Category: Study conduct-All studies (Government funded/NGO Funded/Regulatory)

Title: Responsibilities of the study team
SOP No / Version No: DCP 03/08
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1. Purpose

The purpose of this SOP is to assist in the division and allocation of responsibilities and to clarify boundaries of responsibility within the departmental study team, to ensure smooth running of a study. It will also provide the Funder and Institutional Ethics Committees (IEC-1 / IEC-2/ IEC-3) with an overview of the division of responsibilities within a study.

2. Scope

This SOP is limited to understanding study team responsibilities for ALL clinical studies involving human participants.

3. Responsibilities

Principal investigator (PI), Co-investigator (Co-I), Study Coordinator or any other appropriately qualified member of staff in the team, as delegated by the Principal Investigator, will be responsible for implementing 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.

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- India GCP guidelines (Draft, September 2024), https://ethics.ncdirindia.org/asset/pdf/Indian_GCP_guideline.pdf, accessed on 8th December 2025.

- 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.

5. Reference to other applicable Departmental SOPs

All SOPs (SOP No / Version No. DCP 1/08 to SOP No / Version No. DCP 29/08)

6. Detailed Instructions

1. A clinical study requires appropriately qualified personnel working as a team to ensure that it runs smoothly and correctly. Research personnel involved in a research study include, but are not limited to:
    a. Principal Investigator
    b. Co-Investigator
    c. Study co-ordinators
2. There may also be staff that are associated with, but not directly involved in the research study, such as:
    a. Pharmacists
    b. Laboratory staff
    c. Support staff
3. For a study to run smoothly it is essential that all staff involved are aware of the anticipated extent of their involvement and limits to their authority and responsibility.
4. The Principal Investigator is defined as the authorised health professional responsible for the conduct of that study at a study site, and if the study is conducted by a team of authorised health professionals at a study site, the Principal Investigator is the leader responsible for that team. In all SOPs the term

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Principal Investigator is used as defined above. Other investigators at the same site are Co-Investigators.

5. The Principal Investigator must be:
    - Qualified by education, training and experience for clinical trials
    - Legally allowed to practice medicine(Registered with Maharashtra Medical Council, Government of Maharashtra or National Medical Council, Government of India)
    - Be thoroughly familiar with the study protocol and the investigational product(s)
    - Aware of, and comply with Good Clinical Practice (GCP) and any applicable regulatory requirements pertaining to clinical trial conduct.

6. The Principal Investigator has the overall responsibility of:

    - Ensuring the safety and wellbeing of patients/participants
    - Reading and understanding all the information in all the study documents [including (but not limited to), for example, the protocol, the informed consent, Audio-Visual (AV) recording of the Informed consent process may be done as per protocol requirements and the investigator's brochure]
    - Ensuring maintenance of confidentiality of all study related activities and data.
    - Managing the business aspects of studies, including developing and negotiating study budgets to assure that provisions on publication, intellectual property, insurance, indemnification, records retention, and data ownership are appropriately negotiated with the sponsor.
    - Ensuring that all requirements of the Institution are fulfilled, including ensuring the signing of the Clinical Trial Agreement (CTA) with budget details and payment schedule.

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- Ensuring that the IEC approval has been obtained prior to any trial related procedures. (Refer to SOP No / Version No D 04/0: Obtaining approval from the ethics committee)
- Ensuring that regulatory or HMSC Approval has been obtained prior to any trial related procedures(if applicable).
- Informing all participants/ parents/ children about the research and obtaining written informed consent/assent as applicable. Audio-Visual(AV) recording of the Informed consent process may be done as per protocol requirements.
- Conducting the study in accordance with the applicable guidelines and laws.
- Administration of Investigational Product
- Maintaining appropriate control, inventory, distribution, storage, record keeping and destruction or return of investigational product. (Refer SOP No / Version No DCP 11/08, SOP No / Version No DCP 13/08, SOP No / Version No DCP 22/08, SOP No / Version No. DCP 23/08).
- Reporting Adverse Events(AE) and Serious Adverse Events (SAE) to the Sponsor/IEC/Dean/Regulator as per current ethical and regulatory requirements. (Refer SOP No / Version No D 14/08: Adverse Event (AE) Monitoring, Recording and Reporting and SOP No / Version No. D 15/08: SAE documentation and reporting).
- Maintaining communication with IEC as required during the conduct of the trial
- Maintaining adequate and accurate records and making records available for audits to external and internal monitors and inspection to regulators.

