## GA-102 REVISION HISTORY

| Date of Revision | Page(s)/Section(s) Revised | Revision Explanation |
|---|---|---|
| 01AUG2011 | | |
| 15MAY2017 | | |
| 31OCT2017 | All | Cosmetic Only |
| 26MAR2019 | All | Minor corrections and updates. |
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# GA-102 STANDARD OPERATING PROCEDURE FOR RESPONSIBILITIES OF THE RESEARCH TEAM

## 1. INTRODUCTION AND PURPOSE

The Principal Investigator (PI) is the individual of record who assumes the authority and responsibility for the conduct of a clinical study. By signing Form FDA 1572, the PI agrees to comply with the conditions required by FDA for use of investigational articles. The PI has the authority to delegate responsibility to individual members of the research team; however, the PI is ultimately responsible for the overall conduct of the study.

## 2. SCOPE

This Standard Operating Procedure (SOP) defines the responsibilities of the research team for conducting clinical studies at this investigative site. It identifies administrative accountability as well as general responsibilities of the research team and of individual team members for fulfilling regulatory and clinical requirements.

## 3. APPLICABLE REGULATIONS AND GUIDELINES

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| 21 CFR 312.53 | Selecting investigators and monitors |
| 21 CFR 312.60 | General responsibilities of investigators |
| 21 CFR 312.61 | Control of the investigational drug |
| 21 CFR 312.62 | Investigator recordkeeping and record retention |
| 21 CFR 312.64 | Investigator reports |
| 21 CFR 312.66 | Assurance of IRB review |
| 21 CFR 312.68 | Inspection of investigator's records and reports |
| 21 CFR 312.69 | Handling of controlled substances |
| 21 CFR 54 | Financial Disclosure by Clinical Investigators |

## 4. REFERENCES TO OTHER APPLICABLE SOP'S

All SOPs are applicable to this SOP.

## 5. ATTACHMENTS

N/A

## 6. RESPONSIBILITY

This SOP applies to those members of the clinical research team involved in supervising, managing, or conducting study-related activities. This includes the following:

- Principal Investigator
- Sub-Investigator

- Research Coordinator
- Research Director/Manager
- Support Staff

## 7. 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.

**Investigator:** A person responsible for the conduct of the clinical trial at a trial site. If a trial is conducted by a team of individuals at a trial site, the investigator is the responsible leader of the team and may be called the principal investigator.

**Sub-Investigator:** Any individual member of the clinical trial team designated and supervised by the investigator at a trial site to perform critical trial-related procedures and/or to make important trial-related decisions (e.g., associates, residents, research fellows).

## 8. PROCESS OVERVIEW

A. Administrative responsibilities
B. General responsibilities of the research team
C. Individual responsibilities within the research team

## 9. PROCEDURES

### A. ADMINISTRATIVE RESPONSIBILITIES

| RESPONSIBILITY | DESCRIPTION OF PROCEDURE |
|---|---|
| Research Director/Manager | Participate as appropriate in the hiring and training of individuals recruited as members of the research team.<br>Assign trained research coordinators to manage each clinical study planned or ongoing at this site.<br>Manage the business aspects of studies, including developing and negotiating study budgets and contracts.<br>Design appropriate recruitment strategies and track study enrollment. |

### B. GENERAL RESPONSIBILITIES OF THE RESEARCH TEAM

| RESPONSIBILITY | DESCRIPTION OF PROCEDURE |
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| Research Director/Manager<br>Research Coordinator<br>Support Staff | Conduct clinical studies according to FDA regulations and guidelines and SOPs of this clinical site.<br>Ensure that the PI is informed in a timely manner of all study-related activities through regular follow-up meetings.<br>Ensure the safety and welfare of study subjects by being knowledgeable about ongoing study protocols and investigational articles.<br>All investigators and covered research personnel must comply with federal regulations governing disclosure of personal, professional, or financial interests in a research study that may impact upon its conduct, evaluation, or outcome. |

### C. INDIVIDUAL RESPONSIBILITIES WITHIN THE RESEARCH TEAM

| RESPONSIBILITY | DESCRIPTION OF PROCEDURE |
|---|---|
| Principal Investigator | Sign Form FDA 1572 to acknowledge responsibilities as defined by the regulations.<br>Provide sponsor with required information that either:<br>Attests to the absence of financial interests or arrangements as described in the regulations (CFR 54.4) and reported on Form FDA 3454 that is completed by the sponsor),<br>OR- Provides the sponsor a complete and accurate disclosing of financial interests and arrangements as described in the regulations (CFR 54.4) and reported on Form FDA 3455 that is completed by the sponsor).<br>While retaining knowledge of and overall authority for the conduct of all studies, supervise members of the research team qualified by their education and training to accept these responsibilities for study-related activities not directly performed by the PI.<br>Document the delegation of responsibilities (Attachment A, Delegation of Responsibility Form).<br>Ensure the safety and welfare of study subjects by being knowledgeable about ongoing study protocols and investigational articles.<br>Participate as appropriate in the hiring and training of individuals recruited as members of the research team.<br>Ensure that specific sponsor requirements of the PI are fulfilled as requested.<br>Meet with sponsors' representatives as appropriate to discuss planned and ongoing studies.<br>Meet with auditors (internal, sponsor, and FDA) at the conclusion of their audits to review findings. |
| Research Coordinator | Develop organizational aids and checklists to facilitate patient recruitment and enrollment as well as the collection of complete and accurate study data.<br>Communicate with the IRB as appropriate<br>Enroll subjects in studies and manage their participation according to ethical, regulatory, and protocol-specific requirements.<br>Maintain the regulatory and study files for each research project.<br>Participate in quality assurance activities (monitoring visits, internal audits, sponsor audits, FDA audits). |

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| Research team | Fulfill those job responsibilities specific to that job title according to federal regulations and guidelines as well as the appropriate SOPs. |