follow the procedure described above. If no changes are required, document and file appropriately.

C. PROCEDURE FOR PROVIDING TRAINING ON IMPLEMENTING SOP'S

RESPONSIBILITY	DESCRIPTION OF PROCEDURE
Research Director/Manager Research Coordinator	Provide training to all members of the research team within 1 month of a new or revised SOP becoming effective.
Research Director/Manager	Ensure that each employee documents (Attachment A, Training Compliance Form) the date of training and the SOPs reviewed.
Research Director/Manager	Ensure that each new employee reviews all applicable SOPs prior to undertaking any responsibilities at this site for which SOPs apply. Ensure that each new employee documents (Attachment A, Training Compliance Form) the date of review (or training, if appropriate) and the relevant SOPs.
Research Director/Manager	Maintain a record of SOP training and review for all employees at this site.