Category: Study conduct

Title: Responsibilities of the study team

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SOP Team:

Author: Dr. Ananya Rakshit
DM Resident

Signature with date 30/Dec/2024

Reviewer: Dr. Mahesh Belhekar
Associate Professor

Dr. Mahesh N. Belhekar
Associate Professor
Department of Clinical Pharmacology
New MS Building, First Floor,
Seth GS Medical College and KEM Hospital
Acharya Donde Marg, Parel,
Mumbai - 400 012. India

Signature with date 30/Dec/2024

Approved by: Dr.Nithya Gogtay
Professor and Head

Signature with date 30.12.24

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

Table of Contents

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 Sponsor and Institutional Ethics Committee (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

- 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

All SOPs (SOP No. D 1/7 to SOP No. D 29/7)

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 is aware of the anticipated extent of their involvement and limits to their authority.
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 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
- 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 welfare of patients
- Reading and understanding all the information in all the study documents [including (but not limited to), for example, the protocol, the informed consent, 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, 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 with budget details and payment schedule.
- Ensuring that the IEC approval has been obtained prior to any trial related procedures. (Refer to SOP no D 04/07: Obtaining approval from the ethics committee)
- Informing all participants about the research and obtaining written informed consent from the participants.
- 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 D 11/07, SOP No D 13/07, SOP No. D 22/07, SOP No. D 23/07).

- Reporting adverse events to the Sponsor as per ethical and regulatory requirements. (Refer SOP No D 14/07: Adverse Event (AE) Monitoring, Recording and Reporting and SOP No. D 15/07: 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 inspection to external and internal monitors. Meeting with internal and external auditors at the conclusion of their audits, to review findings and to implement changes to correct weaknesses or deficiencies.

7. 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.
8. The allocation of tasks should be recorded as a "Delegation of Authority" log, with specimen signatures and initials of all involved.
9. 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.
10. 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.

11. The PI should ensure adequate training of all study team members.
12. The study coordinator, with the PI should assess the need for additional staff, and discuss with the Sponsor.
13. 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 informed consent from trial participants 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).
- Ensuring accurate and timely data entry.
- Planning and booking participant appointments as required.
- Proper handling of and accurately processing samples (such as blood and tissues).
- Signing off Case Report Forms (only by medically qualified person).
- Developing organizational aids and checklists to facilitate patient recruitment and the collection of complete and accurate study data.
- Maintaining the regulatory and study files for each research project.
- Maintaining study specific paperwork and study file.
- Communicating with IEC as appropriate.
- Ensure proper handling of the investigational product.

- Reporting adverse events to the IEC and sponsor, as appropriate.
- Overseeing study closure and reporting of results.
- Participating in quality assurance activities of the sponsor and the department.
- Supervising other study team members, as appropriate.
- Participating as appropriate in the training of individuals recruited as members of the study team
- Attending appropriate multidisciplinary team meetings
- Liaising with network personnel regarding the progress of research studies
- Assuring that the PI is informed in a timely manner of all study-related activities.

14. A study coordinator who is not medically qualified may be authorised to take consent for non-interventional studies, not involving medicinal products/treatments where this has been stated in the protocol and IEC approval obtained (See SOP D 05/07 – Administering and documenting informed consent).
15. 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 consent.
16. 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 welfare of study participants by being thoroughly knowledgeable about ongoing study protocols and investigational products.
- Maintain confidentiality of all clinical trial related information (including patient records).
- 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 Committee s

iv. PI: Principal Investigator

v. SOP: Standard Operating Procedure

Reviewer: Dr. Mahesh Belhekar
Associate Professor

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