Roles & Responsibilities

Many individuals and groups are involved in conducting a clinical study. The central roles are those of the Sponsor and Principal Investigator, as defined by Good Clinical Practice (GCP) guidelines.

There are additional roles and responsibilities defined for other individuals and groups whose work is essential to the proper conduct of a clinical study. How these roles are referenced, may vary from one research network to another.

The following is a summary of responsibilities, as outlined in the GCP guidelines according to role.

Central Roles

Sponser

An individual, pharmaceutical company, governmental agency, academic institution, private organization, or other organization that takes responsibility for the initiation, management, and/or financing of a clinical investigation.

Data and Safety Monitoring

Members of each DSMB include experts in the disease area, treatment, clinical trial design, biostatistics, and research ethics.

Their role is to:

- Protect participant safety by being familiar with the study, proposing appropriate analyses, and reviewing outcome and safety data as they become available.
- Ensure study integrity by reviewing data on issues such as participant enrollment, site visits, study procedures, completion of forms, data quality, losses to follow-up, and other measures of adherence to the study protocol.
- Monitor adverse events and recommend changes in the protocol or operation of the study if necessary. This monitoring function is over and above the oversight traditionally provided by the IRB and is particularly important for multicenter research studies.

Quality Assurance and Quality Control

The Sponsor is responsible for implementing and maintaining quality assurance and quality control systems to ensure that studies are conducted and documented in compliance with the protocol, GCP, and regulatory requirements.

Medical Expertise

The Sponsor is responsible for designating appropriately qualified medical personnel to advise on trial-related medical questions or problems.

Study Design and Management

The Sponsor is responsible for designating qualified individuals to carry out all stages of the study process, including:

- Designing the protocol.
- Supervising the overall conduct of the study.
- Managing and verifying the study data.
- Ensuring the safety and rights of human participants.
- Monitoring study performance.
- Planning and conducting the statistical analyses.
- Preparing study reports.

Principle Investigator

Overview

The Principal Investigator (PI) is often the PI at the lead research site and has responsibility over the conduct of a clinical study at that site. For multicenter trials, there are a number of research sites, each with its own Principal Investigator with oversight responsibility and staff involved in the conduct of a study.

The PI retains ultimate oversight responsibility even when specific tasks are delegated to other site research staff. Additionally, PI responsibilities include:

- Documenting the delegation of study responsibilities to qualified and adequately trained research staff.
- Supervising study performance and overseeing the performance of study staff at the research sites.
- Ensuring that:
    - Participants' well-being and safety are protected.
    - All study procedures are conducted at the research sites in accordance with the protocol and GCP.
- Preparing a communication plan for all staff involved in the study.

- Overseeing Investigational Product accountability.

Qualifications and Experience

The PI must:

- Be qualified by education, training, and experience to assume responsibility for the proper conduct of the study.
- If the study involves the use of an investigational product, be thoroughly familiar with the appropriate use of that product as described in the study protocol.
- Be aware of and remain in compliance with GCP and applicable regulatory requirements.
- Maintain a list of qualified persons to whom he or she delegates significant study-related duties.
- Maintain supervisory responsibility for any individual or party delegated to trial-related duties and functions conducted at the trial site.
- Implement procedures to ensure the integrity of the trial-related duties and functions performed and any data generated.

Communication with Institutional Review Board

The PI is identified to the designated IRB. Before and during a study, the PI must comply with all requirements of the designated Institutional Review Boards (IRBs). A study may not begin prior to obtaining IRB approval.

Compliance with the Protocol

The PI is responsible for ensuring that the study is conducted in compliance with the **research protocol**. He or she should ensure that all protocol violations are identified, documented, and reported in accordance **with SGNHC Research Unit** and IRB requirements. Repeated protocol violations may indicate that protocol amendments, procedural changes, or additional training are needed.

Use of Investigational Products

Needs approval from National Health Research Council (NHRC)

Randomization and Blinding

The PI is responsible for ensuring that the study's procedures, if any, for **randomization and blinding** are followed.

