Useful Tips and Recommendations

- It is the PI's responsibility to commit sufficient time in acquiring manpower and procuring adequate resources for the foreseen duration of the study, prior to initiating any study activities.

- The PI is responsible for ensuring that the study staff members are appropriately qualified and trained on their delegated tasks before study initiation.

- Should any amendments to the study documents and/or procedures be necessary, the PI should ensure that written approval is received from the DSRB (and the regulatory authority, if applicable) before implementing these changes.

- Regular and open communication within the study team is encouraged.

- Protocol deviations and any other pertinent information should be promptly and accurately reported to the DSRB (and the regulatory authority, if applicable) for review.

GCP FREQUENTLY ASKED QUESTIONS

WHAT ARE THE PRINCIPAL INVESTIGATOR'S RESPONSIBILITIES WITH REGARD TO THE MANAGEMENT OF A STUDY TEAM?

The Singapore Guideline for Good Clinical Practice (SGGCP) places much responsibility on the Principal Investigator (PI) to secure sufficient manpower and resources, to ensure that a study can be properly carried out. A crucial element to this end would be having appropriately trained and qualified study staff to assist with the delegated responsibilities.

Section 4.1.1 of the SGGCP states that investigators must be "qualified by education, training and experience to assume responsibility for the proper conduct of the trial". Section 4.2.3 further elaborates that "the investigator should have available an adequate number of qualified staff and adequate facilities for the foreseen duration of the trial to conduct the trial properly and safely".

The PI's Role

Listed below are some pointers that PIs should take into consideration prior to the commencement of a clinical research study:

- As a prerequisite, the PI must bear qualifications that satisfy the ethics committee's requirements (and the regulatory authority's requirements, where applicable) to lead the study. These may include having appropriate medical credentials, as well as completing the Collaborative Institutional Training Initiative (CITI) and Singapore Guideline for Good Clinical Practice (SGGCP) courses;

- When conducting clinical trials, the PI should be thoroughly familiar with the study protocol, and the appropriate use of the investigational product as described in the Investigator's Brochure, product information or any other information sources provided by the sponsor;

- The PI should maintain a list of appropriately qualified persons to whom he/she has delegated significant research-related responsibilities. Additionally, the PI will be required to train the study team on their respective roles in the study, based on the protocol requirements; and

- The PI should ensure that all persons assisting with the research are adequately informed about the protocol, investigational product(s) and their research-related duties.

Change of PI

If it is anticipated that the PI will be going away for an extended period of time or resigning from his/her institution, the research project should be formally transferred to another PI to oversee. The incoming PI will then assume the same responsibilities as the outgoing PI as detailed above.

In the process of ensuring a smooth transition of duties, it should be noted that any change of PI must first be reviewed and approved by the ethics committee (and the regulatory authority, where applicable) prior to implementation. Once approval is received, the new PI's start date and delegated responsibilities should be updated accordingly on the delegation log.

The Study Team

Each study staff plays a similarly crucial role in ensuring that the conduct of the study goes smoothly. Aside from accruing study team members with the necessary qualifications to discharge their study responsibilities, the PI needs to ensure the following:

- For any new additions to the study team after study initiation, the PI is responsible for providing protocol-related training for the new staff member(s). Such training should also be documented;

- The delegation log will need to be updated with the roles, responsibilities and signatures of the new study staff, endorsed by the PI ;

- For current staff exiting the study, the PI should ensure that there is a proper handover of responsibilities from the outgoing staff to another member of the study team; and

- The delegation log should be similarly updated with the end date of the outgoing study staff member.

Paying heed to these details will go a long way in ensuring that PIs are better equipped to manage changes in their study team, which will in turn translate into more efficiently-run research studies.

References

- *Singapore Guideline for Good Clinical Practice (SGGCP)*
- *NHG DSRB SOP 201-E01 Responsibilities of Investigators*
- *Good Clinical Practice: A Question & Answer Reference Guide. May 2011. Chapters 2.13 and 2.14*