Final Addendum 3 dated 3rd May 2023
to SOPs version 6.1

1) SOP 2, V 6.1, section 5.9 Hierarchy point 5 & 9 revised as
Old: The Member-secretary, Joint Member-Secretary (if necessary) will be elected by and from amongst the IEC members for 3 years term. These may be re-elected any number of times. Should they resign or be disqualified, the IEC members will elect a replacement for another term.

Replaced by new - The Chairperson, Member-secretary, Joint Member-Secretary will be appointed by the Head of the Institute. Template for appointment letter and acceptance letter added as attachment 2.

SOP 2, V 6.1, section 5.8 Training of the IEC Members in Research Ethics, sub point 2 revised as,
All IEC members should undergo refresher courses in Good Clinical Practice (GCP) annually and IEC will maintain a record for pre and post training evaluation sheets and training material.

2) Addition of the ICF assessment toolkit for IEC members in the SOP 05-A- which has been enlisted below.

Annexure 1
AX 01/ SOP 05-A – addendum
Informed Consent Assessment Toolkit for IEC members

1. Essential documents:

Indicate

	Yes	No
• A statement that the study involves research and explanation of the purpose of the research	☐	☐
• The expected duration of the drug trial and individual patient's participation and frequency of visits during the study.....	☐	☐
• The approximate number of study Subjects	☐	☐
• A description of the procedures to be followed, including all invasive procedures ..	☐	☐
• Identification of any procedures which are experimental	☐	☐
• A description of any reasonably foreseeable risks or discomforts to the Subject.....	☐	☐
• A description of any benefits to the Subject or others reasonably be expected from the research. If no benefit is expected the Subject should be made aware of this	☐	☐
• A disclosure of specific appropriate alternative procedures or therapies available to the Subject	☐	☐
• A statement describing the extent to which confidentiality of records identifying the Subject will be maintained & who will have access to Subject's Medical Records.....	☐	☐
• Trial treatment schedule and the probability for random assignment to each treatment (for randomized trials).....	☐	☐

- Statement describing the financial compensation and payment for the medical management as under:
  a) In case of the injury occurring to the Subject during the Clinical Trial, free medical management shall be given as long as required or till such time it is established that the injury is not related to the Clinical Trial, whichever is earlier..... ☐ ☐

  b) In the event if a trial related injury or death , the Sponsor and its representative or the investigator or the centre, as the case may be, in accordance of the rule 39, as the case may be, shall provide financial compensation for the injury or death... ☐ ☐

- An explanation about whom to contact for trial related queries, rights of the Subjects and in the event of any injury ..... ☐ ☐
- The anticipated prorated payment, if any, to the Subject for participating in the trial.. ☐ ☐
- Responsibilities of Subject on participation in the trial..... ☐ ☐
- Statement that participation is voluntary, that the subject can withdraw from the study at any time and that refusal to participate will not involve any penalty or loss of benefits to which the Subject is otherwise entitled..... ☐ ☐
- Statement that there is a possibility of failure of investigational product to provide intended therapeutic effect..... ☐ ☐
- Statement that in the case of placebo controlled trial, the placebo administered to the subjects shall not have any therapeutic effect..... ☐ ☐
- Any other pertinent information..... ☐ ☐

2 Additional elements, which may be required :

- Statement of foreseeable circumstances under which the participation of the subject may be terminated by the Investigator without his or her consent..... ☐ ☐
- Additional costs to the subject that may result from participation in the study... ☐ ☐
- The consequences of a Subject's decision to withdraw from the research and procedures for orderly termination of participation by Subject..... ☐ ☐
- Statement that the Subject or Subject's representative will be notified in a timely manner if significant new findings develop during the course of the research which may affect the Subject's willingness to continue participation will be provided... ☐ ☐
- A statement that the particular treatment or procedure may involve risks to the Subject (or to the embryo or foetus, if the Subject is or may become pregnant), which are currently unforeseeable..... ☐ ☐

3) Addition of the project risk benefit assessment tool for IEC members in the SOP 05-A- which has been enlisted below.

