CONTINUATION OF PARTICIPATION IN CLINICAL TRIALS AT STEP-DOWN CARE FACILITIES

Step-down care facilities play an important role in Singapore's healthcare system, and consist of community and chronic sick hospitals, nursing, psychiatric rehabilitation and sheltered homes, inpatient hospice institutions, day rehabilitation, dementia day care and psychiatric day care centres. Step-down care facilities, in particular, cater to patients who require inpatient convalescent and rehabilitative care, those who do not have families or caregivers to look after them at home, or where the caregiver is unable to provide the nursing care required.

For clinical trials approved by the DSRB, subjects by and large are recruited and consented at acute care hospitals. Currently, there are no clear guidelines defining obligations of investigators who wish to have their clinical trial protocols continued uninterrupted at step-down care facilities. However, as a responsible researcher and physician, the investigator must ensure that trial-related information is properly communicated to members of the staff at the step-down care facility. Communication plans are essential to maintaining compliance to the trial protocol, ensuring continuity of the clinical trial, and more importantly, providing the assurance to subjects and their caregivers that their safety and welfare are not being overlooked. The investigator is encouraged to communicate the following items to members of the staff at the step-down care facility:

- Contact number and person for trial-related issues;
- Trial procedures to be followed, especially when it relates to the administration of Investigational Product(s) (IP);
- The foreseeable adverse events;
- Arrangements in the event of trial-related injury;
- Circumstances under which the subject's participation in the trial may be terminated;
- Communication of non-compliance and adverse events to investigators.

"Therefore, before conducting a clinical trial or research study, the investigator should anticipate and plan ahead. If there is a likelihood that the study subjects may be transferred from the acute care hospitals to step-down care facilities, appropriate communication plans should be put in place."

The Singapore Guideline for Good Clinical Practice (SG-GCP) Section 4.2.4 states that the investigator is responsible for ensuring that all persons assisting with the trial are adequately informed about the protocol, the IP and their trial-related duties and functions. Negligence of the investigator to ensure proper communication of the research to the staff at the step-down care facility, or failure of the investigator to protect the safety and welfare of the subjects may be considered as non-compliance.

References:
- *Singapore Guideline for Good Clinical Practice (SG-GCP)*