

**Category** : Study conduct  
**Title** : Birth Control measures for male participants.  
**SOP No.** : D 08/06  
**Date first effective:** 01 Jan 2024

**Review date:** 31 Dec 2024

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

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**SOP Team:**

**Author:** Dr. Roopa Parida  
DM Resident

Signature with date

*R Parida*  
26/Dec/2023

**Reviewer:** Dr. Mahesh Belhekar  
Associate Professor

Signature with date

*MB*  
27/DEC/2023

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

**Approved by:** Dr. Nithya Gogtay  
Professor and Head

Signature with date

*N* 31-12-23  
**Dr. Nithya Gogtay**  
Professor & Head  
Department of Clinical Pharmacology  
1<sup>st</sup> Floor, MS Building,  
Seth GS Medical College & KEM Hospital,  
Parel, Mumbai - 400 012.

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## **1. Purpose**

The purpose of this Standard Operating Procedure (SOP) is to describe the responsibilities of the research team towards counseling of male participants regarding the birth control measures to be adopted during the study period and the procedures to be followed in case the female partner of the participant is found to be pregnant during the study period.

## **2. Scope**

This SOP is applicable to all males who are likely to participate in a clinical trial.

## **3. Responsibilities**

Principal investigator (PI), Co-investigator (Co-I), Study Coordinator or any other appropriately qualified staff in the team, as delegated by the Principal Investigator, can counsel male participants regarding the birth control measures to be adopted during the study period.

## **4. Applicable rules, regulations and guidelines**

- Ethical Guidelines for Biomedical and Health Research involving Human Participants, ICMR 2017  
[http://www.icmr.nic.in/guidelines/ICMR\\_Ethical\\_Guidelines\\_2017.pdf](http://www.icmr.nic.in/guidelines/ICMR_Ethical_Guidelines_2017.pdf)  
(last accessed 20 Dec 2023)
- ICH-GCP E6 (R3) Draft Guidelines dated 19<sup>th</sup> May 2023  
[https://database.ich.org/sites/default/files/ICH\\_E6%28R3%29\\_DraftGuideline\\_2023\\_0519.pdf](https://database.ich.org/sites/default/files/ICH_E6%28R3%29_DraftGuideline_2023_0519.pdf)
- New Drugs and Clinical Trials 2019  
[https://cdsco.gov.in/opencms/export/sites/CDSCO\\_WEB/Pdf-documents/NewDrugs\\_CTRules\\_2019.pdf](https://cdsco.gov.in/opencms/export/sites/CDSCO_WEB/Pdf-documents/NewDrugs_CTRules_2019.pdf) (last accessed 20<sup>th</sup> Dec, 2023)

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#### **5. Reference to other applicable SOPs**

SOP No. D 03/06: Responsibilities of the Study Team

SOP No. D 15/06: SAE documentation and reporting

SOP No. D 14/06: AE documentation and reporting

#### **6. Detailed Instructions**

1. During the screening visit, record and document a detailed medical history of the male participant.
2. Ask the participant regarding the use of any birth control measures by self and /or spouse at the present moment, as well as in the recent past.
3. If yes, document the type of birth control method used and advise the participant to continue the same, if the protocol permits that method of contraception.
4. If not, assess the willingness of the participant to adopt birth control measures recommended in the protocol and offer the available options to the participants e.g. condoms for the participant and/or oral contraceptives/barrier contraception/intra uterine device to the female partner following consultation with a Gynecologist.
5. Gynecology consultation should be sought with the relevant OPD of KEM Hospital as decided by the PI.
6. If the participant is not willing to adopt birth control measures and this is necessary as per the protocol, then he cannot be recruited in the study.
7. It is necessary to adequately emphasize the risk of pregnancy of the female partner while the participant is in the study and its consequences and therefore the need for effective contraception.
8. Ensure that the participant understands the importance about reporting to the study physician in case his female partner misses her periods. In such cases, she should be advised to undergo a pregnancy test, obstetric counseling and ultrasonography.

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9. In the event that during the study, pregnancy is confirmed, follow the guidelines as for a serious adverse event (SAE) (See SOP D 15/06) and follow the mother through the pregnancy period till delivery to monitor the mother's and baby's health status.
10. If the woman is the partner of the participant, then re-emphasize the importance of preventing a pregnancy during the trial duration and use of appropriate birth control measures to both partners.
11. Always follow the instructions in the protocol regarding withdrawal from the study.

### 7. Abbreviations:

- i. AE: Adverse Event
- ii. Co-I: Co-investigator
- iii. OPD: Out Patient Department
- iv. PI: Principal investigator
- v. SAE: Serious Adverse Event
- vi. SOP: Standard Operating Procedure

Reviewer: Dr. Mahesh Belhekar  
Associate Professor

Signature with date

*BM*  
*27 Dec 2023*

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

Approved by: Dr. Nithya Gogtay  
Professor and Head

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*W* *31-12-23*  
**Dr. Nithya Gogtay**  
Professor & Head  
Department of Clinical Pharmacology  
1<sup>st</sup> Floor, MS Building,  
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Parel, Mumbai - 400 012.

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