

## **104.1 RESPONSIBILITIES OF RESEARCH TEAM**

### **I. PURPOSE**

To define the responsibilities of the Principal Investigator and other significant team members in the conduct of the clinical trial research team. To ensure the creation and/or review of SOPs by significant research team members in compliance with FDA regulations and guidelines, as well as the policies and procedures of GSM.

### **II. SCOPE**

This SOP applies to the following members of the research team:

- Principal Investigator
- Sub or Co Investigators
- Clinical Trials personnel
- Study Pharmacist
- Any support staff significantly involved in the study

### **III. REGULATIONS/GUIDELINES**

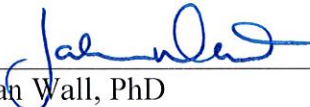
- 21CFR 312.53g: ...investigator will “ensure that all associates, colleagues, and employees assisting in the conduct of the study (ies) are informed of their obligations in meeting the commitments”.
- ICH E6 Good Clinical Practice: Consolidated Guidelines: e.g. 2.13: “Systems with procedures that assure the quality of every aspect of the trial should be implemented” and 4.2.4 “The investigator should ensure that all persons assisting with the trial are adequately informed about the protocol, the investigational product(s), and their trial-related duties and functions”.

### **IV. ROLES/PROCEDURES**

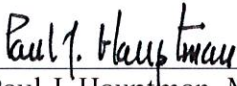
1. The PI is ultimately responsible for the conduct of the trial; however, he/she may delegate certain authority to appropriate members of the research team.
2. The PI assumes the following responsibilities when conducting a clinical research study involving patients:
  - a. Assures that he/she and other significant members of the study team are qualified by education, training *and* experience as appropriate experts to conduct clinical study procedures and activities.
  - b. Assures that documentation of the appropriate education/training credentials for all significant team members are provided to the GSM Assistant Director of Research if requested prior to performing any clinical trial activities.
  - c. Will be aware of, and will comply with, GCP guidelines, and IRB and FDA regulatory requirements.
  - d. Will maintain a list of research team members and delegated duties.
  - e. Will maintain up-to-date training logs for all clinical trial personnel.

- f. Assures that adequate resources/personnel are available to conduct the clinical trial and that the PI has adequate time to properly conduct the trial and provide oversight.
  - g. Assures protocol compliance.
  - h. Reports protocol non-compliance appropriately *to all* regulating authorities.
  - i. Obtains IRB approval of the trial.
  - j. Follows regulations and guidelines to protect subject rights, safety, and welfare.
  - k. Controls the accountability of the investigational product(s)
  - l. Prepares and maintains accurate case histories and records all observations and other data pertinent to the clinical trial on each subject.
  - m. Disclosures of applicable conflicts of interest
  - n. Permits access to investigational records upon request from properly authorized officers or employees of the FDA, Sponsor, IRB, GSM research oversight or other authorized entities.
  - o. Demonstrates familiarity with the use of the investigational product(s), as described in the protocol, in the Investigators Brochure.
  - p. Assures compliance by all research team members of GCP regulations.
3. The Research Study Coordinator assumes the following responsibilities when conducting a clinical study:
- a. Has the knowledge, experience and expertise to assist the PI with the management of clinical study activity including those addressed above, as delegated by the PI.
  - b. Demonstrates thorough understanding of GCP regulations, the protocol and the importance of protocol compliance.
  - c. Complies with applicable SOPs.
  - d. Will be aware of, and comply with, ICH E5 GCP guidelines and FDA regulatory requirements.
  - e. Performs study activity per the protocol including, but not limited to recruitment of subjects, obtaining subject consent, performing screening activity, enrollment of subjects, collecting subject data, documentation of subject data, monitoring of subject status, collecting and reporting of adverse event data, coordinating subject visits, keeping and retaining appropriate study records, etc.,
  - f. Complies with audits/inspections.

APPROVED:

  
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9/23/2021  
Date

  
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09/23/2021  
Date