CHICKEN SOUP FOR THE BUSY COORDINATOR

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The Responsibilities of PI, Co-I and Clinical Research Coordinators?

Scenario

Dr K is assigned to be a Principal Investigator (PI) for a diabetes clinical research. As this is his first time being a PI, he is unsure of his responsibilities in the study. Therefore, an experienced mentor is engaged to guide him through the responsibilities for different study roles.

Principal Investigator - If a trial is conducted by a team of individuals at a site, the investigator is the responsible leader of the team and may be called the principal investigator.

NB: *An investigator is a person responsible for the conduct of a clinical trial at a trial site. The investigator must therefore be qualified by education, training and experience to assume responsibility for the proper conduct of the trial, and should be thoroughly familiar with the appropriate use of the investigational product. For these reasons, an investigator is typically a qualified practitioner with the relevant experience in the therapeutic area under study or, in the case of certain low risk trials involving only locally registered therapeutic products initiated by a pharmacist principal investigator, a qualified pharmacist (please refer to MOH's Guidance on Pharmacists as Principal Investigators for more information). As the Clinical Trial Regulations require that informed consent must only be obtained by an investigator of a clinical trial, who is delegated by the PI and qualified to obtain consent, a pharmacist should only be involved in obtaining consent if the pharmacist is a principal investigator or investigator of the trial (e.g., in a pharmacist PI-initiated trial) who assumes responsibility for the conduct of a clinical trial.*

Responsibilities of the PI may include the following but not limited to:

- ✓ Ensure that study team members delegated are qualified by education, training and experience to carry out the delegated responsibilities
- ✓ Comply to protocol, applicable regulations, and the principles of Good Clinical Practice (GCP)
- ✓ Have adequate facilities and resources
- ✓ Have sufficient oversight of the trial and time to conduct and supervise the research study and complete it within the agreed period
- ✓ Obtain proper informed consent from subjects

Communicate effectively with participants, research team, IRB, regulatory authority and sponsor (where applicable)

- ✓ Maintain proper study records (E.g. Study Delegation Log)

Co-Investigator – Any individual member of the research team designated by the PI to perform critical trial/research related procedures and/or make important research-related decisions.

Responsibility:

- ❖ Sharing similar responsibilities but not limited to those of PI.

Clinical Research Coordinator (CRC)/ Research Assistant (RA)/ Research Nurse (RN)

Responsibilities of the CRC/ RA/ RN may include the following but not limited to:

- ✓ Assist the PI to develop enrollment / follow-up mechanism
- ✓ Assist with enrollment and follow-up of study participants
  - Screening and enrollment procedures
  - Participant follow-up procedures
  - Data Collection Form/ Case report Form completion and study documentation
  - Ensure adverse events are assessed by investigators, documented and reported to IRB, regulatory authority and sponsor (where applicable)
  - Maintain and update essential documents
  - Assist PI to respond to the monitoring/audit/inspection report within stipulated timeline
- ✓ Assist with study close-out
  - Ensure all study documentations are completed and filed
  - Ensure all reportable events are submitted to IRB, regulatory authority and sponsor (where applicable)
  - Assist with archival of study files for the time period required for the study

References:

1) NHG PCR SOP 501-A02: Responsibility of the Research Team
2) HSA website: Conducting Clinical Trial, Study Staff
HSA | Study staff

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