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

Category: Study conduct

Title: Recruitment of research participants

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Author: Dr. Dhruve Soni
DM Resident

Signature with date 31/DEC/2022

Reviewer: Dr. Palvi Kudyar
Assistant Professor

Signature with date 31/Dec/2022

Department of Clinical Pharmacology
Seth GS Medical College & KEM Hospital,
Parel, Mumbai - 400 012.

Approved by: Dr. Nithya Gogtay
Professor and Head

Signature with date 31.12.22

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

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

Table of Contents

1. **Purpose:**

This SOP describes the procedures study personnel will use in meeting study enrollment goals while fulfilling ethical responsibilities for protecting the rights and welfare of participants.

2. **Scope:**

This SOP is limited to the procedure carried out in recruiting clinical study participants in studies approved by the institutional ethics committee.

3. **Responsibilities:**

Principal investigator, Co-investigator, Study Coordinator or any other appropriately qualified staff in the team, as delegated by the Principal Investigator, will be responsible for meeting study enrollment goals.

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

- Ethical Guidelines for Biomedical and Health Research involving Human Participants, ICMR 2017
- International Conference on Harmonization; GCP Guidelines: 1996
- ICH E6(R3) EWG Draft Guidelines dated 19th April, 2021.
- New Drugs and Clinical Trials 2019

5. **Reference to other applicable SOPs**

- SOP No. D 04/05: Obtaining approval from the Ethics Committee
- SOP No. D 05/05: Administering and documenting Informed Consent
- SOP No. D 06/05: Screening volunteers/participants for participation in any clinical study

- SOP D 13/05: Dealing with protocol deviations and violations in any clinical study

6. Detailed instructions

1. The designated team members must identify, approach, select, recruit and enroll participants in a research study in a planned fashion, under the supervision of the Principal Investigator. The procedure for screening of potential participants is described in SOP No. D 06/05: Screening volunteers/participants.
2. The recruitment of the participants will be usually done on **"word of mouth"** basis. However, if any new recruitment strategy or any advertisement is planned that has to be approved a priori from the Institutional Ethics Committee. (see Appendix)
3. The designated team members must ensure that participant has given written informed consent prior to enrollment (or screening if any study related clinical examination or procedure is to be conducted) (Refer to SOP No. D 06/05: Screening volunteers/participants and SOP No. D 05/05: Administering and documenting Informed Consent)
4. PI and the study team must avoid improper participant recruitment as this can lead to failure of a study with subsequent early termination of the participant who did not meet entry criteria. This is also an important and avoidable protocol violation.
5. While recruiting participants, the PI and study team must strictly follow:
    - Applicable ethical guidelines
    - Inclusion and exclusion criteria of most recent IEC approved version of study protocol.
    - Fair procedures and outcomes in the selection of research participants
6. The PI should describe and justify a sound recruitment plan prior to study initiation which should consider the following points:
    - Number of participants targeted
    - Identification of potential participants

- Whether participants may be employees or students of the research staff (Please refer to SOP D 06/05)
- Plans for contacting potential participants (e.g. methods, medium, communication, advertisement)
- Compensation (in case of Investigator initiated studies)
- Approvals needed (other than IEC e.g. administrative approvals)

7. PI should ensure that all of the above are incorporated in the protocol and should receive prior ethics committee approval (Refer SOP No. D 04/05: Obtaining approval from the Institutional Ethics Committee).
8. When subjects are to be recruited for participation in research as a result of pre-screening done previously, initial contact, whether *via* telephone or letter, should be made by someone directly involved in the study (e.g. study physician, nurse, or designee).
9. The PI or designee must approach the person identified from the community to speak for the group for permission to recruit from that group or organization when research is being conducted in a community group or organization.
10. The PI/study team MUST NOT initiate recruitment or screening until IEC approval has been obtained for the study, including the recruitment process, method, mode and material(s).
11. If a participant is screened but he/she does not meet the inclusion and exclusion criteria then this is considered a ***screen failure***.
12. If he/she is eligible, and if applicable, consent the participant using the study participation informed consent form. If there is only one consent document which the participant has signed prior to screening, he/she can be recruited into the study.
13. Every participant who is considered eligible for the study after screening should be entered in the Enrolment Log (based on study inclusion and exclusion criteria). Note whether individuals have enrolled in the study and, if not, document the reason (including refusal/withdrawal of consent, screen failure).

14. In case the PI would like to enroll a participant who does not meet the inclusion and exclusion criteria, permission of the sponsor and the IEC should be obtained as a "Protocol exception" on a case-by-case basis before he/she is enrolled into the study [Refer SOP D 13/05 – Dealing with protocol deviations and violations in any clinical study].
15. PI must ensure that, if the study is suspended by or terminated by the IEC, there is no further screening or recruitment.
16. In case additional sites have to be included from where participants will be recruited, the PI must obtain approval from Head of Institute and Institutional Ethics committee before using that site.
17. The study team MUST ensure that there is no coercion or undue influence while recruiting such population.
18. The PI should monitor recruitment rates regularly at pre-decided time intervals during the recruitment period. Recruitment strategy should be reassessed if recruitment targets are not being met.
19. The Study Coordinator should keep records of recruitment and inform the PI of progress in recruiting participants/patients at pre-decided intervals.

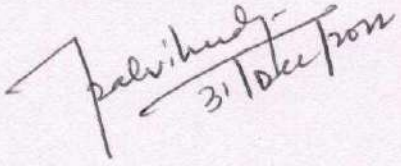
Appendix: Guidelines for Advertisement for recruiting research participants

1. Advertisements to recruit participants should be limited to the information prospective participants need to determine their eligibility and interest.
2. In general, the following items may be included in advertisements:
   a. The name and address of the investigator and/or research facility
   b. The location of the research and person or office to contact for further information
   c. The purpose of the research, the disease being studied
   d. In summary form and simple language, the criteria that will be used to determine eligibility for the study
   e. A brief list of participation benefits, if any (e.g. a no-cost health examination)
3. The time or other commitment required from participants (e.g. number of visits and total duration of participation).
4. Advertisements may state that subjects will be paid, but should not emphasize the payment or the amount to be paid by such means as larger or bold type.
5. Advertisements submitted to the IEC must be indicative of the size of type and other visual effects that will be employed in the final form.
6. IEC review and approval of listings of clinical trials on the internet is not required when the system format limits the information provided to the basic trial information, such as the title, purpose of the study, protocol summary, basic eligibility criteria, study site location(s), and how to contact the site for further information.
7. Advertisements to recruit participants shall NOT:
   - Mislead participants;
   - Claim, either explicitly or implicitly, that the drug or device is safe or effective for the purpose under investigation or that the drug or device is in any way equivalent or superior to any other drug or device;
   - Use terms such as "new treatment," "new medication", or "new drug" without an explanation that the test article is investigational;

- Include exculpatory language;
- Imply the research or investigator has a unique or special skill, remedy, or treatment;
- Promise "free medical treatment," when the intent is only to say participants will not be charged for taking part in the investigation. Advertisements may state that participants will be paid but shall not emphasize the payment or the amount to be paid by such means as larger or bold type.
- Include monetary amounts as rewards or inducements to participate (they may, however, mention there will be compensation for the participant's time or travel).

8. Advertisements may include:
   - A statement that the study involves research
   - A brief description of the disorder that the study is investigating
   - Eligibility criteria (in summary form)
   - A truthful description of potential benefits, if any, to the subject from study participation
   - The name of the institution conducting the study
   - The name and phone number of person to be contacted for further information

Reviewer: Dr. Palvi Kudyar
Assistant Professor

Signature with date 

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