Principal Investigator Responsibilities and Oversight

The purpose of this document is to provide investigators and clinical research staff who are involved in study and subject management with expectations and requirements of performing the duties of a principal investigator and to ensure documentation of this critical process.

Every research study protocol has a Principal Investigator (PI). The PI is an individual who actually conducts the investigation. It is expected that all principal investigators will adhere to the Code of Federal Regulations (CFR) and International Conference on Harmonisation (ICH) Good Clinical Practice (GCP).

Prisma Health Clinical Trial Department Principal Investigator Qualifications for interventional studies:

- Any interventional study that involves investigational product (drug) or device, the PI must have an active State of South Carolina professional license for which that intervention is within their scope of practice. With rare exception, this would include:
  - Physician (MD, DO)

The PI is personally responsible for conducting and supervising the conduct of human subjects research by “protecting the rights, safety, and welfare of subjects under the investigator’s care.” The PI also must ensure that all the research conducted is done so in an ethical manner and in accordance with all federal, state, and local laws and regulations, institutional policies/procedures, the study protocol/plan, and the requirements of the IRB.

Oversight is defined as “management by overseeing the performance or operation of a person or group; watchful care, superintendence, general supervision”. Any person serving as a PI has voluntarily accepted these responsibilities and is expected to fully comply with these requirements.

To provide PI oversight and to ensure that the rights, safety, and welfare of research subjects is protected the PI should, at a minimum, confirm:

- Any individual to whom a task is delegated is qualified by education, training, and experience to perform the task
- There is adequate training for all staff participating in the conduct of the study
- The PI or another qualified individual associated with the study to provide study subjects with reasonable medical care for any adverse events, including any clinically significant laboratory values, related to the research
- The PI or another qualified individual associated with the study is available to study subjects to answer questions or provide care during the conduct of the research
- All research staff adhere to the research plan (i.e., inclusion/exclusion criteria, safety assessments, safety monitoring and reporting of unanticipated problems)
➢ There are processes to safeguard the protection of privacy and confidentiality of identifiable data

➢ There is minimization of risks to the subjects

➢ Informed consent is obtained and documented by a qualified individual in accordance with the regulations and local policy.

These requirements and expectations should be adequately and consistently documented thus demonstrating the involvement of the PI in providing study oversight. As such, a systematic approach to support these needs is required.

Expected Practices

I. The PI should work closely with the clinical research staff to ensure oversight of the research study and the necessary documentation of such activities.

   a. All clinical trials should have a Delegation of Authority Log prior to opening to accrual. This log should be maintained accurately during the life of the study.

   b. All clinical trials should have a Training log prior to opening to accrual. This log should be maintained accurately during the life of the study.

   c. The PI or delegated Sub-I will sign-off on all study-related documents (i.e., eligibility verification) prior to subjects beginning study treatment per protocol.

   d. PI’s will sign-off on all adverse events and serious adverse events.

   e. The PI or delegated Sub-I will sign-off on all laboratory results and other study related documents per protocol and to insure the safety of the study participants.

II. Study teams should have open, honest, and timely communication with the PI to ensure patient safety.

   i. The PI and SC should establish the method in which they will consistently communicate. At a minimum, this is intended to be through a combination of electronic, audio, and face to face interactions. Details and specifics of these interactions should be established by the PI and SC prior to activation of each study.

III. Communication regarding SAEs should be documented in real-time. If the PI is not available, the delegated Sub-I(s) should be notified. Regular meetings with the PI to discuss subject participation, including adverse events and treatment, is required to ensure adequate oversight.

   i. The PI and study team will schedule regular meetings, as appropriate to the needs of the study, to discuss all elements of the clinical trial. This is in addition to the immediate availability of the PI, or delegated Sub-I, to address SAE, protocol interpretation or other urgent needs. Involvement of the treating sub-investigator is recommended but not required.
IV. Documentation of PI oversight.

i. Timely and accurate documentation of oversight is required and expected to be provided by the PI consistent with FDA1572 and this guidance document. The nature of oversight documentation is through written and electronic means. Verbal oversight does not meet requirements for documentation of oversight unless converted to a written or electronic format.

ii. PI or Sub-I (as delegated) completion of urgent documents including initial SAE review and sign-off are expected to be done within 24 hours of notification of the event.

iii. PI completion of non-urgent regulatory documents including IRB submission/revisions, AE attribution assignments, AE grading are expected to be done within two (2) weeks, unless explicitly stated otherwise by the requesting unit.

iv. Additional study documents including but not limited to research notes, email correspondences, and study logs are to be reviewed at least on a monthly basis by the PI and/or prior to site monitoring visits, whichever is shorter, and filed in the research chart.