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

Category: Study conduct

Title: Administering and documenting written informed consent

SOP No.: D 05/06 **Total pages:** 08

Date first effective: 01 Jan 2024 **Next Review date:** 31 Dec 2024

Version: 06

SOP Team:

Author: Dr. Ananya Rakshit
DM Resident

Signature with date 27/Dec/2023

Reviewer: Dr. Mahesh Belhekar
Associate Professor

Signature with date 28/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

31st Dec '23

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

Signature with date

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

Table of Contents

No.	Contents	Page No.
1	Purpose	3
2	Scope	3
3	Responsibility	3
4	Applicable rules/guidelines	3
5	Detailed instructions	4
6	Glossary	7
7	Abbreviations	8

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

1. Purpose

The purpose of this Standard Operating Procedure (SOP) is to outline the procedure for obtaining written informed consent from a potential participant.

2. Scope

This SOP applies to administering and documenting written informed consent, assent process. All clinical studies involving human participants require documenting written informed consent. If a consent waiver is envisaged, an appropriate application must be made (see SOP D 04/06) and approval from the Institutional Ethics Committee must be obtained.

3. Responsibilities

Principal investigator (PI), Co-Investigator (Co-I) or any other medically qualified member of staff in the team, as delegated by the Principal Investigator, will be responsible for obtaining and documenting written informed consent from a potential participant.

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

- SOP No D 27/06: Audio visual recording of informed consent process

5. Detailed Instructions

1. A written informed consent is mandatory for all clinical trials, unless a consent waiver or permission for verbal consent is obtained from the Institutional Ethics Committee (IEC) in certain situations. In the institute, there are three Institutional Ethics Committees (IEC – 1 for pharma sponsored studies, IEC – 2 & IEC 3 for biomedical and health research) which oversee the research.
2. A written informed consent is needed from all potential participants before any trial related procedure (including e.g. physical examination, screening tests to assess eligibility, radiological tests, etc.)
3. Ensure that the written informed consent form and any other written information provided to a subject or subject's legal representative is approved by one of the IECs.
4. Ensure that the most recent version approved by the IEC is being used.
5. Ensure that "Final Approved Version" stamp with date of approval has been put on the most recent version approved by the IEC and signed by the PI.
6. Keep a checklist of informed consent process approved by the principal investigator to ensure that all information will be communicated to the volunteer.
7. Ensure that the volunteer is given the consent documents in the language he/ she is literate and document the same in the source.
8. Ensure that any information given to subject or subject's legally acceptable representative is in a language that they understand and describe this in the source document.

9. While a person is being administered consent, ensure adequate privacy and time for discussion.
10. Ensure that the volunteer is as comfortable as possible.
11. If the potential participant is unable to give consent for medical (e.g. psychiatric condition, dementia, unconsciousness etc.) or legal (age below 18 years) reasons the consent must be administered to the legally acceptable representative (LAR).
12. In all the above conditions, if during the course of the study, the patient either for medical or legal reason is able to give consent, then he/she should be consented using a fresh consent form which should be kept in the study file with source notes explaining why he/she has been consented.
13. Where appropriate, pediatric subjects should additionally assent to enroll in the study. Mature minors and adolescents (7-17 years) should personally sign and date the separately designed written assent form.
14. In such cases, ensure that the assent form provided to a subject has the written approval of the concerned Institutional Ethics Committee and ensure that the most recent version of the assent form approved by the ethics committee is being used.
15. In case the subject / legally acceptable representative is illiterate, then ensure that an impartial witness is present during the informed consent process.

    Note: The impartial witness must be literate and be able to read and understand the language which the patient understands. Other patients (of different disease than the disease of the current study) relatives can be an impartial witness. Do not take the department members or ward staff as an impartial witness. Do not take one impartial witness for all the illiterate participants.
16. Discuss all the elements of the informed consent document with the volunteer thoroughly. Provide a complete description of the study using non-technical language.
17. Allow the subject or subject's legally acceptable representative sufficient time to read the document and ask questions. (Note: the volunteers can take the informed consent document home to contemplate their participation).

18. Encourage inputs from family members and other care providers, if appropriate, and, only if the potential participant consents to the involvement of the family in the consent process. (Note this is very important, for example, in studies related to sensitive topics like HIV)
19. Ensure that there is no excessive influence on an individual to participate or to continue to participate in a trial.
20. Once the subject/LAR has agreed, the consent has to be documented. Ensure that the subject writes his/ her name, signs and dates the document himself or herself along with the time after all elements have been discussed, all questions have been addressed and the subject verbally consents to participate.
21. The informed consent document must be signed by the volunteer in the presence of qualified research team members who have discussed the trial with him/her and conducted the consent process.
22. In case the subject or, where applicable the legally acceptable representative is illiterate, the left thumbprint should be taken instead of a signature. In this situation the entire consent process as well as documentation of the consent has to be performed in the presence of an impartial witness who must be literate. Note that the thumbprint of the subject has to be dated by the witness, and NOT the investigator.
23. The PI / designated member of the research team who obtained informed consent from the subject should also sign and date the informed consent document in the appropriate place after the subject/LAR and where applicable the impartial witness has signed.
24. Provide a photocopy of the fully signed and dated informed consent document to the subject (or legally acceptable representative). Document that this has been provided in the source notes with signature/ left thumb impression of the subject, LAR (if applicable), impartial witness (if applicable) and the investigator.
25. Retain the original informed consent form in the subject file at the site.
26. Note in the subject's in the Informed consent narrative the entire process, date and time of the informed consent.

27. Also note in the consent narrative, the contact details of the impartial witness (If applicable).
28. Document all the questions asked by the subject and the responses given by the research team member/s carrying out the consent process.
29. If the subject refuses consent, then this must be noted in the narrative, along with the reasons if given (this is because the subject can refuse participation without giving reasons).
30. If there are any changes in the older version of ICD, new version has to be approved by IEC and once it is approved, all older version copies should be shredded and discarded except for the copy which is placed in the master file with a stamp of "superseded". The superseded copy should be signed off by the PI. The participant should be reconsented if any changes are made in the ICD during the study process.
31. Informed consent narrative should be written and signed by the member of the research team who obtained the informed consent.

6. Glossary

a. Legally Accepted Representative (LAR)

An individual or juridical or other body authorized under applicable law to consent on behalf of a prospective participant, to the participant's participation in the clinical trial. (ICH E6R3, accessed 20th Dec 2023, www.ich.org)

b. Impartial witness

A person who is independent of the trial, who cannot be unfairly influenced by people involved with the trial, who attends the informed consent process if the participant or the participant's legally acceptable representative (LAR) cannot read, and who reads the informed consent document and any other written information supplied to the participant. (ICH E6R3, accessed 20th Dec 2023, www.ich.org)

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

7. Abbreviations:

i. Co-I: Co-investigator
ii. ICD: Informed Consent Documents
iii. LAR: Legally Acceptable Representative
iv. ICH: International Conference on Harmonization
v. PI: Principal Investigator
vi. SOP: Standard Operating Procedure

Reviewer: Dr. Mahesh Belhekar
Associate Professor

Signature with date 28/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

Signature with date 31-12-23

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