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Category: Study conduct

Title: Contact and communication with sponsor

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Table of Contents

1. Purpose

The purpose of this standard operating procedure (SOP) is to instruct the study team in communication with the sponsor.

2. Scope

This SOP applies to all forms of communications on the site (email, telephone, fax etc.) with the sponsor.

3. Responsibilities

Principal investigator (PI), Co-Investigator (Co-I), study coordinator or the delegated study team members will be responsible for communication with the sponsor.

4. Applicable rules, regulations and guidelines

- New Drugs and Clinical Trials Rules 2019
  https://cdsco.gov.in/opencms/export/sites/CDSCO_WEB/Pdf-documents/NewDrugs_CTRules_2019.pdf

- National Ethical Guidelines for Biomedical and Health Research involving Human Participants ICMR, 2017
  https://www.indiascienceandtechnology.gov.in/sites/default/files/file-uploads/guidelineregulations/1527507675_ICMR_Ethical_Guidelines_2017.pdf

- 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 SOPs

- SOP No. D 17/07: Continued interaction with the Institutional Ethics Committees
- SOP No. D 15/07: Serious Adverse Event (SAE) Monitoring, Recording and Reporting

- SOP No. D 2A/07: Preparing the site team for a clinical study sponsored by pharmaceutical company.

6. Detailed Instructions

1. The PI will be responsible for the initial communication with the sponsor.
2. PI or Co-I inform the sponsor about the study team and keeps the sponsor updated on the changes in the study team in the course of the trial.
3. The PI or a Co-I delegate routine communication to the study coordinator on updates, document submissions and receipt.
4. Communications pertaining to financial, technical, and regulatory aspects should be done only by the PI or Co-I unless otherwise instructed.
5. If the sponsor/s collaborate with Contract Research Organization (CRO) for any study, majority of the communication will be done with the CRO. However, specific aspects may be communicated with the sponsor/s as well as CRO and have to be decided a-priori.
6. Any telephonic conversation should be immediately transcribed to the emails and will be communicated to all the members of the study team and sponsor/s and CRO (if relevant)
7. All the emails should be acknowledged by the study team members.
8. All the study members should be kept in the email loop to keep them updated.
9. All the study team members should be objective, precise, polite, and professional in all communication with the sponsor/s.
10. Etiquette should always be maintained in the communication. e.g. Doctor XYZ should be addressed as Dear Dr. XYZ.
11. The study team members will put a "Vacation reply" mentioning the dates and duration of absence, date of resumption and backup person's name, email, and mobile number during the absence.
12. All important communications should be documented in printed form and kept in the trial master file.

13. Sponsor should be updated at specified intervals [depending on the SOP of the sponsor] about the progress of the trial through formal email.
14. During all the phases of the trial, scanned documents of relevant Institutional Ethics Committee communications should be conveyed through formal email.

7. Abbreviations:

i.	Co-I	: Co-Investigator
ii.	CRO	: Contract Research Organization
iii.	PI	: Principal investigator
iv.	SOP	: Standard Operating Procedure
v.	GCP	: Good Clinical Practice
vi.	ICH	: International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use
vii.	ICMR	: Indian Council of Medical Research
viii.	IEC	: Institutional Ethics Committee

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