Annexure 2
AX 02 / SOP 05-A – addendum

Project Risk Benefit Assessment Tool for IEC members

High Risk/ Low Benefit (Class-A)	**High Risk/ High Benefit (Class-B)**
Risks:	**Risks:**
• Completely new drug / formulation	• Completely new drug/formulation
• Highly Toxic substances	• Highly Toxic substances
• Safety/Effectiveness not established through earlier studies	• Safety/Effectiveness not established through earlier studies
• High incidence of SAEs/side effects in prelim studies	• High incidence of SAEs/side effects in prelim studies
• Inadequate or no risk AE handling mechanisms	• Inadequate or no risk AE handling mechanisms
• High data disclosure and data leakage possibilities	• High data disclosure and data leakage possibilities
• Affects large no. Of participants	• Affects large no. of participants
• Violation legal/statutory regulations	• Violation legal/statutory regulations
• Inadequate project documentation	• Inadequate project documentation
• Inadequate PI/Staff expertise	• Inadequate PI/Staff expertise
• New/untried procedures	• New/untried procedures
Benefits:	**Benefits:**
• Cost of treatment/drug borne by participant	• Completely new cure
• Replaces current drugs with no extra benefits either treatment wise or cost wise	• Preventive for life i.e. Vaccinations
• Short term relief as opposed to long term action	• Significant improvement over o Existing cures/treatments
• No post-trial alternatives	• Minimal side effects vis a vis existing treatments
	• Elimination of disease rather than temporary curative
	• Significant reduction in treatment costs/mode (ex. Pelvis surgery)
	• Extension of benefits/ availability of Treatment post trial
	• Benefits large no. of participants
Low Risk/Low Benefit (Class-D)	**Low Risk/High Benefit (Class-C)**
Risks:	**Risks:**
• Proven/Acceptable toxicity	• Proven/Acceptable toxicity
• Proven safety and efficacy	• Proven safety and efficacy
• Drug/formulation a variation of approved drug/class of drugs	• Drug/formulation a variation of approved drug/class of drugs
• SAEs indicate minor/acceptable reactions, side effects	• SAEs indicate minor/acceptable reaction, side effects

• No drug but only data analysis	• No drug but only data analysis
• Minimal data disclosure /leakage possibilities	• Minimal data disclosure/leakage possibilities
• Minimal risk to legal/statutory regulations	• Minimal risk to legal/statutory Regulations
• Standard operating / surgical procedures	• Standard operating/ surgical procedures
Benefits:	**Benefits:**
• Cost of treatment/drug borne by participant	• Completely new cure
• Replaces current drugs with no extra benefits either treatment wise or cost wise	• Preventive for life i.e. Vaccinations
• Short term relief as opposed to long term action	• Significant improvement over existing cures/treatments
• No post trial alternatives	• Minimal side effects vis a vis existing treatment
	• Elimination of disease rather than temporarily curative
	• Significant reduction in treatment costs/mode (e.g.. Pelvis surgery)
	• Extension of benefits/availability of treatment post-trial
	• Benefits large no. of patients

IEC member to mark the class as per the project risk benefit assessment.

4) **Grievance redressal:**
The SOP 17 section 5.1 added as Participant grievance redressal policy:

5.1 Participant Grievance redressal policy
In case of a complaint received from a research participant, the Member Secretary, in consultation with the Chairperson will initiate a process to address any injustice that may have occurred. Depending on the seriousness of the matter, the Chairperson will direct the Member Secretary to:

- Appoint a subcommittee of two or more IEC members for enquiry in order to resolve the matter.
- Call an emergency meeting of two or more IEC members for discussion or
- Consider the matter for discussion at the next full board meeting.
- The Member Secretary/ designated IEC members will assess the situation and mediate a dialogue between the research participant and PI in an attempt to resolve the matter.
- The IEC will insist on factual details to determine the gap, if any, between truth and individual perception.
- Call an mediator or arbitrator as required
- Do Report writing and documentation of the facts.
- Prepare recommendation to the research participant.

The final decision will be taken by the Member Secretary in consultation with the Chairperson based on the recommendation of any one of the above and it will be informed to the research participant and the PI by the Secretariat.
The information including any action taken or follow-up and final decision will be recorded in the form AX 01/ SOP 17/V6.1 and the form is signed and dated.
The IEC members will be informed about the action taken and the outcomes in the forthcoming IEC meeting (in case of requests/ complaints not discussed in full board meeting) and will be minuted.
The Secretariat will place all documents in the relevant study file.

