Category: Study Conduct
Title: Ensuring continuity of trial in case of staff and investigator attrition
SOP No: D 28/07
Date first effective: 1 Jan 2025 **Review date:** 31 Dec 2025

Department of Clinical Pharmacology, 1st Floor, New MS Building,
Seth GS Medical College & KEM Hospital, Parel, Mumbai-400012

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1. Purpose

The purpose of this SOP is to describe the procedure to be used when a new study member joins the study team due to a study team member leaving the team.

2. Scope

This SOP is limited to the process of assigning responsibilities to new team member in a study in the case of absence, resignation or leave of another team member from the study concerned.

3. Responsibilities

Principal Investigator, Co-investigator, Study Coordinator or any other appropriately qualified member of staff in the team, as delegated by the Principal Investigator, will be responsible for implementing this SOP.

Detailed Instructions

1. During the conduct of the study, there may be attrition of study team due to transfer, resignation, long leave or demise.

2. For a clinical study to run smoothly, an appropriately qualified and experienced person needs to be identified to replace the person who has left the team.

3. For a defined role in a clinical trial, two persons (primary and secondary) are responsible. At the time of appointment of the primary person who is principally accountable for the role, a secondary person must be identified and allocated the role as a back-up. Both the person designated for the primary and secondary role need to be trained by the principal investigator.

4. If a person wants to resign or is being transferred from the job, he/she needs to submit a prior resignation or transfer letter and serve a notice period of 30 days in the same role.

5. A new individual will be recruited for the secondary role within a period of 30 days of resignation of the primary or secondary person and will be trained within 15 days. The primary person will further train his back up within a span of 15 days from the date of his

resignation. A training certificate needs to be issued by the primary investigator within a period of 15 days after completion.

6. The outgoing person should hand over all his documents pertaining to the trials to the principal investigator or to the immediate successor within 15 days of leave/resignation/transfer during the 30 days notice period.

7. A point of contact need (address, email id and phone number) to be kept of the person leaving the study so that he/she can be contacted whenever necessary.

8. In case of unplanned attrition like demise or person leaving the study without intimating the principal investigator, the secondary person responsible takes the charge immediately and a new person will be appointed within 30 days. Protocol and study related training will be provided to both of them by the principal investigator/designee and will be certified accordingly within 15 calendar days.

9. Any change of responsibilities in the study team needs to be notified in writing to the Institutional Ethics Committee within a period of 7 days by the Principal Investigator/ designated study coordinator.

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