Category : Pre study procedures
Title : Preparing the site team for a clinical study sponsored by a Pharmaceutical company (Sponsored or Regulatory Study)
SOP No. : D 02A/07
Date first effective: 01 Jan 2025 Review date: 31 Dec 2025

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

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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 clinical research and should 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

- 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 20 Dec 2024)
- New Drugs and Clinical Trials Rules, 2019 https://cdsco.gov.in/opencms/export/sites/CDSCO_WEB/Pdf-documents/NewDrugs_CTRules_2019.pdf (last accessed 20th Dec, 2024)
- Indian GCP Guidelines 2001 https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=MzM5NQ==(last accessed 20th Dec, 2024)
- International Conference on Harmonization, Guidance on Good Clinical Practice

ICH GCP E6 (R3)
https://database.ich.org/sites/default/files/ICH_E6%28R3%29_Step4_FinalGuideline_2025_0106.pdf (Adopted on 06 January 2025)

5. Reference to other applicable Departmental SOPs

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

6. Detailed instructions

1. The PI should ensure that the following documents are in place, prior to the start of the study:
   - Administrative approval (Signed by the Head of the Institute)
   - Signed Clinical Trial Agreement (CTA)
   - Institutional Ethics Committee (IEC-1 or IEC-2) approval as applicable.
   - Trial Master File (TMF) (Refer to SOP No. D 16/07 Establishing a Trial master file)
   - Clinical Trial Registry – India (CTRI) Registration
   - Confidentiality Disclosure Agreement (CDA), if applicable
   - Department Development Fund (DDF) / Diamond Jubilee Society Trust (DJST) / Research Society details for issue of grants
   - Central Drug Standard Control Organization (CDSCO) vide notification: File No. CT/SAE-Misc-10/2020-Part.B
2. The Principal Investigator should ensure that,
   - All staff has undergone Good Clinical Practice (GCP) training, Ethical Guidelines for Biomedical and health research involving Human Participants ICMR-2017 training and New Drug Clinical Trials Rules-2019 training.

- These trainings should be documented.
- All study staff should have valid GCP certificate throughout the study.
- All staff in the study are trained both in the general SOPs and study specific SOP, 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 site initiation.
- The trial is registered in www.ctri.in before the first patient/participant is recruited in the study (if applicable).
- The CTRI registration number should be immediately sent to IEC as soon as viewed and a letter of acknowledgement received from them.
- The sponsor should have registered the PI with the SUGAM portal for the study and the Login should be provided to the PI. All details of the PI should be completed on the SUGAM portal using the Login provided.

3. The Principal Investigator and all research study team members who are delegated responsibilities should be present during the initiation visit conducted by the Sponsors.

7. Abbreviations:

i. CDSCO: Central Drug Standard Control Organization
ii. CTA: Clinical Trial Agreement
iii. CTRI: Clinical Trial Registration 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
xi. PI: Principal Investigator
xii. SOP: Standard Operating Procedure

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