5) **In the SOP 5-A Annexure 2 Format of Project approval letter (Interventional study) the revised section will be as follows:**

The Clinical Trial was unanimously approved by all the IEC members present in the IEC meeting. This clinical Trial has been approved by the IEC to be **conducted in its presented form**. The approval is valid for the entire duration of the study. However, continued study approval beyond is incumbent on submission of the periodic review report at the end of six months. If the periodic review report is not received in time, the study approval will cease to be valid.

6) SOP 5 section 5.4 and SOP 13 section 5.2 the clause has been added as in regard to regulatory clinical trials, a maximum of 5 initial protocols will be taken up for discussion at every monthly meeting.

7) In Addendum 2 dated 27th Dec 2022 effective from 2nd Jan 2023, the following clause will be added:
All IEC members to send acknowledgement email stating that project documents are received for review and the privacy and confidentiality of these documents will be maintained by the concerned IEC member.
Record of Emails will be maintained in the project master file.

8) A separate draft SOP 25 version 1 dated 20 April 2023 is prepared on AV consenting process and review. Annexure 2 the AV checklist and Annexure 3 Guidance document for audiovisual recording of AV consent process in SOP 12 have been deleted from that SOP and added in SOP 25 which is attached as Attachment-1.

9) SOP 5, sample format of covering letter by Principal investigator for review of clinical trial, section 3, under Recruitment strategies the following points are added.

a) Word of mouth
b) OPD or IPD
c) Notices / Advertisement (English, Hindi and Marathi)
d) Consecutive – roll over.
e) Collaboration with other departments or institutes
f) Departmental database

10) In the SOP 20 for vulnerable participants, for infant recruitment the following section is added:
Recruitment strategies for infant studies
a) OPD or IPD
b) By a qualified pediatrician or neonatologist
c) From the departmental database
d) From the well baby clinic

11) SOP 5A, Annexure 3, AX 03/ SOP05-A-Addendum, IEC decision form is modified to incorporate column on comments / recommendations to be enlisted in the approval letter.

Annexure 3
AX 03/SOP 05-A-Addendum
IEC Decision Form

Date of IEC meeting: _____

Protocol number: _____

<table>
<tr><td></td><td colspan="3">IEC Protocol No. and Title:</td></tr>
<tr><td colspan="2">Principal Investigator:</td><td colspan="2">Department:</td></tr>
<tr><td rowspan="3">Final Decision at the meeting:</td><td>Approved</td><td></td><td></td></tr>
<tr><td rowspan="2">Revision with minor modification/amendments</td><td>Member Secretary (MS)</td><td></td></tr>
<tr><td>MS + Primary Reviewer (PR)</td><td></td></tr>
</table>

Revision with major modification	MS + PR		
	MS + PR+ Full Board (FB)		
Not approved (Reason)			
Monitoring required (Reason)			

No.	Names of Members present	Approved	Modification		Disapproved	Comments/ Recommendations to be incorporated in the Letter of permission	Signature
			Major	Minor			

Comments:
No. of members voting for the decision:

No. of members voting against the decision:No. of members abstaining from voting: Any Dissent (mention details):

Signature of Chairperson **Date:** _____

12) Regarding consent of IEC members, the attendance register will record consent and attendance in the template described below:

Template for consent for recording and attendance

Meeting Date: XXX
Venue: xxx
Time: xxx
I consent for recording of the IEC meeting held on xxxxx.

Sr. No.	Name	Designation in the IEC	Signature with Date
1.	Dr. Manju Sengar	Chairperson	
2.	Dr. Raakhi Tripathi	Member Secretary (Basic Medical Scientist)	
3.	Dr. Nithya Gogtay	Jt. Member Secretary (Basic Medical Scientist)	
4.	Dr. Milind Nadkar	Clinician	
5.	Dr. Vyankatesh Shivane	Clinician	
6.	Ms. Veera Gayakwad	Legal Expert	
7.	Ms. Alpana Purohit	Lay person	

8.	Ms. Meera Shah	Social scientist	
9.	Dr. Monty Khajanchi	Clinician	
10.	Dr. Dhiraj Kumar	Clinician	
11.	Dr. Charulata Londhe	Clinician	
12.	Dr. Sushma Save	Clinician	

13) SOP 10 in section 5.3 the following clause is added

If protocol deviations in any study meet the any of the following criteria will warrant additional necessary action
- Deviations reported > 20% of the approved sample size.
- >5 deviations are reported in the same patient.

