Western Connecticut Health Network
Danbury Hospital · New Milford Hospital · Norwalk Hospital

All research projects are to be overseen by a Principal Investigator (PI) who has overall accountability of the study. Principal Investigators (PI) will follow Good Clinical Practice (GCP) guidelines established by the International Conference on Harmonization (ICH) and the FDA Code of Federal Regulations 21CFR312. The PI is responsible for ensuring that an investigation is conducted according to the signed investigator statement, the investigational plan, and applicable regulations; for protecting the rights, safety, and welfare of subjects, and for the control of investigational product under investigation. Research Coordinators and Sub investigators will work within their scope of practice, knowledge, and experience.

The purpose of this document is to describe the expected responsibilities of the Principal Investigator (PI), provide guidance as to the tasks that can be reasonably delegated to other members of the research team, and ways to evidence oversight.

Research team: Includes Sub Investigators, Research Coordinators, Research Assistants, Pharmacists and/or pharmacy staff, other staff (as applicable), and other department staff as necessary per protocol.

1. Roles and Responsibilities

a. Commitments of the PI outlined in the Investigator Statement on the FDA Form 1572 summarized here include:

- Will conduct the study in accordance with the relevant, current protocol and will only make changes in the protocol after notifying the sponsor, and IRB, except when necessary to protect the safety, the rights, or welfare of subjects.
- Will personally conduct or supervise the described investigation.
- Will inform any patients, or any persons used as controls, that the drugs are being used for investigational purposes and will ensure that the requirements relating to obtaining informed consent and IRB review and approval are met.
- Will report to the sponsor adverse experiences that occur in the course of the investigation. Will read and understand the information in the IB, including the potential risks and side effects of the drug.
- Will ensure that all associates, colleagues, and employees assisting in the conduct of the study are informed about their obligations in meeting the above commitments.
- To maintain adequate and accurate records and make those records available for inspection.
- To ensure that an IRB complies with 21CRF Part 56 and is responsible for the initial and continuing review and approval of the clinical investigation and promptly report any changes in research activity and all unanticipated problems involving risks to human subjects or to others. Will not make any changes in the research without IRB approval, except where necessary to eliminate apparent immediate hazards to human subjects.
- Comply with all other requirements regarding the obligations of clinical investigators and all other pertinent requirements.

b. The PI will also follow 21 CRF 312 and ICH - E6 Good Clinical Practice Section 4 with regards to Investigator qualifications, agreements, and responsibilities.

2. Delegation:

a. PI must perform or delegate to qualified sub-investigators and research team all of the necessary tasks to carry out a study. Even when specific tasks are delegated, the PI remains ultimately responsible for proper

conduct of the study and fulfillment of all associated obligations as documented on the Delegation of Authority (DOA) log.

b. A Delegation of Authority (DOA) log (or similarly named log) is maintained and updated as needed throughout the study with any changes being signed or initialed by the PI.
c. The PI will ensure that all associates, colleagues, and employees assisting in the conduct of the study are informed about their obligations in meeting the above requirements as documented on DOA log.

3. Training:

a. PI and the Research Team will complete GCP training at least every three years.
b. Specific protocol training will be completed with the PI and Research Team as applicable to their role upon study initiation and with any significant changes (i.e. amendments, IB, and/or IFU changes).
c. The PI is responsible to read and understand the information in the investigator's brochure and/or Instructions for Use (IFU) Manual including potential risks and side effects of the drug or device. This is documented by signature on an IB or IFU signature page or front page of document.
d. PI oversight of this training is documented by PI signature and/or initials on a training log.

Oversight of the Research Team

a. Reviewing Inclusion/Exclusion and Consenting

The PI will review and sign inclusion and exclusion criteria for each patient consented.

Appropriate members of the research team may be delegated the responsibility for obtaining Informed Consent. Any changes in Informed Consent, once IRB approved, will be reviewed and study participants will be re-consented as appropriate. The PI will review and sign consent process documentation.

Patients wishing to withdraw from study and/or discussing any concerns with the Research Team will be reviewed with the PI and the discussion and follow up documented.

b. Trial maintenance:

Appropriate members of the research team will coordinate to collect data required by protocol for patient visits. PI will review patient data (i.e. labs, imaging, ECG) in a timely manner. Any subject study related concerns may be addressed via paging or secure texting with PI and/or SI, if PI is unavailable. The PI will then follow up when available. This communication follow up may be completed and documented.

Advanced practice providers completing a clinical assessment within their scope of practice, will be trained on the protocol and IB and delegation of such assessments listed on the DOA log.

Appropriate members of the research team will collect information around Adverse Events (AE) and Endpoints and record. PI will review and assess severity and causality with initials/signature. Any follow up and/or interventions will be documented as needed.

IND Safety Reports, SUSAR reports, or other Sponsor generated Safety reports will be logged and the log reviewed and signed by the PI. The log will be reviewed and submitted to IRB per IRB requirements. Local SAEs will be individually signed as with severity and causality documented, and submitted to the local IRB as required by IRB policy. IRB submissions are electronically signed by the PI.

IP accountability will be maintained by appropriate members of the research team as delegated by PI. Any changes in dosing, starting or stopping IP will be directed by the PI and documented.

The PI and appropriate members of the research team will review study information that affects patient safety and/or the process of conducting the protocol (i.e. memos, newsletter, and significant email) by a Sponsor or CRO and document review.

All efforts will be made to schedule routine monitoring during a day that the PI will be available to meet with the monitor. However, if the schedule does not allow a meeting during the onsite visit, a phone meeting will take place with the PI or the meeting will occur at a subsequent monitoring visit as agreed by both.

Protocol deviations or violations, depending on frequency and severity, may require an action plan documented in a note to file or other IRB and/or sponsor required communication. Any such communication will be reviewed and signed by the PI.

A communication log, which may be in singular or combination of electronic copies, handwritten or email, will be maintained to document all trial-related discussions between Investigators and delegates (including third party delegates such as medical imaging or local labs).

Patient screening and enrollment will be reviewed with the PI and appropriate members of the research team and be documented as such.

References:

ICH Guideline for Good Clinical Practice E6, March 2018
21CFR312 Code of Federal Regulations Title 21, part 312 Investigational New Drug Application (May 2, 2018)
FDA Information Sheet guidance for Institutional Review Boards (IRBs), Clinical Investigators, and Sponsors (June 2010).

Approved: _____ _____

Title: Director of Clinical Trials