The Principal Investigator's Roles & Responsibilities

No. 6 : ASSURE PROTOCOL COMPLIANCE THROUGHOUT STUDY

Protocol Compliance

The investigator or institution maintains protocol compliance by agreeing to conduct the trial in accordance with the approved protocol agreed to by the sponsor and, if required, by the regulatory authority and which was given approval by the relevant institutional review board (IRB), or the Domain-Specific Review Boards (DSRB).

Assuring Protocol Compliance

The PI should assess the feasibility of the protocol and ensure that there are adequate resources (e.g. manpower) and time to conduct the trial so that the protocol may be carried out reasonably to ensure protocol compliance. The inclusion and exclusion criteria of the study need to be determined if they are applicable to the study population as well.

The PI should also put in place realistic and attainable recruitment targets, be thoroughly well-versed with the protocol requirements, and adhere to the trial procedures so as to assure protocol compliance.

To ensure compliance, the PI may employ practical measures such as:-

- using an eligibility checklist for screening or enrolling subjects,
- reviewing the inclusion and exclusion criteria, visit schedules, study end-point criteria,
- training the research team on investigational product use *(if applicable),*
- training new study team members adequately.

Protocol Deviation

A protocol deviation occurs when the PI or study team deviates from the procedures or requirements stipulated in the protocol. No deviation or change to the protocol should be implemented without prior agreement by the sponsor and approval by the DSRB, except where necessary to eliminate immediate harm or hazard to the participant, or if it involves administrative changes to the research study.

Noncompliance

A noncompliance occurs when the PI fails to conduct a study as explicitly described in the protocol, whether by accident, on purpose, or due to negligence.

Reporting of Noncompliance and/or Protocol Deviation

The PI should report any occurrence of noncompliance to the DSRB via the DSRB Noncompliance/Protocol Deviation Event Report Form. A non-study team member may also report the noncompliance to the DSRB. In this case, the confidentiality of the reporter will be protected unless a disclosure is required.

If the allegation is determined to be valid, the investigator will be required to give an explanation and provide a corrective action plan to avoid repeating the noncompliance.

For serious or continuing noncompliance, the DSRB will notify the Department and Institution Representatives, Health Science Authority (HSA) and the Sponsor. Other relevant authorities such as the Research Ethics Committee (REC), Food and Drug Administration (FDA) or OHRP (Office of Human Research Protection) may also be notified. Punitive actions may be taken by the institution, and the DSRB must be kept informed.

When should the non-compliance be reported?

The investigator should document a non-compliance occurrence and explain the deviation in an event reporting form to the DSRB within **7 calendar days.** The sponsor should be notified as soon as possible.

References:

SG GCP : Investigator – Compliance with Protocol

www.gcphelpdesk.com/index.php/knowledge-base/item/download/6

NHG PCR SOP 501-A02 Responsibilities of Investigators

http://www.research.nhg.com.sg/wps/wcm/connect/romp/nhgromp/resources/research+sops