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Category: Study conduct

Title: Screening participants for participation in any clinical study

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Table of Contents

1. Purpose

This standard operating procedure (SOP) describes the procedures to be followed by the research team for screening individuals for participation in investigator initiated and sponsored studies.

2. Scope

This SOP is limited to screening procedures prior to recruitment of a participant in a clinical study.

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, will be responsible for screening participants for taking part in any study.

4. Applicable rules, regulations and guidelines

- ICMR's Ethical Guidelines for Biomedical and Health research involving Human Participants,ICMR(2017)http://www.icmr.nic.in/guidelines/ICMR_Ethical_Guidelines_2017.pdf (last accessed 20 Dec 2023)
- New Drugs and Clinical Trials Rules, 2019 https://cdsco.gov.in/opencms/export/sites/CDSCO_WEB/Pdf-documents/NewDrugs_CTRules_2019.pdf (last accessed 20th Dec, 2023)
- Indian GCP Guidelines 2001 https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=MzM5NQ==(last accessed 20th Dec, 2023)
- ICH-GCP E6 (R3) Draft Guidelines dated 19th May 2023 https://database.ich.org/sites/default/files/ICH_E6%28R3%29_DraftGuideline_2023_0519.pdf(last accessed 20th Dec, 2023)

Reference to other applicable SOPs

SOP No D 02A/06, D 02B/06: Preparing the site for a trial
SOP No D 03/06: Responsibilities of the Study Team
SOP No. D 04/06: Obtaining approval from Institutional Ethics Committee
SOP No. D 05/06: Administering and documenting Informed Consent
SOP No. D 12/06: Source documentation
SOP No. D 17/06: Continued interaction with the Institutional Ethics Committees (IEC-1 and IEC-2)
SOP No. D 18/06: Archiving documents.

5. Detailed instructions

1. Ensure that IEC-1 (for Pharma sponsored studies) or IEC-2/3 (for biomedical and health research) approval is obtained for the study prior to starting any study related activities (Ref. to SOP No. D 04/06)
2. Be fully familiar with all screening procedures as per protocol requirements, since these vary from study to study. Also refer to the SOP on responsibilities of the study team (SOP No. D 03/06) as well as the SOP on preparing the site for a trial (SOP D 02A/06, D 02B/06).
3. The PI should ensure that any advertisements or brochures to be seen or heard by prospective participants to solicit participation in research must be submitted along with an explanation of the mode of communication at the time of protocol submission and must be approved by the Institutional Ethics Committee.
4. If recruitment or advertising methods are to be changed, the PI must submit the methods and materials to be used to the Institutional Ethics Committee (IEC) as an amendment [SOP No. D 17/06 continued interaction with the Institutional Ethics Committee]. These recruitment methods must be reviewed and approved by the Institutional Ethics Committee prior to their use.
5. The PI must submit to the IEC (for review and approval), materials which may not be given to or seen by the potential participants and are to be given to health

providers to solicit research participants (e.g. "dear doctor" letters), as well as the process to be followed (e.g. contacting health providers for referrals).

6. If PI plans to recruit participants from among employees, colleagues, or students, this must be explained and justified in the protocol, reviewed and approved by the IEC.
7. The students and medical/ paramedical staff of the department will not be recruited/ be participants of the clinical trials conducted in the department.
8. Site will maintain a file with the certified photocopies of relevant documents establishing date of birth and place of work/ study of all the participants or volunteers.
9. Explain to the participant why you are asking him/her to undergo screening. Explain all the relevant tests that need to be done as per the protocol including COVID-19 testing, HIV, HCV and HbSAg if applicable. Give the participant sufficient time to arrive at a decision as to whether or not to participate in the screening process.
10. If the protocol requires HIV testing to be done, ensure that the participant is counseled regarding the same. All tests for HIV in the institute are done by the Department of Microbiology ONLY (if not specified in the protocol). This is as per the guidelines of the National AIDS Control Organization (NACO). The HIV testing center of the Department of Microbiology is located on the 5th floor of the multistoried building. Reports are sent to the Principal Investigator within 24-48 hrs in a sealed envelope.
11. The consent form used for screening (if applicable) should be the latest version that has approval of the institutional ethics committee. The PI or designee must ensure, while approaching or recruiting participants, that information is presented in a language that is understandable to the participant or the representative.
12. If the protocol requires 2 consent forms to be used, i.e. the screening consent form and the study participation informed consent form, ensure that the screening

consent form is used first. Only if the screening shows that the participant satisfies all eligibility criteria, the study participation informed consent form should be used, in the event that the participant agrees to participate and is found eligible.

13. Once the subject indicates interest, give the subject an IEC approved participant information sheet and informed consent document to read.
14. Subsequently, ask him/her to sign the study participation informed consent form or the screening consent form as appropriate. Refer to the SOP for administering and documenting informed consent (SOP No. D 05/06).
15. Ensure that the subject to be screened has given written, informed consent prior to any screening related procedure/activity (e.g. physical examination/blood test etc.).
16. Document the contact details (address and telephone number) of the subject in the source notes.
17. Document the participant's detailed demographic information, medical history, present illness, concomitant medication and other details, if any, as per the protocol requirements, in the source data file.
18. Document the results of the physical examination including vital parameters like pulse, blood pressure (supine and/or sitting position(s)), respiratory rate, and heart rate in the source data file.
19. Carry out the various laboratory and other investigations specified in the protocol to be performed at the screening visit.
20. If body fluids are to be collected for trial related investigations, ensure that they are collected as per the procedures specified in the relevant standard operating procedure if available (Ref. SOP No. D 10/06 for blood collection).
21. Ensure that the study physician is present at the time of any study related procedure.

22. Results of all screening tests are source documents and should be maintained and archived fully (Refer to SOP No. D 12/06 on source documents and SOP No. D 18/06 on archiving documents).
23. Once the results of screening are available, assess whether the subject is eligible to participate in the study.
24. Assign the subject with identification number once he/she consents to participate.
25. In the event that the screening results show that the subject is not eligible, inform him/her and exclude from the study. Refer the subject to the appropriate clinical unit/department in the event of an abnormality in the screening tests, which requires medical attention.
26. Results of the screening must be recorded in the Screening log and this will also include information on reason for screen failure.
27. If the participant asks, give a photocopy of the screening laboratory reports.
28. Reimburse the subject for the study visit as per the provisions made for the same in the study protocol and as per Institutional Ethics Committee approval/ recommendation.
29. Maintain a departmental diary recording details of all individuals who were counseled about the study and the number that actually consented to participate in the screening process. Document the reasons, if possible, for why subjects declined to participate in the screening.
30. Follow all protocol related procedures after screening.

6. Abbreviations:

i. NACO: National AIDS Control Organization
ii. PI: Principal Investigator
iii. SOP: Standard Operating Procedure

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