

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

Title: Contact and communication with sponsor

SOP No/Version No: DCP 21/08

Date first effective: 01 Jan 2026

Review date: 31 Dec 2026

Department of Clinical Pharmacology, 1st Floor, New MS Building,
Seth GS Medical College & KEM Hospital, Parel, Mumbai 400012.

19th Category: Study conduct-All studies (Government funded/NGO
funded/Regulatory)

Title: Contact and communication with sponsor

SOP No/ Version No: DCP 21/08

Total pages: 05

Date first effective: 01 Jan 2026

Next Review date: 31 Dec 2026

Version: 08

Author: 1) Dr. Shiva Krishna Rao.T
1st Year DM Resident

Shiva
11 JAN / 2026

2) Dr. Shital Bendkhale
Project Scientist- II

~~Bendkhale~~
11 JAN / 2026

Signature with date

Reviewer: Dr. Roopa Parida
Assistant Professor

Signature with date

Parida
01/Jan/2026

Approved by: Dr. Nithya Gogtay
Professor and Head

Signature with date

u
1.1.26

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

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

Title: Contact and communication with sponsor

SOP No/Version No: DCP 21/08

Date first effective: 01 Jan 2026

Review date: 31 Dec 2026

Department of Clinical Pharmacology, 1st Floor, New MS Building,
Seth GS Medical College & KEM Hospital, Parel, Mumbai 400012.

Table of Contents

| No. | Contents | Page No. |
|-----|----------------------------------------------|----------|
| 1 | Purpose | 3 |
| 2 | Scope | 3 |
| 3 | Responsibility | 3 |
| 4 | Applicable rules, regulations and guidelines | 3 |
| 5 | Detailed instructions | 3 |

11/1/26
Dr Nithya Gogtay
Professor & Head
Department of Clinical Pharmacology
1st Floor, MS Building
Seth GS Medical College & KEM Hospital
Parel, Mumbai 400 012

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

Title: Contact and communication with sponsor

SOP No/Version No: DCP 21/08

Date first effective: 01 Jan 2026

Review date: 31 Dec 2026

Department of Clinical Pharmacology, 1st Floor, New MS Building,
Seth GS Medical College & KEM Hospital, Parel, Mumbai 400012.

1. Purpose

The purpose of this SOP is to instruct the study team in communication with the sponsor.

2. Scope

This SOP applies to all forms of communications of 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

- National Ethical Guidelines for Biomedical and Health Research involving Human Participants (2017), https://ethics.ncdirindia.org/ICMR_Ethical_Guidelines.aspx, last accessed on 1st Jan 2026
- 2.
- New Drugs and Clinical Trials Rules (2019), <https://cdsco.gov.in/opencms/opencms/en/Acts-and-rules/New-Drugs/>, last accessed on 1st Jan 2026.
- ICH HARMONISED GUIDELINE GOOD CLINICAL PRACTICE (GCP) E6(R3), https://database.ich.org/sites/default/files/ICH_E6%28R3%29_DraftGuideline_2023_0519.pdf, last accessed on 1st Jan 2026.
- India GCP guidelines (Draft, September 2024), https://ethics.ncdirindia.org/asset/pdf/Indian_GCP_guideline.pdf, last accessed on 1st Jan 2026.
- National Ethical Guidelines for Biomedical Research Involving Children. https://ethics.ncdirindia.org//asset/pdf/National_Ethical_Guidelines_for_BioMedical_Research_Involving_Children.pdf last accessed on 1st Jan 2026.
- Standard-Operating-Procedures of Institutional Ethics Committee, Seth GS Medical College and KEM Hospital, Mumbai

4
1-1-26
Dr Nithya Gogtay
Professor & Head
Department of Clinical Pharmacology
1st Floor, MS Building
Seth GS Medical College & KEM Hospital
Parel, Mumbai 400 012

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

Title: Contact and communication with sponsor

SOP No/Version No: DCP 21/08

Date first effective: 01 Jan 2026

Review date: 31 Dec 2026

Department of Clinical Pharmacology, 1st Floor, New MS Building,
Seth GS Medical College & KEM Hospital, Parel, Mumbai 400012.

[https://www.kem.edu/wp-](https://www.kem.edu/wp-content/uploads/2025/03/SOPs_V7_effective_from_9th_Dec_2024_Seth_GSMC_&_KEMH_Mumbai.pdf)

[content/uploads/2025/03/SOPs_V7_effective_from_9th_Dec_2024_Seth_GSMC_](https://www.kem.edu/wp-content/uploads/2025/03/SOPs_V7_effective_from_9th_Dec_2024_Seth_GSMC_&_KEMH_Mumbai.pdf)

[&_KEMH_Mumbai.pdf](https://www.kem.edu/wp-content/uploads/2025/03/SOPs_V7_effective_from_9th_Dec_2024_Seth_GSMC_&_KEMH_Mumbai.pdf) V7-effective-from-9th-Dec-2024_.pdf (last accessed 19th Jan, 2025)

5. Reference to other applicable SOPs

- SOP No/ Version No. D 17/08: Continued interaction with the Institutional Ethics Committees
- SOP No/ Version No. D 15/08: Serious Adverse Event (AE) Monitoring, Recording and Reporting
- SOP NO/ VERSION NO. D 2A/05: 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 study team and keeps the sponsor updated on 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 and the specific aspects with the sponsor/s and CRO which has to be decided a priori.
6. Any telephonic conversations 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.

Dr. Nithya Gontav
Professor & Head

Department of Clinical Pharmacology
1st Floor, MS Building
Seth GS Medical College & KEM Hospital
Parel, Mumbai 400 012

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

Title: Contact and communication with sponsor

SOP No/Version No: DCP 21/08

Date first effective: 01 Jan 2026

Review date: 31 Dec 2026

Department of Clinical Pharmacology, 1st Floor, New MS Building,
Seth GS Medical College & KEM Hospital, Parel, Mumbai 400012.

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 trial master file.
13. Sponsor should be updated at specified interval [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 EC communications should be conveyed through formal email.

Reviewer as appropriate:

Signature with date

Roopa Parida
01/Jan/2026
Dr. ROOPA PARIDA
Department of Clinical Pharmacology
Seth GS Medical College & KEM Hospital,
Parel, Mumbai-400 012.

Approved by Head of Department:

Dr. Nithya Gogtay
Professor and Head

Signature with date

Nithya Gogtay
1.1.26

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