However, the nature of the deviations will be looked at prior to this – for example – distinguishing between patient related protocol deviations versus investigator related deviations

14) SOP 5 an additional annexure on site assessment checklist has been added. PI has to fill this checklist and submit this along with initial project submission. IEC members to review this checklist and in case of doubt to confirm with onsite monitoring.

Annexure 4
AX 04/ SOP 05-A – addendum
Site Assessment Checklist

		State Y (Yes) or N (No)	If No, Comment
1.	**Patient Population**		
	1. Do you have access to the desired participants pool?If no direct access, is the collaborating department providing access?		
	2. Will you need to recruit patients from external sources? If so, will sponsor /CRO provide funding?		
	3. Is the proposed enrollment goal for a given period realistic?		
	4. Will enrollment compete with other studies seeking the same patients?		
	5. Is Patient Charter of Rights of Participants in research available and displayed at the site, including English and vernacular languages		
	6. Is Participant's Request/ Complaint Record form drop box available?		
	7. Are services/ investigations available (e.g., lab, radiology-accreditation) t o meet the protocol requirements present Are these laboratories accredited		
	8. Are necessary equipment /instruments (availability, validation and calibration) required for protocol execution present at site?		
	9. Does protocol execution require dedicated internet / phone / fax facilities If yes, are they available at the site? -eCRF - patient monitoring (eg phone call)		
2.	**Procedures**		
	1. Are the study visits frequent? (more than those in clinical		

	practice for a given disease)		
	2. Are the procedures during each visit difficult and time consuming? If yes measures taken to minimize patient risk at the site		
3.	**Study Team**		
	1. Does the study require special study team members with additional expertise?		
	2. In case study visits are complex, do they present scheduling difficulties for the team?		
	3. How many study team members will be required /participant / visit?		
	4. In case of unavailability of any protocol required equipment / procedures willsponsor / CRO provide it If yes: permanent / rental for the trial period		
4.	**Trial Procedure**		
	1. Is adequate space available?		
	2. Does the site have dedicated with restricted access area for - Investigational product (IP) storage / - Mention IP accountability		
	3. IP storage room has facility to record temperature/ humidity 24*7		
	4. Will electronic or remote data retrieval systems be used? If so, will sponsor /CRO provide training?		
	5. Does the site have dedicated computer, printer, cupboard, stationary for storage of study documents		

Name and Signature of the PI & Date: _____

IEC office use only:

Date of the physical site assessment: _____ Time in_____Time out_____

Assessment performed by

Name of IEC member 1) _____

2) _____

3)_____

Type of facilities _____

Confirmation of all items in AX 04/ SOP 05-A addendum, Site Assessment Checklist Yes __No____ if no list the deficiencies 1) _____

2) _____

3)_____

Interaction with clinical trial members at the site:

Name of the trial team members	Query asked	Reply provided
PI		
Co-I 1		
Co-I 2		

Co-I 3		
CRC1		
CRC2		
CRC3		
Lab Technician		
Any other trial team member		

Date and signature of the monitors 1) _____2)_____3)_____

15) SOP 16 section 5.1 to include the following:

Shift the contents (hard copy) to the archival room specifying the cupboard / shelf / location of the files as per Annexure 5 AX 05/ SOP 16 addendum.

Annexure 5
AX 05/ SOP 16 addendum
Template Log of archived files and their location

IEC Project registration number	Protocol ID	Date of completion	Date of Archival	Location of File		Proposed Date of Shredding	Signature of IEC Secretariat
				Cupboard No.	Shelf No.		

The following statements are added in the SOP 16 section Purpose and scope:

Purpose

This policy is made to ensure protection, maintenance and archival of its documents submitted to the IEC -1 and confirms to the NDCT rules 2019 and ICMR guidelines 2017.