Blinding/Masking

A procedure in which one or more parties to the trial are kept unaware of the treatment assignment(s). **Single blinding** usually refers to the subject(s) being unaware, and **double blinding** usually refers to the subject(s), investigator(s), monitor, and, in some cases, data analyst(s) being unaware of the treatment assignment(s). (ICH GCP 1.10)

Randomization
The process of assigning trial subjects to treatment or control groups using an element of chance to determine the assignments in order to reduce bias. (ICH GCP 1.48)

Informed Consent

The PI is responsible for ensuring that procedures for obtaining and documenting informed consent comply with GCP and with the ethical principles originating in the Declaration of Helsinki.

Records and Reports

The PI is responsible for ensuring that all study data that are reported to the Sponsor are accurate, legible, contemporaneous, original, accurate, and complete. Changes to the source data should be traceable, should not obscure the original entry, and should be explained if necessary (e.g., via an audit trail).

The PI should provide written reports on the status of the study to the Sponsor and IRB when and as often as required to do so at each institution where the study is conducted.

All serious adverse events must be reported immediately to the Sponsor. The PI must also comply with regulatory requirements to report serious adverse events to the IRB and regulatory authorities.

Final Study Reports

On completion of the study, the PI is responsible for providing:

All required reports to the Sponsor and regulatory authorities.

A summary of the study outcome to the Institutional Review Board and SGNHC Research Unit.

Premature Suspension or Termination of Study

If the study is suspended or stopped early for any reason, the PI is responsible for:

- Promptly informing all study participants.
- Ensuring that all participants receive appropriate therapy and follow-up.
- Complying with all requirements to inform regulatory authorities.

Other roles

Overview

The investigator convenes a Protocol Team to assist with all aspects of the operation of the study. In addition to the responsibilities listed under Principle Investigator, other responsibilities represented on the Protocol Team usually include, but are not limited to, Quality Assurance, Training, and Regulatory Affairs.

Quality Assurance

Quality Assurance (QA) staff is responsible for:

- Reviewing the protocol to check for inconsistencies and problematic wording that will increase the likelihood of protocol violations.
- Reviewing monitoring reports of site visits to ensure that all identified issues are addressed in an appropriate and timely fashion and are communicated to the investigative team.
- Conducting site visits on the behalf of the Sponsor as needed.

Training

Training staff is responsible for:

- Developing a study-specific training plan.
- Ensuring that all training of study staff is conducted as planned and documented on the study specific training log.

Regulatory Affairs

Regulatory Affairs staff is responsible for:

- Writing the study informed consent documents.
- Submitting the protocol, consent documents, and SGNHC Research Unit and I documents to the nstitutional Review Board (IRB) and making any changes in those documents required by the IRB.
- Distributing the IRB-approved protocol, consent documents, and Institutional Review Board (IRB) documents to participating research sites to assist them in preparing their IRB submissions.
- Preparing and distributing a checklist of items that participating sites must have, and

- Providing regulatory guidance to the study sites as necessary.

This responsibility continues throughout the duration of the trial e.g. submission of a Protocol Amendment.

Research site staff

Research Coordinator/Assistant

Under the supervision of the PI at the site, examples of responsibilities for the Research Coordinator/Assistant may include:

- Ensuring that study data is accurately collected and reported.
- Reporting any study or participant problems.
- Maintaining regulatory files at the study site.
- Working with the Quality Assurance Monitor and data management staff to identify and resolve data and reporting issues.

The Research Assistant's role frequently also includes interacting with study participants by performing assessments (for example, assessing quality of life) and other protocol procedures.

Nurses, Pharmacists, Counselors, Supervisors and Other Staff

Nurses, pharmacists, and other staff are responsible for carrying out study procedures as described in the protocol (e.g., receiving and dispensing medications, conducting physical examinations, delivering behavioral interventions) and for assessing and reporting adverse events to appropriate staff.