No.8: Direct all Relevant Site Operations

Proper Delegation of Responsibilities

Prior to the initiation of any study, the Principal Investigator (PI) has to ensure that the study team members are familiar with the protocol and possess the appropriate training and qualifications for the duties they are delegated.

The study team will be required to be trained on the protocol and attend all study-related training and start-up meetings before initiation of the study.

In addition, the PI has to ensure appropriate delegation of duties in the study. An example is: a study coordinator who has qualifications in phlebotomy being delegated for the blood specimen collection procedure in the study.

Another example of appropriate delegation would be the PI or Co-Investigator (Co-I) being delegated the task of obtaining informed consent from potential participants.

This will ensure that medical opinions and advice will be available to all subjects before they agree to participate in the study.

Meanwhile, a list of qualified persons and their corresponding research-related delegated duties in the study responsibility log should be maintained. This list has to be updated accordingly whenever there are changes to manpower or delegation of duties in the study.

Assuring Continuing Protocol Compliance

During the study, the PI is accountable for continuing protocol compliance and dissemination of information to the participants and relevant authorities.

Participants have to be informed of any new information that may affect their willingness to continue participation. This may be done through, but not limited to, the following means:

- Information Letter
- Addendum to previously signed consent form – to be signed by subject
- Revised consent form – to be signed by subject

The PI also ought to be familiar with reporting requirements to the relevant authorities, and ensure prompt reporting on issues, such as unanticipated problems involving risks to subjects or others (UPIRTSO), and protocol deviations.

Reporting requirements to the NHG Domain Specific Review Board (DSRB) will include the following issues:

- UPIRTSO
- Protocol Deviation and Noncompliance
- Continuing Review Reports
- Protocol Amendments

Monitoring and Auditing

During the study, there may be instances of monitoring and audits by the Sponsor, NHG Research Quality Management and Regulatory Authorities. The PI should see to the availability of all necessary documents during monitoring and audits and that study team members are available for queries.

The PI may also consider providing oversight of protocol compliance and progress by meeting the study team regularly to discuss and identify issues relating to the study, and ensuring that necessary actions are taken.

References:

- *NHG PCR SOP 501-A02 Responsibiities of the Research Team*
- *NHG PCR SOP 501-C01 Informed Consent Document and Process*
- *NHG DSRB SOP 201-C05 Continuing Review*