Department of Clinical Pharmacology, First Floor, New MS Building, Seth GS Medical College & KEM Hospital, Parel, Mumbai 400012.

Category: Pre study procedures

Title: Preparing the site team for an Investigator initiated clinical study(Academic or Government Funded or NGO Funded). (Academic or Government Funded or NGO Funded)

SOP No / Version No: DCP 02B/08 **Total pages:** 06

Date first effective: 01 Jan 2026 **Next Review date:** 31 Dec 2026

Version: 08

SOP Team:

Author:

1) Dr. Shiva Krishna Rao. T
1st Year DM Resident

2) Dr. Shital Bendkhale
Project Scientist- II

Signature with date

Shiva Krishna Rao T
8/12/25

8/12/25

Reviewer: Dr. Roopa Parida
Assistant Professor

Signature with date

8/Dec/25

Approved by: Dr. Nithya Gogtay
Professor and Head

Signature with date

8.12.25

Dr. Nithya Gogtay
Professor & Head
Department of Clinical Pharmacology
1st Floor, MS Building,
Seth GS Medical College & KEM Hospital,
Parel, Mumbai - 400 012.

1. Table of Contents

8/12/25

Dr. Nithya Gogtay
Professor & Head
Department of Clinical Pharmacology
1st Floor, MS Building,
Seth GS Medical College & KEM Hospital,
Parel, Mumbai - 400 012.

1. Purpose:

The objective of this standard operating procedure (SOP) is to explain to the research team how to prepare the site for an Investigator initiated clinical study(Academic or Government Funded or NGO Funded).

2. Scope

This SOP is limited to describing the requirements that the research team should meet in setting up an Investigator initiated clinical study(Academic or Government Funded or NGO Funded) after obtaining Institutional Ethics Committee approval.

3. Responsibilities:

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

4. Applicable rules, regulations and guidelines

- National Ethical Guidelines for Biomedical and Health Research involving Human Participants (2017), https://ethics.ncdirindia.org/ICMR_Ethical_Guidelines.aspx, accessed on 8th December 2025.
- New Drugs and Clinical Trials Rules (2019), https://cdsco.gov.in/opencms/opencms/en/Acts-and-rules/New-Drugs/, accessed on 8th December 2025.
- ICH HARMONISED GUIDELINE GOOD CLINICAL PRACTICE (GCP) E6(R3), https://database.ich.org/sites/default/files/ICH_E6%28R3%29_DraftGuideline_2023_0519.pdf, accessed on 8th December 2025.
- India GCP guidelines (Draft, September 2024), https://ethics.ncdirindia.org/asset/pdf/Indian_GCP_guideline.pdf, accessed on 8th December 2025.

8/12/25

Dr. Nithya Gogtay
Professor & Head
Department of Clinical Pharmacology
1st Floor, MS Building,
Seth GS Medical College & KEM Hospital,
Parel, Mumbai - 400 012.

- National Ethical Guidelines for Biomedical Research Involving Children. https://ethics.ncdirindia.org//asset/pdf/National_Ethical_Guidelines_for_BioMedical_Research_Involving_Children.pdf accessed on 8th December 2025.
- National Guidelines For Stem Cell Research https://dbtindia.gov.in/sites/default/files/National_Guidelines_StemCell Research-2017.pdf accessed on 8th December 2025.

5. Reference to other applicable Departmental SOPs

- SOP No/Version No. DCP 03/08 Responsibilities of the study team
- SOP No/Version No. DCP 04/08 Obtaining approval from the Institutional ethics committee

6. Detailed instructions

1. The PI/Designee should ensure that the following documents are in place, prior to the start of the study:
   - Confidentiality Disclosure Agreement (CDA), if applicable
   - Administrative approval for the study and Administrative approval to send samples outside the institute if applicable(Signed by the Head of the Institute)
   - Signed Clinical Trial Agreement (CTA; usually tripartite)
   - Institutional Ethics Committee approval.
   - Trial Master File (TMF) (Refer to SOP No/Version No. DCP 16/04 Establishing a Trial Master File)
   - Clinical Trial Registry – India (CTRI) Registration(Sponsor's responsibility)
   - Department Development Fund (DDF) / Diamond Jubilee Society Trust (DJST) / Research Society bank details for issue of grants

Dr. Nithya Gogtay 8.12.25
Professor & Head
Department of Clinical Pharmacology
1st Floor, MS Building,
Seth GS Medical College & KEM Hospital,
Parel, Mumbai - 400 012.

- Regulatory approval if Applicable
- Health Ministry Screening Committee (HMSC) Approval if Applicable
- PI registration with SUGAM Portal if Applicable for the study

2. The Principal Investigator should ensure that the following trainings have been completed and documented,
   - Good Clinical Practice (GCP) ICH E6 (R3)
   - Ethical Guidelines for Biomedical and health research involving Human Participants ICMR-2017
   - New Drug Clinical Trials Rules-2019
   - General SOPs and study specific SOPs, if relevant.
   - Delegation of responsibilities is done and submitted to the Institutional Ethics Committee and the sponsors.
   - Two rounds of protocol readings are completed and are documented in the training log before study initiation.
3. The Principal Investigator and all research study team members who are delegated responsibilities should be present during the site initiation visit(If applicable for multicentric studies) and any visit by Government or NGO personnel.

7. Abbreviations:

i. CDSCO: Central Drug Standard Control Organization
ii. CTA: Clinical Trial Agreement
iii. CTRI: Clinical Trial Registration India
iv. DBT: Department of Biotechnology
v. DCP: Department of Clinical Pharmacology
vi. DJST: Diamond Jubilee Society Trust

Dr. Nithya Gogtay
Professor & Head
Department of Clinical Pharmacology
1st Floor, MS Building,
Seth GS Medical College & KEM Hospital,
Parel, Mumbai - 400 012.
8.12.25

vii. GCP: Good Clinical Practice

viii. HOD: Head of the Department

ix. ICH: International Conference on Harmonization

x. ICMR: Indian Council of Medical Research

xi. IEC: Institutional Ethics Committee s

xii. PI: Principal Investigator

xiii. SOP: Standard Operating Procedure

Reviewer as appropriate:

Signature with date

Approved by the Head of Department:

Signature with date

Dr. Nithya Gogtay . 8.12.25
Professor & Head
Department of Clinical Pharmacology
1st Floor, MS Building,
Seth GS Medical College & KEM Hospital,
Parel, Mumbai - 400 012.