Category: Study conduct
Title: Contact and communication with sponsor
SOP No.:D 21/04
Date first effective: 04 May 2022 **Review date:**03 May 2023

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

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SOP No.: D 21/04 **Total pages:** 05

Date first effective: 04 May 2022**Next Review date:** 03 May 2023

Version: 04

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Signature with date 04/MAY/2022

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Approved by: Dr. Nithya Gogtay
Professor and Head

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1. Purpose

The purpose of this SOP is to instructthe 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

- New Drugs and Clinical Trials Rules, 2019
- Ethical Guidelines for Biomedical and Health Research involving HumanParticipants, ICMR 2017.
- ICH E6 (R2) Integrated Addendum to ICH E6 (R1), Current Step 4 version dated 9th November, 2016.

5. Reference to other applicable SOPs

- SOP No. D 17/04:Continued interaction with the Institutional Ethics Committees
- SOP No. D 15/04: Serious Adverse Event (AE) Monitoring, Recording and Reporting
- SOP NO.D 2A/04:Preparing the site team for a clinical study sponsored byPharmaceutical company

6. Detailed Instructions

1. The PIwill be responsible for the initial communication with the sponsor.
2. PI or Co-Iinform the sponsor about study team and keeps the sponsorupdated 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.
9. All the study team members should be objective, precise, polite and professional in allcommunication with the sponsor/s.
10. Etiquetteshould 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.

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