Category: Study procedures
Title: Preparing Standard Operating Procedures (SOPs) for clinical trial related activities in the Department of Clinical Pharmacology, K.E.M. Hospital, Mumbai
SOP No.: D 01/04
Date first effective:02May 2022**Review date:**01May 2023

Department of Clinical Pharmacology, 1st Floor, New MS Building,
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Category: Pre study procedures

Title: Preparing Standard Operating Procedures (SOPs) for clinical trial related activities in the Department of Clinical Pharmacology, K.E.M. Hospital, Mumbai.

SOP No: D01/04 **Total pages:** 14

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Table of Contents

1. Purpose

The purpose of this Standard Operating Procedure (SOP) is to define the process for writing, reviewing, distributing and amending the SOPs of the Department of Clinical Pharmacology (DCP), Seth GS Medical College and KEM Hospital, Mumbai. The SOPs provide clear, unambiguous instructions so that the related activities of the department are conducted in accordance with applicable institutional, national and international guidelines and laws.

2. Scope

This SOP covers the procedures of writing, reviewing, distributing and amending the SOPs of the DCP.

3. Responsibility

It is the responsibility of the Head of the Department (HOD) of DCP to appoint an SOP Team to formulate the SOPs of the applicable procedures related to clinical research in the DCP. The SOP Team shall do this by following the same procedures, format, and coding system when drafting or editing any SOP of the DCP for clinical research.

1. The Secretarial Office of the Department of Clinical Pharmacology will

    - Co-ordinate activities of writing, reviewing, distributing and amending SOPs
    - Maintain on file all current SOPs and the list of SOPs
    - Maintain an up-to-date distribution list for each SOP distributed to the members of the Department of Clinical Pharmacology
    - Maintain a record of the staff to whom SOPs are distributed

- Ensure that all the DCP members and involved administrative staff have access to the SOPs
- Maintain on file all past SOPs of the Department of Clinical Pharmacology
- Assist HOD to formulate an SOP Team

2. SOP team will
    - Select the format and coding system for SOPs
    - Draft the SOP in consultation with the involved DCP members and administrative staff
    - The senior-most member of the SOP team will review the draft SOP
    - Submit the draft for approval to HOD

3. HOD of the DCP will
    - Assess the request(s) for SOP revision
    - Appoint the SOP Team
    - Approve the SOPs
    - Sign and date the approved SOPs
    - Ensure that all the Department of Clinical Pharmacology members and involved staff are working according to current version of SOPs

4. Dept. of Clinical Pharmacology members and involved administrative staff will:
    - Sign and date the approved SOP when they receive it
    - Maintain a file of all SOPs received

4. Detailed instructions

1. Identify the need for new or amending SOP

   - Any member of the DCP, Secretariat or administrative staff who would like a revision or notices an inconsistency/ discrepancy / has any suggestions on how to improve an existing SOP or requests to design an entirely new SOP can make a written application to the HOD.
   - If the HOD believes that the new SOP/revision of old SOP is justified, the HOD will appoint an SOP team and designate to them the task of revising/ formulating the SOP.
   - The SOP writing team will carry out the subsequent steps (2-5).

2. Design a format and layout

   - Each SOP should be given a number and a title that is self-explanatory and is easily understood. A unique code number with the format SOP xx / yy will be assigned to each SOP item by the Secretariat. xx will be a two-digit number assigned specifically to that SOP. yy will be a two-digit number identifying the version of the SOP . The number of version should be started from 01 hence for example, SOP 01/01 is the SOP number 01 with version 01.
   - A master SOP would be created for all the division (i.e Phase 1, Conducting a research, Laboratory works etc)
   - Each SOP number shall not be repeated even in superseding SOPs.
   - The prefixes would be given to SOP no for identification as per

- D: Departmental SOP
- P: Phase 1 SOP
- TDM: TDM SOP
- L: Laboratory SOP

- Each SOP will be prepared according to the standard template in Appendix 1.

- Each page of the SOP will bear the header which will have the following information:

Category:
Title:
SOP No.: xx/yy
Date first effective: Review date:
Department of Clinical Pharmacology, 1st Floor, New MS Building,
Seth GS Medical College & KEM Hospital, Parel, Mumbai 400012.

Each page of the SOP will bear a footer which will have the following information:

Confidential Page a of b

3. Write and review a new/revised SOP

- If an SOP supersedes a previous version, indicate the previous SOP version and maintain changes in the Document History Book maintained with the Secretarial office.

- When the need for a new SOP has been identified and agreed on, a draft will be written by a designated member of the SOP team appointed by the HOD.

4. Review by Consultation

- The draft SOP written by SOP team will be reviewed by a senior staff member as designated by the HOD

5. Approve a new/ revised SOP
   - The final version will be presented to the HOD for review and approval.
   - The HOD will sign and date the SOP on the first and last page of the SOP document.
6. Ensure Implementation, distribute and file all SOPs
   - The approved SOPs will be implemented from the effective date.
   - The approved SOPs will be distributed to the DCP members according to the distribution list.
   - One complete original set of current SOPs will be filed centrally in the SOP Master file, in the office of DCP.
   - When the revised version is distributed, all the DCP members will be requested to destroy the earlier version.
   - One copy of the earlier version will be filed centrally in the file entitled 'Past SOPs of the DCP' by the Secretariat of the DCP in the DCP office.
   - The Departmental SOP will be available online on https://www.kem.edu/clinical-pharmacology/

Review and request for a revision of existing SOPs

- The DCP will review the SOPs as per the review date specified on each SOP.

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5. Glossary

1. SOP (Standard Operating Procedure)

Standard Operating Procedures (SOP) are detailed, written instructions, in a certain format, describing activities and actions undertaken by an organization to achieve uniformity of the performance of a specific function. The aim of the SOPs and their accompanying checklists and forms is to simplify the functioning, whilst maintaining high standards of Good Clinical Practice.

2. Master SOP files

An official collection of the Standard Operating Procedures (SOP) of DCP for Research on Human Subjects accessible to all staff members, auditors and government inspectors as a paper copy with an official stamp on each page and the approval signatures. Photocopies made from these official paper versions of the SOP cannot be considered current or official.

6. References

1. International Conference on Harmonization, Guidance on Good Clinical Practice (ICH GCP) 1996- http://www.ich.org/LOB/media/MEDIA482.pdf (last accessed on 30th April 2021)
2. ICH E6 (R2) Integrated Addendum to ICH E6 (R1), Current Step 4 version dated 9th November,2016. http://www.ich.org/fileadmin/Public_Web_Site/ICH_Products/Guidelines/Efficacy/E6/E6_R2__Step_4.pdf (last accessed 30th April, 2021)
3. ICMR's Ethical Guidelines for Biomedical and Health research involving Human Participants,ICMR(2017) http://www.icmr.nic.in/guidelines/ICMR_Ethical_Guidelines_2017.pdf (last accessed 30 April 2021)
4. New Drugs and Clinical Trials 2019

Appendix 1 Standard Template for SOPs of Dept. of Clinical Pharmacology

Cover page:

Category:

Title:

SOP No.: **Total pages:**

Date first effective: **Next Review date:**

Version:

Author: Name, Designation

Signature with date

Reviewer:
Signature with date

Approved by:

Signature with date

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Main text

1. Purpose
2. Scope
3. Responsibilities
4. Applicable rules, regulations and guidelines
5. Reference to other applicable SOPs
6. Detailed instructions
7. Appendix

Last page:

Reviewer:

Signature with date

Approved by:

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