Category : Study conduct-All studies (Government funded/NGO funded/Regulatory)
Title : Birth Control measures for male participants.
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Version: 08

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1. Purpose

The purpose of this SOP is to describe the responsibilities of the research team towards counseling of male participants regarding 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 diagnosed to be pregnant during the study period.

2. Scope

This SOP is applicable to all males who are likely to consent to participate in any clinical trial regardless of the sponsor.

3. Responsibilities

Principal investigator, Co-investigator, 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

- National Ethical Guidelines for Biomedical and Health Research involving Human Participants (2017), https://ethics.ncdirindia.org/ICMR_Ethical_Guidelines.aspx, accessed on 20th March 2026.
- New Drugs and Clinical Trials Rules (2019), https://cdsco.gov.in/opencms/opencms/en/Acts-and-rules/New-Drugs/, accessed on 20th March 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, accessed on 20th March 2026.
- India GCP guidelines (Draft, September 2024), https://ethics.ncdirindia.org/asset/pdf/Indian_GCP_guideline.pdf, accessed on 20th March 2026.

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- National Ethical Guidelines for Biomedical Research Involving Children.https://ethics.ncdirindia.org//asset/pdf/National_Ethical_Guidelines_for_BioMedical_Research_Involving_Children.pdf accessed on 20th March 2026.
- Standard-Operating-Procedures of Institutional Ethics Committee, Seth GS Medical College and KEM Hospital, Mumbai https://www.kem.edu/wpcontent/uploads/2025/03/SOPs_V7_effective_from_15th_Dec_2024_Seth_GSMC_&_KEMH_Mumbai.pdf V7-effective-from-15th-Dec-2024_.pdf (last accessed 19th January, 2026)

5. Reference to other applicable SOPs

SOP No / Version No D 03/08: Responsibilities of the Study Team

SOP No / Version No D 15/08: SAE documentation and reporting

SOP No / Version No D 14/08: 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 sexual partner at the present moment, as well as in the recent past(6 months).
3. If yes, document the type of birth control method used and advise the participant to continue the same, if the protocol permits that particular method of contraception.
4. If not, assess the willingness of the participant to adopt birth control measures recommended in the IEC approved 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 for the female partner if she gets pregnant.

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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 and must be clearly told so.This must also be documented in the source notes.
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 and any other procedure as determined by the Obstretics and Gynaecology.
9. In the event that during the study, pregnancy is confirmed, follow the guidelines as for a serious adverse event (SAE) (See SOP No/ Version No DCP 15/08) and follow the mother through the pregnancy period till delivery to monitor the mother's and baby's health status.
10. Always follow the instructions in the protocol regarding withdrawal from the study.

Reviewer as appropriate:

Signature with date Rparida 01/Jan/26

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