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| **TGHN-256x151px**  **Standard Operating Procedure** | | | **SOP No:**  **Version: 1**  **Effective Date:** | |
| **Title: Study Team Training and Study Handover** | | | | |
|  | **NAME** | **SIGNATURE** | | **DATE** |
| **PREPARED BY** |  |  | |  |
| **REVIEWED BY** |  |  | |  |
| **QA UNIT**  **AUTHORITY** |  |  | |  |
| **APPROVAL**  **AUTHORITY** |  |  | |  |

**16.1 Purpose**

This SOP defines the procedure and recommendation of training of study team members and adequate handover to CTC/study team member, to ensure that the patient safety, protocol compliance, data integrity and overall quality assurance at the investigational site is protected and integrated as per the applicable regulations and guidelines.

Study team members must understand the responsibilities of the trials conducted at site and be appropriately qualified by education, training and/or experience to perform his or her research-related task(s). Some training may be obtained through internal hospital accepted training and certification program(s) or through external hospital accepted training and certification program(s).

The purpose of a handover is to ensure continuity of operations when the study team member, usually responsible, is not available due to temporary or permanent absence. A handover can be supported by a discussion to explain the status of the tasks, a summary of the work status in an email/ memorandum or, a more detailed file.

**16.2 Scope**

This SOP will apply to all study team members conducting studies in [Institution].

**16.3 Procedure**

**16.3.1 Study Team Training**

On appointment, all study team members will be given an appropriate study depending on the job specification to possess the right experience and qualifications and further training may be provided to bring them up to the required level for specific tasks. Duty delegation / job responsibility document will be given to every Clinical Trial Coordinator (CTC)/ team member.

The Medical Director and department of clinical research recommend that all Investigators, CTC and other study team members must undergo training which will enable them to understand their responsibilities, applicable regulations, guidelines and research studies and training should be documented in the training log.

Each Investigator, CTC and study team members will review and learn the site's SOPs. It is recommended that SOP training must be included in the orientation of new clinical research personnel. All applicable clinical research personnel should be knowledgeable of new or revised SOPs.

Good Clinical Practice (GCP) is a universal standard in clinical research that must be followed in every research protocol. GCP training and education are recommended for research team members, especially the Investigator and CTC. However, any member of the research team with a significant role in the conduct of a research study must be knowledgeable in GCP. All members of the clinical research team should GCP trained and certified.

If scheduled, the PI and CTC will attend the Investigator Meeting (organized by Sponsor) and complete all required training for a study. If PI is unable to attend the meeting, PI can recommend other study team member(s) to attend the IM. PI should be informed regarding the study contents discussed in IM.

Before study initiation the Sponsor/CRO will organize SIV meeting at site to train all study team members and all study team members should attend the meeting for thorough understanding of the study.

The PI and study team member(s) should be prepared to demonstrate all training received. CVs, GCP and other training certificates should be updated as required. It is recommended that an assessment of the employee’s knowledge of the regulations and guidelines can be conducted upon recruiting and on a regular basis. It is recommended that an assessment of any additional protocol-specific skill requirements be conducted prior to activation of each new study.

The Department annually conducts two training programmes namely Clinical Research Methodology (CRM) and GCP. Study team members should attend the course to acquire training or to update themselves.

The department will arrange a SOP training workshop to train PI and study team in addition PI can also train the study team and should maintain the training record (AX1-V3/SOP16/V3).

It is recommended that the PI and study team must maintain the Site SOP training Record (AX1-V3/SOP16/V3) at their respective unit and should make available whenever asked by the DOCR

**16.3.2 Study Handover**

If any study team member is planning for leave or to resign, he/she must ensure that the proper handover is given to concern person identified by the PI, the identified person should be briefed in time before the person goes on leave to allow for any follow up questions.

Prior to leaving the study, the existing study team member should complete the following:

* Training on protocol and procedures e.g. SOPs and explanation of relevant documents
* Information regarding study subjects, study documents and all study related activities
* Outstanding data entry and/or data queries
* Training to complete source documents
* Explanation on the objectives & priorities
* Notification to the sponsor of the study team changes
* Notification to the active subjects of the study team changes if the research team contact information will change for the subjects.
* Provide a list of study-specific contacts (e.g., sponsor, monitor, vendors involved etc)
* Provide a list of outstanding issues
* The leaving person has to make sure that the documentations concerned for the tasks is up to date and easily available, and if needed, revise it when preparing the hand over.

If there is a change in PI, the following documents need to be revised and completed;

* Inform Sponsor and IEC regarding the change in PI in the Study team.
* Consider revising the protocol and informed consent form, as appropriate. Also consider notifying current subjects; correspondence sent to all subjects must be approved by the IEC, if applicable.
* Update the Form FDA 1572 or the Investigator Agreements, Investigator Undertaking and other required forms
* Update the Duty Delegation log
* Ensure that the new PI has completed the SOP required training and study-specific training
* Written hand over should be given in order to ensure the continuity of work. The format can be a briefing note, a check list, or a schedule prepared to give all information.

When the study member returns from leave a hand over should be prepared to give updates on the status of the tasks.

The existing and new study team member should document the study handover in a note to file or other documentation in the TMF. The note should contain some of the items above and the date of the handover. The new study team member should obtain documented study-specific training and any required approvals prior to being added to the duty delegation log.

**16.4 Applicable Staff**

This SOP applies to all the existing personals of the clinical research team and any new member appointed who may be responsible for training and study handover as mentioned in this SOP( as per the delegation log).

These include the following:

* Investigator
* Research Team (listed in the delegation log)
* CTC

**16.5 Staff responsible for Implementation**

The department and Investigator will ensure that the research team involved in the conduct of the study will comply with this site SOP.

The department and PI will ensure that at the time of implementation of the SOP, that the research team at the clinical research unit in [Institution] are trained and in the event that an SOP is modified, provide training regarding the change(s) and ensure their compliance with the changes.

It is the responsibility of each individual who are about to go on short / long term absences or leave their current position / the Agency to prepare a hand over file.

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| **16.8** | **References** |

1) ICH GCP

2) Schedule 7