DEPARTMENT OF CLINICAL PHARMACOLOGY
SETH GSMC AND KEMH, MUMBAI – 400012

DCP/Ph1/012: Obtaining written informed consent from potential participants taking part in clinical trials

Version 1.1
Effective date: 1st of January 2024
Revision due date: 31st of December 2024

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1. Purpose: The purpose of this SOP is to outline the procedure for obtaining written informed consent from a potential participant in all phases of a clinical trial with any investigational product (IP).

2. Scope: This SOP is limited to obtaining written informed consent in clinical trials (including academic studies) conducted at our institute.

3. Responsibilities: The responsibilities for ensuring implementation of this SOP lies with the Principal Investigator (PI). The responsibilities for the individual tasks are mentioned under the Section 6. 'Detailed Instructions'.

4. Applicable rules, regulations and guidelines:

- Ethical Guidelines for Biomedical and Health Research involving Human Participants, ICMR, 2017
- International Council on Harmonization (ICH); Good Clinical Practice Draft Guidelines: (R3) dated 19th May, 2023
- Medical Devices Rules, 2017
- New Drugs and Clinical Trials Rules, 2019

5. References (to other SOPs)

- Ph. 1 SOP A4: Preparation, review, and finalisation of informed consent document for a Phase I clinical trial with an Investigational product

- Ph. 1 SOP A5: Preparation, review, and finalisation of informed consent document for a Phase I clinical trial with an Investigational product in vernacular languages

6. Detailed instructions

S.No	Task	Person responsible
1	Ensure that the participant information sheet (PIS), informed consent form (ICF), and any other written information for screening and recruitment of potential participants is approved by any one of the IECs	PI / Co-I / Study co-ordinator
2	Introduce yourself to the participant and / or his / her legally acceptable representative (LAR)	PI / Co-I
3	Ask the participant and / or the LAR in which language he / she is comfortable, and whether he / she is literate, and document these in the source document / narrative	PI / Co-I
4	In case the subject / LAR is illiterate, then ensure that an impartial witness is present during the informed consent process*.	PI / Co-I
5	Take the informed consent document (ICD) in the appropriate language, ensuring that it is the most recent version approved by the IEC (The most recent version should have the stamp of the PI with signature and date of approval)**	PI / Co-I
6	Ensure privacy and adequate time for discussion while administering the informed consent (preferably administer the consent in a separate	PI / Co-I

	room)	
7	Ensure that the participant and / or LAR are as comfortable as possible	PI / Co-I
8	In case of potential participants between 7-17 years, obtain written assent form from the participant in the presence of the LAR, in addition to the written informed consent from LAR.	PI / Co-I
9	Discuss all the elements of the ICD with the participant and / or LAR thoroughly. Provide a complete description of the study using non-technical language.	PI / Co-I
10	Provide the ICD to the participant and / or LAR to read. (The participant and / or LAR can take the ICD home to contemplate their participation).	PI / Co-I
11	Ask the participant and / or LAR if they have any questions or concerns (Allow sufficient time to address the participant and / or LAR's queries and concerns)	PI / Co-I
12	Encourage inputs from family members and other care providers, if appropriate, and, only if the potential participant and / or LAR consents to the involvement of the family in the consent process	PI / Co-I
13	Ensure that there is no coercion on a potential participant to participate in a trial.	PI / Co-I
14	Ask the participant and / or LAR one or two questions pertaining to the study to ensure the comprehension of the study information by the participant and / LAR	PI / Co-I

15	Once the participant and / or LAR has agreed, ensure that the subject writes his / her name, signs and dates the document himself or herself along with the time*#	PI / Co-I
16	In case the participant and / or LAR is illiterate, the left thumbprint should be taken instead of a signature. (The thumbprint of the subject has to be dated by the impartial witness, and **not** the investigator).	PI / Co-I
17	Sign and date the ICD in the appropriate place after the participant and / or LAR, and where applicable the impartial witness, has signed.	PI / Co-I
18	Provide a photocopy of the fully signed and dated ICD to the participant and / or LAR. Document that this has been provided in the source notes with signature / left thumb impression of the participant and / or LAR, impartial witness (if applicable), along with that of the investigator.	PI / Co-I / Study co-ordinator
19	Prepare the narrative of the informed consent process, mentioning the following: • Participant initials, • Date and time of the informed consent, • How the informed consent was taken, • Queries raised and answered by the participant and / or LAR, • Questions asked by the person administering the consent and answered by the participant and / or LAR,	PI / Co-I (The person who has administered the consent should prepare the narrative)

	• The total duration of the consent process, • Details of the impartial witness including contact details (if applicable), • The name and signature of the person administering the consent	
20	If the participant and / or LAR declines consent, then document this in the narrative, along with the reasons (if given)	PI / Co-I
21	Review the ICD and the narrative and sign with date	PI
22	Retain the original ICD in the participant file at the trial site	PI / Co-I / Study co-ordinator

* The impartial witness must be literate and be able to read and understand the language which the participant understands. Relatives of other patients (of different disease than the disease of the current study) can be an impartial witness. Do not take the department members or ward staff or study team members as an impartial witness. Do not take one impartial witness for all the illiterate participants.

** If there are any changes in the older version of ICD, the 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 re-consented if any changes are made in the ICD during the study process.

*# The ICD must be signed by the participant and / or LAR in the presence of qualified research team members who have discussed the trial with him / her and conducted the consent process. Ensure that the participant and / or LAR signs the ICD only after all

elements have been discussed, all questions have been addressed and the subject verbally consents to participate

7. Abbreviations

Co-I	Co-Investigator
ICD	Informed Consent Document
ICF	Informed consent form
ICH	International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use
ICMR	Indian Council of Medical Research
IEC	Institutional Ethics Committee
IP	Investigational product
LAR	Legally acceptable representative
PI	Principal Investigator
PIS	Participant Information Sheet
SOP	Standard Operating Procedure

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Associate Professor

Signature with date: Belk 29-Dec-2023

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