Scope

The Policy seeks to enhance transparency, accountability, and better relationship with stakeholders, by providing a framework for archival that can be viewed by all stakeholders.

Attachment -1

SOP 25/V 1 dated 20th April 2023
Audio Visual (AV) Recording of Informed Consent Process

SOP 25/V1 **Effective from XXXXX**	**IEC (KEMH, Mumbai)** **Valid up to xxxxxx**
Title:	**Audio Visual Consent**
SOP Code:	**SOP 25/V 1 dated 20th April 2023**

Prepared by **Signature with date**	Reviewed by **Signature with date**	Approved by **Signature with date**	**Accepted by**

Dr. Raakhi Tripathi **Member Secretary, IEC-I**	Dr. Nithya Gogtay **Joint-Member Secretary, IEC-I**	Dr. Manju Sengar **Chairperson, IEC-I**	**IEC-I**

1. Purpose

The purpose of this SOP is to describe the procedures for Audio-Visual (AV) recording, storage and archival of the informed consent and assent process for regulatory studies.

2. Scope

This SOP applies to all those regulatory clinical trials approved by the DCGI, which require documenting of the written informed consent and assent process.

2.1 An audio-video recording of the informed consent process in case of vulnerable subjects in clinical trials of New Chemical Entity or New Molecular Entity including procedure of providing information to the subject and his understanding on such consent, shall be maintained by the investigator for record:

2.2 Provided that in case of clinical trial of anti-HIV and anti-leprosy drugs, only audio recording of the informed consent process of individual subject including the procedure of providing information to the subject and his understanding on such consent shall be maintained by the investigator for record.

2.3 Statement that there is a possibility of failure of IP to provide intended therapeutic effect

2.4 Statement that in case of Placebo controlled trials, the placebo administered to thesubjects shall not have any therapeutic effect

2.5 Any other pertinent information

3. Responsibility

1. IEC will ensure that Principal investigator will conduct AV recording of the informed consent process, store and archive without violating the participant confidentiality as detailed below in section 6.
2. IEC will specifically ask for consent for AV Consenting in addition to the ICF
3. AV recordings may be reviewed periodically by IEC members

4. Applicable rules, regulations and guidelines:

GSR 227-E, New Drugs and Clinical Trials Rules, 2019 published in the Gazette of India dated 19th March 2019.

5. Detailed Instructions for PI to follow:

All basic principles and procedures for the administration and documentation of the informed consent process are described in SOP Initial review of submitted protocol.

1) If the participant is unable to give consent for medical or legal reasons, the consent should be taken from the legally acceptable representative (LAR) and the process recorded.
2) If the participant/LAR is illiterate, then an impartial witness is needed. This person should also be in the frame for the entire duration of the consent process.
3) AV recording should be done with assent wherever applicable.
4) Ensure the following infrastructure is available prior to counseling of potential participant:
   a. The informed consent process should be carried out in the designated area when the following conditions should be met) that is -
      i. Free from disturbance
      ii. Well lit
      iii. Ensures privacy for the participant

iv. Participant should be comfortable

b. Camera having video facility with
- ✓ Good resolution (at least1280x720 pixels)
- ✓ Sufficient memory (at least 4 GB)
- ✓ Sufficient battery backup (at least 2 hours)
- ✓ Show non-editable date & time on video (preferably)

a. Mike system
b. Computer/laptop with CD/DVD writer
c. Blank CDs/DVDs with cover
d. External Hard disk (at least 500 GB to 1 TB)

5) Before starting the informed consent process (and the AV recording of the same)

i. Ensure that all the necessary equipment mentioned above is functional.

ii. The potential participant/LAR/ Impartial witness should be informed that the whole process of taking the consent is being recorded as per Govt. of India notification to ensure that he/she has understood all the potential risks and benefits involved in the study including failure of the IMP, study details and his/her rights for the purpose of documentation and the confidentiality of the same is assured.

iii. The potential participant/LAR/ impartial witness should be made aware that his/her recording may be shown to government agencies or members from the IEC and independent auditors.

iv. His/her consent should be documented in a separate ICD that states the same. The process of obtaining signatures of the potential participant/LAR/ impartial witness & Principal Investigator or her designee on this Audio-video consent form should be carried out as per specified in Annexure AF/IEC/04/08/V-8.0 of SOP/08/V-8.0.

