

Category: Study procedures

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

SOP No./Version: DCP 01/08

Date first effective: 01 Jan 2026

Review date: 31 Dec 2026

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Category: Pre study procedures

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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. This SOP provides clear, unambiguous instructions so that the related activities of the department are conducted in accordance with applicable departmental, institutional, national and international guidelines, laws and regulations.

2. Scope


This SOP covers the procedures of writing, reviewing, distributing and amending the SOPs of the Department of Clinical Pharmacology.

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, formats, and coding systems 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 distributing 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
- Maintain training record of the staff
- Maintain on file all current and past SOPs

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- Maintain lists of SOPs
- 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

2. SOP team will

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

3. Head of the Department (HOD) of the DCP will

- 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
- Assess the request(s) for SOP revision /ammendments

4. Dept. of Clinical Pharmacology members and involved administrative staff will:

- Will undergo SOP training (including self training)
- Sign and date the approved SOP when they receive it
- Maintain a file of all SOPs received

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4. Detailed instructions

1. Identify the need for SOP (new or amended)

- 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 an appointment and discuss with 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 will 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 SOP team. This 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 / Version : 01/01 is the SOP number 01 with version 01.
- SOP would be created for all the divisions of the department (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
 - DCP: Departmental SOP
 - P: Phase 1 SOP


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- TDM: TDM SOP
- LB: Laboratory SOP (Biochemistry)
- LP: Laboratory SOP (Pharmacogenetics)
-
- 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./Version No: xx/yy

Date first effective:

Review date:

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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 Secretariat.
- 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

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- 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, discussion and final approval.
- The HOD will sign and date the SOP on all pages 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 DCP Staff.
- One complete original set of current SOPs will be filed in the SOP Master file, and kept with the secretariat in the office of DCP.
- When the revised version is distributed, all the DCP members will be requested to write superseded on the earlier version.
- One copy of the earlier version will be filed entitled 'Past SOPs of the DCP' by the Secretariat of the Department of Clinical Pharmacology in the Archival room, Second Floor, Multi-storey building, Ward no. 24, Seth G. S Medical College and KEM Hospital, Mumbai.

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.



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6. References

- National Ethical Guidelines for Biomedical and Health Research involving Human Participants (2017), https://ethics.ncdirindia.org/ICMR_Ethical_Guidelines.aspx, accessed on 5th December 2025.
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- National Ethical Guidelines for Biomedical Research Involving Children. https://ethics.ncdirindia.org//asset/pdf/National_Ethical_Guidelines_for_BioMedic_al_Research_Involving_Children.pdf accessed on 5th December 2025.
- National Guidelines For Stem Cell Research https://dbtindia.gov.in/sites/default/files/National_Guidelines_StemCellResearch-2017.pdf accessed on 5th December 2025.


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

Cover page:

Category:

Title:

SOP No/Version No:

Total pages:

Date first effective:

Next Review date:

Version:

SOP Team:


Author: Name, Designation

Signature with date

Reviewer:

Signature with date

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Signature with date

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Main text

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2. Scope
3. Responsibilities
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Last page:

Reviewer:

Signature with date

Approved by:

Signature with date


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8. Abbreviations:

- i. DCP: Department of Clinical Pharmacology
- ii. HOD: Head of the Department
- iii. SOP: Standard Operating Procedure
- iv. TDM: Therapeutic Drug Monitoring

Reviewer as appropriate:

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Approved by Head of Department:

Signature with date


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