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

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• 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),	PI / Co-I / Study co-
	informed consent form (ICF), and any other written	ordinator
	information for screening and recruitment of	
	potential participants is approved by any one of the	Scope: The SOP is that
	IECs	o (zoilma oimobauc gnibiliani)
2	Introduce yourself to the participant and / or his / her	PI / Co-I
	legally acceptable representative (LAR)	Responsibilities: The responsibilities:
3	Ask the participant and / or the LAR in which	PI / Co-I
	language he / she is comfortable, and whether he /	beliander the Section 6. 'Distailed.
	she is literate, and document these in the source	
	document / narrative	obidogar, rolor skindliga A. Applicable
4	In case the subject / LAR is illiterate, then ensure	PI / Co-I
	that an impartial witness is present during the	Participants, ICMR, 20
	informed consent process*.	disease a denoitement
5	Take the informed consent document (ICD) in the	PI / Co-I
	appropriate language, ensuring that it is the most	e felded Devices Roles
	recent version approved by the IEC (The most	New Drugs and Clinical
	recent version should have the stamp of the PI with	
	signature and date of approval)**	Seletrores (to other SOPs)
6	Ensure privacy and adequate time for discussion	PI / Co-I
	while administering the informed consent	o Phase Leftminal trial w
	(preferably administer the consent in a separate	

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	room)	magisimen sin south
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,	PI / Co-I
	obtain written assent form from the participant in the	smajornaq adi sassani
	presence of the LAR, in addition to the written	foreign defined and the first
	informed consent from LAR.	primuli's all is separate
9	Discuss all the elements of the ICD with the	PI / Co-I
	participant and / or LAR thoroughly.	divestigative).
	Provide a complete description of the study using	GOI salvolab Les reje
	non-technical language.	na V ban Rassisirana arti
10	Provide the ICD to the participant and / or LAR to	PI / Co-I
	read. (The participant and / or LAR can take the ICD	Provide a pictorapy o
	home to contemplate their participation).	ICD to the participant of
11	Ask the participant and / or LAR if they have any	PI / Co-I
	questions or concerns (Allow sufficient time to	onusia Hal \ sautusije
	address the participant and / or LAR's queries and	sepail , RELL in A. Lines.
	concerns)	a sett av andreiber garde
12	Encourage inputs from family members and other	PI / Co-I
	care providers, if appropriate, and, only if the	process, area londer the
	potential participant and / or LAR consents to the	gilm magarart .
	involvement of the family in the consent process	Date and time of
13	Ensure that there is no coercion on a potential	PI / Co-I
	participant to participate in a trial.	Cuertes raised
14	Ask the participant and / or LAR one or two	PI / Co-I
	questions pertaining to the study to ensure the	bakes anoliensQ - #
	comprehension of the study information by the	the consent and
	participant and / LAR	SIA Line Volume

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15	Once the participant and / or LAR has agreed,	PI / Co-I
	ensure that the subject writes his / her name, signs	since out out subsets
	and dates the document himself or herself along	adizor a difendino
	with the time*#	and ladgement to sens at
16	In case the participant and / or LAR is illiterate, the	PI / Co-I
	left thumbprint should be taken instead of a	WAY SHOW SHOW THE SHO
	signature. (The thumbprint of the subject has to be	med system of homeologic
	dated by the impartial witness, and not the	indo-pit-lin-sursiki k (
	investigator).	IS I've Villax Matistrian
17	Sign and date the ICD in the appropriate place after	PI / Co-I
	the participant and / or LAR, and where applicable	oguseant tretoriost-son
	the impartial witness, has signed.	at at CO at them?
18	Provide a photocopy of the fully signed and dated	PI / Co-I / Study co-
	ICD to the participant and / or LAR. Document that	ordinator
	this has been provided in the source notes with	par musifatraty site stary in a stary
	signature / left thumb impression of the participant	anasaos to andissupi
	and / or LAR, impartial witness (if applicable),	animinimal and months:
	along with that of the investigator.	Asimonia
19	Prepare the narrative of the informed consent	PI / Co-I (The person who
	process, mentioning the following:	has administered the consent
	Participant initials,	should prepare the narrative)
	Date and time of the informed consent,	trial sal to memova ozal
	 How the informed consent was taken, 	Si Session that there is
	• Queries raised and answered by the	nigrama at magazing
	participant and / or LAR,	a Jacquillag off 38A
	• Questions asked by the person administering	mestions perioding t
	the consent and answered by the participant	all To noisealoughout
	and / or LAR,	SE,1 but importing

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el) prima	The total duration of the consent process,	meznielb dowl nord whenete
	Details of the impartial witness including	constituted in formations
	contact details (if applicable),	
	• The name and signature of the person	
	administering the consent	
20	If the participant and / or LAR declines consent,	PI / Co-I
	then document this in the narrative, along with the	made and o'colored leans
	reasons (if given)	and bancoul Con
21	Review the ICD and the narrative and sign with date	PI
22	Retain the original ICD in the participant file at the	PI / Co-I / Study co-
	trial site	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

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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

Reviewer:

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Associate Professor

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