GA-103 REVISION HISTORY

Date of Revision	Page(s)/Section(s) Revised	Revision Explanation
01AUG2011		
06JUN2017		
31OCT2017	All	Cosmetic Only
26MAR2019	All	Minor corrections and updates.

GA-103 STANDARD OPERATING PROCEDURE FOR TRAINING AND EDUCATION

1. INTRODUCTION AND PURPOSE

Research studies will be conducted according to FDA and HHS regulations to protect the safety and welfare of study subjects that must be ensured by a research team knowledgeable about ongoing study protocols and investigational articles.

Investigators and all key members of the research team who are working in or overseeing programs that conduct research on human subjects will receive initial and ongoing training regarding the responsible conduct of research.

2. SCOPE

This standard operating procedure (SOP) describes the process and documentation required by this institution for the initial and ongoing education of the principal investigator and research staff in Good Clinical Practices (GCPs) and the ethical conduct of research conducted at this research site.

3. APPLICABLE REGULATIONS AND GUIDELINES

21 CFR 312.60	General responsibilities of investigators
45 CFR 46	46DHHS Part 46 Protection of Human Subjects
21 CFR 812	Subpart E Responsibilities of Investigators

4. REFERENCES TO OTHER APPLICABLE SOP'S

All SOPs are applicable to this SOP.

5. RESPONSIBILITY

This SOP applies to the principal investigator and staff at this research site who participate in the hiring, orientation, and ongoing training of investigators and research staff involved in supervising, managing, or conducting study-related activities at this institution.

This includes the following:

- Principal Investigator
- Sub-Investigator
- Administrators
- Research Director/Manager
- Research Coordinator

6. DEFINITIONS

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

Good Clinical Practice (GCP): A standard for the design, conduct, performance, monitoring, auditing, recording, analyses, and reporting of clinical trials that provides assurance that the data and reported results are credible and accurate, and that the rights, integrity, and confidentiality of trial subjects are protected.

7. PROCESS OVERVIEW

A. Process for education and documentation by research staff

8. PROCEDURES

A. PROCESS FOR EDUCATION AND DOCUMENTATION BY RESEARCH STAFF

RESPONSIBILITY	DESCRIPTION OF PROCEDURE
Research Director/Manager Research Staff	Ensure that all members of the research team are provided access to this organization/site's educational program. Each coordinator shall participate in bi-annual review of GCPs. All coordinating staff should be up to date with Shipping of Dangerous Goods regulations. This will be reviewed as regulations require.
Research Director/Manager	Determine that each member of the research team provides appropriate documentation that he/she has fulfilled the education and training requirement.
Research Director/Manager Research Staff	Maintain a record of initial and ongoing educational activities and certification for all research staff at the investigative site.