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

Category: Pre study procedures

Title: Preparing the site team for a clinical study sponsored by a pharmaceutical company (Sponsored or Regulatory Study)

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1. Table of Contents

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1. Purpose:

The objective of this standard operating procedure (SOP) is to prepare the site team for a clinical study sponsored by a pharmaceutical company.

2. Scope

This SOP is limited to describing the requirements that the research team should meet in setting up a clinical study after obtaining Institutional Ethics Committee approval. This SOP concerns all departmental personnel working in pharmaceutical industry funded research and should also be followed by all those working on clinical studies involving human participants.

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 6th December 2025.
- New Drugs and Clinical Trials Rules (2019), https://cdsco.gov.in/opencms/opencms/en/Acts-and-rules/New-Drugs/, accessed on 6th 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 6th December 2025.
- India GCP guidelines (Draft, September 2024), https://ethics.ncdirindia.org/asset/pdf/Indian_GCP_guideline.pdf, accessed on 6th December 2025.

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- 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 6th December 2025.
- National Guidelines For Stem Cell Research https://dbtindia.gov.in/sites/default/files/National_Guidelines_StemCellResearch-2017.pdf accessed on 6th December 2025.

5. Reference to other applicable Departmental SOPs

- SOP No/Version. D 04/07 Obtaining approval from the Institutional Ethics Committee (IEC-1 or IEC-2)
- SOP No/Version. D 03/07 Responsibilities of the study team.
- SOP No/Version. D 21/07 Contact and communication with sponsor

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
   - Regulatory approval
   - PI registration with SUGAM Portal

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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 conducted by the Sponsor/CRO.

7. Abbreviations:

i. CDSCO: Central Drug Standard Control Organization
ii. CTA: Clinical Trial Agreement
iii. CTRI: Clinical Trials Registry of India
iv. DCP: Department of Clinical Pharmacology
v. DDF: Department Development Fund
vi. DJST: Diamond Jubilee Society Trust
vii. GCP: Good Clinical Practice
viii. HOD: Head of the Department
ix. IEC: Institutional Ethics Committee
x. ICH: International Conference on Harmonization

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xi. PI: Principal Investigator

xii. SOP: Standard Operating Procedure

Reviewer as appropriate:

Signature with date

Approved by Head of Department:

Signature with date 6-12-25

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