7. Meeting with internal and external auditors and inspectors at the conclusion of their audits/inspection for Corrective Action and Preventive Action (CAPA).

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8. The Principal Investigator (PI) should, where required, allocate day-to-day responsibility to one member of the department – known as the study coordinator. The study coordinator should discuss and agree with the Principal Investigator the allocation of tasks with other study team members.
9. The allocation of tasks should be recorded as a "Delegation of Authority" log, with specimen signatures and initials of all involved.
10. While retaining knowledge of and overall authority for the conduct of all research studies, the PI should supervise members of the research team qualified by appropriate education and experience to accept responsibility for study-related activities not directly performed by the PI. Assuring that delegation of responsibilities is appropriate and is documented and that individuals recruited as members of the research team are appropriately licensed and trained.
11. A copy of this "Delegation of Authority" log should be given to the Sponsor and the ethics committee to make them aware of the planned division of tasks. Contact names and roles of other individuals involved in the study (e.g., Pharmacy, laboratory staff) should also be communicated to the Sponsor and ethics committee.
12. The PI should ensure appropriate training of all study team members.
13. The study coordinator, with the PI should assess the need for additional staff, and discuss with the Sponsor as and when necessary.
14. The following activities should be conducted by a member of the study team as delegated by the PI (who could be the PI, co-investigator, study coordinator or any other appropriate member of the study team)

    - Screening and enrolling participants in studies and managing their participation according to ethical, regulatory, and protocol-specific requirements.
    - Obtaining written informed consent/assent from trial participants/children, Audio -Visual(AV) recording of the Informed consent process may be

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done as per protocol requirements before performing any study related procedures (only by medically qualified person).

- Confirming eligibility of study participants (only by medically qualified person).
- Design appropriate recruitment strategies and track study enrollment.
- Signing prescriptions (only by medically qualified person).
- Conducting clinical examinations, evaluating laboratory and other reports and carrying out any assessments of a medical nature (only by medically qualified person).
- PI/Designee should ensure ALCOA regarding data

  - Accurate
  - Legible
  - Contemporaneous
  - Original
  - Attributable

- Planning and booking participant/parental appointments as required and developing organizational aids and checklists to facilitate patient recruitment.
- Proper handling of and accurately processing samples (such as blood and tissues).
- Timely signing off Case Report Forms (only by medically qualified person).
- Maintaining the regulatory and Trail Master Files(TMF) for each research study.
- Maintaining study specific paperwork and study files.
- Overseeing study closure and reporting of results.

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- Participating in Quality Assurance (QA) activities of the sponsor and the department.
- Participating as appropriate in the training of individuals recruited as members of the study team.
- New members who join the study team should be trained as necessary.
- Attending appropriate multidisciplinary team meetings.
- Liaising with network personnel regarding the progress of research studies
- A study coordinator who is not medically qualified may be authorised to take written informed consent for non-interventional studies, Audio - Visual(AV) recording of the Informed consent process may be done as per protocol requirements not involving medicinal products/treatments where this has been stated in the protocol and IEC approval obtained (See SOP No/Version No DCP 05/08 – Administering and documenting informed consent).
- A study coordinator who is not medically qualified may participate in the discussion of the study with the prospective participant even when not permitted to obtain written informed consent Audio -Visual(AV) recording of the Informed consent process may be done as per protocol requirements.

15. All members of the research team will:

- Conduct the clinical studies according to Institutional, Local, National and International guidelines and Departmental SOPs.
- Assure the safety and well being of study participants/ patients / children by being thoroughly knowledgeable about ongoing study protocols and investigational products.
- Maintain confidentiality of all clinical trial related information (including patient records).

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- Assure that the PI is informed in a timely manner of all study-related activities.

7. **Abbreviations:**
   i. Co-I: Co-investigator
   ii. GCP: Good Clinical Practice
   iii. IEC: Institutional Ethics Committees
   iv. PI: Principal Investigator
   v. SOP: Standard Operating Procedure
   vi. HMSC: Health Ministry Screening Committee

Reviewer as appropriate:

Signature with date

Approved by the Head of Department:

Signature with date

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