6. Actual AV recording process:

i. The PI/Co-I/medically qualified person delegated by the PI and the potential participant/LAR (and if need be the impartial witness) should sit comfortably facing each other / side-by-side in such a way that their faces will be captured in the frame simultaneously.

ii. The PI/Co-I/medically qualified person delegated by the PI should introduce himself/herself by name, designation and his/ her role in the research, and state the current date and time.

iii. Participant/LAR should be requested to introduce his/her name, age and address and in case of LAR, he/she should clearly state relation to actual participant as well as the reason why the participant cannot give consent. Participant/LAR should also state the language he/she understands best and is literate in. The PI/Co-I/medically qualified person delegated by the PI may facilitate this process to ensure all above points are captured in the recording.

iv. In case participant/LAR is illiterate and an impartial witness is needed, the impartial witness should be requested to introduce him/her, give his/her address and state the language that he/she is literate in.

v. The Participant/LAR should state that he has been informed about the fact that the entire consent process is being recorded and that he/she has agreed for the same.

vi. The Informed Consent Process should be carried out as per SOP 08/V-8.0: Administering and documenting informed consent.

vii. The participant should be allowed to read the consent document (and this process should be recorded)

viii. The PI/Co-I/medically qualified person delegated by the PI should explain all the elements of the approved ICF in the language best understood by the potential participant

ix. Explanation or narration given by the PI/Co-I/medically qualified person delegated by the PI, all the questions asked by the potential participant/LAR and answers given to them should be clearly audible and recorded.

x. At any point during the consent process, if the participant wishes to take more time to read/ understand the consent document, including, for example, take it home to discuss with relatives the recording shall be stopped mentioning the time of stopping.

xi. The participant/LAR (wherever applicable) should be invited to sign the consent form only after satisfactory answers (in the investigator's judgement) have been given by the participant/ LAR to all the above-mentioned questions.

xii. Participant/LAR should read out all the statements mentioned in ICF as per Schedule-Y and state whether he/she agrees or not for each statement and affix signature/thumb print at the end

xiii. The actual signing process should be recorded.

xiv. The impartial witness should be requested to enter the name and details of the participant and the date the consent is documented. The impartial witness will also be requested to sign and date the consent form.

xv. The PI/Co-I/medically qualified person delegated by the PI will also sign and date the consent form at the end of the process.

xvi. The recording will be stopped after thanking the participant.

- The recording should be checked for completeness and clarity of both audio and video recording.
- No editing should be done on the recording so as to maintain authenticity.
- The computer/laptop should be password protected. The password will be known only to the PI and members of the study team as designated by the PI. A register should be maintained wherein, each time the data is accessed, the details of who accessed thedata, date and reasons for the same this should be entered into the designated register.
- The recording should be then transferred to a CD labeled according to study name, unique identifier assigned to the participant, date and time of the recording, no. of recordings (applicable during re-consenting) and archived in the external Hard drive. The CD should be filed in the participant binder.
- The study participants should be informed that there is possibility of failure of investigational product to provide intended therapeutic effect.
- In case of placebo-controlled trial, the placebo administered to the subjects shall not have any therapeutic effect.

7. Archival

a. The soft copies of the recordings should be stored in a password protected external hard drive for minimum of five years.

b. The original recording in the computer/laptop will be deleted when study is closedout.

8. Annexure

Annexure 1	*AX 01/SOP 25/* V1	Checklist for Monitoring of Audiovisual recording of AV consent Process
Annexure 2	*AX 03/SOP 25/* V1	Guidance document for audio visual recording of AV consent Process

Annexure 1
***AX 02/SOP 25/* V1**
Checklist for Monitoring of Audiovisual recording of AV consent Process

1. Facility where informed consent process should be carried out - (well lit, free from noise, privacy ensured, dedicated room, camera permanently set /temporary arrangement, voice recording to betested before hand):
   a. Yes_____No_____
   b. Remarks: _____

2. Whether consent for AV recording already taken before start of recording/ it is taken in front of thecamera Yes_____No _____

