Category: Pre study procedures

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

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1. Table of Contents

1. Purpose:

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

2. Scope

This SOP is limited to describing the requirements that the research team should meet in setting up an Investigator initiated clinical study 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

- ICMR's Ethical Guidelines for Biomedical and Health research involving HumanParticipants,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 03/07 Responsibilities of the study team
- SOP No. D 04/07 Obtaining approval from the Institutional ethics committee

6. Detailed instructions

1. The PI should ensure the following documents are in place prior to the start of the study:
   - Administrative approval (Signed by the Head of the Institute)
   - Approval of the Government agency if the study is funded by any Government Body [Example: Indian Council of Medical Research (ICMR), Department of Biotechnology (DBT) and Diamond Jubilee Society Trust (DJST)].
   - Institutional Ethics Committee Approval
   - Trial Master File (TMF) (Refer to SOP No. D 16/07 Establishing a Trial master file)
   - Clinical Trial Registration – India (CTRI)
2. The PI should ensure identification of the members of the study team assigning to them their individual responsibilities. (Refer to SOP No. D 03/07 Responsibilities of the study team.)
3. The PI 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 Ethics committee.
- Two rounds of protocol readings are completed and this is documented in the training log and the photocopy of the training log to be placed in the Trial Master File before initiation of the study.
- The trial is registered in www.ctri.nic.in before the first patient/participant is recruited in the study (if applicable).
- The CTRI registration number should be immediately sent to IEC (IEC-1 or IEC-2 or IEC-3 as applicable), as soon as viewed and a letter of acknowledgement received from them.

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
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

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