Ensure Documentation of Study Related Procedures and Events

The Principal Investigator (PI) assumes the responsibility to ensure that study-related procedures and events are properly documented and essential research documents well-maintained.

Documenting Informed Consent

Both the person conducting the consent procedure and the subject (or the subject's legally acceptable representative) should sign and date on the Informed Consent Form (ICF), as a form of documentation that informed consent has been obtained prior to the subject's participation. For studies involving access to subjects' medical records, information about the consent process, such as the study title, date of consent and the fact that a copy of the ICF was given to the subject, should also be documented in the medical records by the person who conducted the consent procedure.

Recording Research Information and Documenting Changes to Data and Case Report Forms

Prior to study initiation, the PI and the study team should agree upon the source documentation required for the study. The PI should also ensure the accuracy, completeness, and legibility of recorded research information and data reported in the Case Report Form (CRF). The data in the CRF must be consistent with the source documents and any discrepancies should be explained. Changes or corrections to the CRF should be made by crossing out the original entry with a single line without obscuring the original data. The correct entry should then be written near the original entry. The change should also be dated, initialed, and explained (if necessary). This is to ensure that the recorded study information will allow for accurate reporting, interpretation and verification.

Documenting Adverse Events

The PI is responsible for ensuring that all study-related adverse events and the management of these events are accurately documented in the medical records. Documentation should include details, causality, severity, date of onset, end date, treatment provided and outcome of the event.

Documenting Deviations

Any protocol deviation(s) from the approved protocol, during the course of the study (except to eliminate any immediate hazard(s) to the subject), should be adequately documented. The agreement by the sponsor and necessary Institutional Review Board (IRB) documented approval should also be obtained prior to implementing the deviations.

Documenting Premature Un-blinding of Investigational Product

For blinded studies, any premature un-blinding of the investigational product (e.g. accidental un-blinding, un-blinding due to a serious adverse event) should be well-documented with explanation provided for the premature un-blinding.

Providing Study Reports According to Requirements

It is the PI's responsibility to provide any written reports on changes significantly affecting the conduct of the trial and/or increasing the risk to subjects, study status reports or study completion reports, as requested by sponsor, DSRB and HSA.

Ascertaining the Reason for Subject's Premature Withdrawal

In the case of a participant's premature withdrawal from the study, the investigator should make a reasonable effort to ascertain the reasons for the withdrawal (while respecting the participant's rights) and the reasons recorded in the Subject Enrolment Log and the subject's medical notes.

Maintenance and Retention of Research Documents as Per Requirements

During the course of the study and throughout the period required for its retention, PI is responsible for ensuring that all essential documents are maintained. According to MOH guidelines, inactive medical records are culled. Hence, to enable retention of these medical records, the PI must indicate on the cover of the medical records, the retention requirements of the trial, so as to prevent accidental or premature destruction of these documents. The PI (with help of the clinical research coordinator) must also arrange for archiving of all other essential study documents in a secure location that is access controlled. Information regarding the period of time required for retention of these documents can be found in SGGCP Section 4.9.6.

References:

- *Singapore Guideline for Good Clinical Practice (SG-GCP)*
- *NHG Proper Conduct of Research SOP 501-A02 Responsibilities of the Research Team*
- *NHG Proper Conduct of Research SOP 501-B05 Documentation*