3. Whether elements enlisted in Appendix V of NDCTR is covered during discussion.

a. Yes_____No_____
b. Remarks: _____

4. Introduction of each person – name , age (person conducting the informed consent discussion participant/ legally acceptable representative (LAR) wherever relevant / impartial witness wherever relevant) involved during informed consent process and information about necessity for audiovisual recording - by name, designation and his/ her role in the research, current date and time, enquiry of the language participant understands , showing the consent form in the camera which is going to beused for the study
   a. Yes_____No_____
   b. Remarks: _____

5. The following minimum elements should feature in the recording of the informed consent process: (Purpose , treatment allotment ,randomization , procedure , follow up , benefit/risks, compensation for Participation, Compensation for Study related Injury, nominee name and details , voluntariness and right to withdraw and contact for further information – Investigator name and EC Chair/member secretary name)
   a. Yes_____No_____
   b. Remarks:_____

6. If Inclusion Criteria has been administered by a designated person who is not medically qualified?
   a. Yes_____No_____
   b. Remarks: _____

7. Is there evidence that subject's queries of a medical nature were answered in the process orassurance was given to clarify the same later?
   a. Yes_____No_____
   b. Remarks: _____

8. The consent is taken in language the participant/ legally acceptable representative (LAR) understands best and is literate in.
   a. Yes_____No_____
   b. Remarks: _____
9. Information to the participant/ LAR and impartial witness (as applicable) that the process of taking the consent is being recorded for the purpose of documentation as required by the government rules.
   a. Yes_____No_____
   b. Remarks: _____

10. Information to the participant/ LAR and impartial witness (as applicable) that the confidentiality ofinformation and privacy of participants is assured.
    a. Yes_____No_____
    b. Remarks: _____

11. Information to the participant/ LAR and impartial witness (as applicable) that the recording may beshown to government agencies or members from the IEC.
    a. Yes_____No_____
    b. Remarks: _____

12. Explanation or narration by the person conducting the informed consent discussion.
    a. Yes_____No_____
    b. Remarks: _____

13. Whether audio-visual recording is performed for all subjects, independently.
    a. Yes_____No_____
    b. Remarks: _____
14. Questions regarding participation asked by the potential participant/LAR are answered satisfactorily.
    a. Yes_____No_____
    b. Remarks: _____
15. Ample time was given to read and understand the consent as per the content?
    a. Yes_____No_____
    b. Remarks: _____
16. Opportunity to discuss the same with family members
    a. Yes_____No_____
    b. Remarks: _____
17. Reading out by the participant/LAR (or having read out by impartial witness) the statements mentioned in Informed Consent
    a. Yes_____No_____
    b. Remarks: _____
18. Stating whether participant agrees or not for each statement.
    a. Yes_____No_____
    b. Remarks: _____
19. Whether checked for participants understanding of the informed consent process
    a. Yes_____No_____
    Remarks: _____
20. Documentation of signatures of all those involved in the Informed Consent Process.
    a. Yes_____No_____
    b. Remarks: _____
21. Clarity and completeness of AV recording (pages vis-a- vis timing)
    a. Yes_____No_____
    b. Remarks: _____
22. Check whether re-consenting is done for changes in ICF/LAR inclusion in the beginning if any.
    a. Yes_____No_____
    b. Remarks: _____
23. Check whether re-consenting is done by the same Investigator
    a. Yes_____No_____
    b. Remarks: _____
24. Whether re-consenting is done in same language
    a. Yes_____No_
    b. Remarks: _____
25. How much timing taken for the re-consent
    a. Yes_____No_____
    b. Remarks: _____

26. Storage of recording in password protected laptop/ desktop computer and/ or hard drive and labelled CD
    a. Yes_____No_____ Remarks: _____

27. Access of AV consent recorded allowed only to the principal investigator and designated membersof the study team.
    a. Yes_____No_____ Remarks: _____

Signature and date of PI /Co-inv _____

Annexure 2
AX 03/SOP 25/V1

Guidance document for audiovisual recording of AV consent Process

Pre-recording checklist:

1. Equipment is functioning correctly - YES /NO
2. All parties (trial team personnel conducting the consent, the patient and as applicable legally acceptable representative (LAR), impartial witness and/or translator are seated comfortably and are seen within the frame of the video recording. YES /NO
3. All parties are reminded that this AV recording is in compliance with regulatory requirements YES /NO
4. All parties are informed that this AV recording will be kept confidential but can be shown to others as per legal requirements or for ensuring compliance with law. YES /NO

AV recording:

1. Reconfirm that the video recording frame includes all concerned parties. YES /NO
2. The member of the research team should state the date, time, title of the research protocol and the language of the written informed consent document. YES /NO
3. All concerned parties should identify themselves by stating their names, designation and role with respect to the consent process for this research. YES /NO
4. If LAR is involved, he/she should state relation to participant. YES /NO
5. If translator is involved, he/she should confirm that he/she is proficient in the language of the informed consent document as well as the language in which the medically qualified authorized member of the research team is proficient in for the consent process. YES /NO
6. At any point during the recording, any participant may request for a break (*e.g.* to go to the bathroom or answer a phone or if mother want to feed her baby). In such a case, the AV recording shall be stopped mentioning the time of stopping. It will be resumed/ restarted by stating the date and time of restarting the recording. YES /NO
7. The medically qualified authorized member of the research team administering the consent shall use the checklist to ask the potential participant/ LAR questions to document the authenticity of the informed consent process. Translation will be done as applicable. The answers of the participant/ LAR shall be recorded for each point. YES /NO
8. The actual signing process by all concerned parties should also be recorded. YES /NO

Post recording checklist:

1. The memory card/ storage device used in the camera for video recording will be the source document. Check the file for clarity regarding the audio and video recording. YES /NO
2. The memory card/ storage device used in the camera for video recording will be the source document. Check the file for clarity regarding the audio and video recording. YES /NO
3. Rename the file with the unique number for the patient on this research protocol. YES /NO
4. Make backup one by copying that file onto the dedicated external Hard Disk which will be used to

document all consent AV recording for a specific research protocol. YES /NO
5. This external HDD should be suitably labeled and password protected. YES /NO
6. Store the external HDD in a secure location to ensure confidentiality. YES /NO
7. Make backup two by copying that file onto a remote cloud storage with encryption using the computer with internet access. YES /NO
8. This should also be suitably located, labeled and password protected. YES /NO

Attachment - 2

Template of appointment letter of IEC member

Date:xxxxxx

To,

XXXXX.

(Non affiliated)

Sub: Appointment and tenure of responsibilities and membership as **'Chairperson of IEC-I'**.

Dear XXXXXX,

You have been appointed on the Institutional Ethics Committee–I (IEC-I) as a **chairperson** for the period of three years from xxxxxx to xxxxx.

You will have to carry out the following activities as Chairperson:

1. To conduct IEC-I meetings and lead all discussions and deliberations pertinent to the review of research proposals.
2. To preside over all administrative and financial matters pertinent to the committee's functions.
3. To ratify minutes of the previous meetings.
4. To identify & select one or more IEC member or independent monitor who along with IEC member for conducting the site monitoring.
5. To represent the IEC-I at various meetings and forums.
6. To sign documents and communications related to IEC-I functioning.
7. To delegate his responsibilities to appropriate individuals in accordance with IEC SOPs.
8. To nominate a committee member as Acting Chairperson, in case of anticipated absence.
9. To maintain confidentiality of the documents and deliberations of IEC-I meetings.
10. To declare any conflict of interest.
11. To sign the Confidentiality/ Conflict of Interest Agreements regarding meeting, deliberations, applications, information on research participation, and related matters.

You are expected to comply with the Standard Operating Procedures (SOPs) of the IEC of Seth GS Medical College and KEM Hospital, Mumbai.

XXXXXXXXXXX,
Dean, Seth GSMC & KEMH.

Xxx

To,
XXXXX.
(Affiliated)

Sub: Appointment letter and tenure of responsibilities and membership as **'Member Secretary of IEC-I'.**

Dear xxxxxxx,

You have been appointed on the Institutional Ethics Committee–I (IEC-I) as a Member Secretary for the period of three years from xxxx to xxxxx.

You will have to carry out the following activities as Member Secretary:

1. To receive research proposals.
2. To organize an effective and efficient tracking procedure for each proposal received.
3. To prepare, maintain and distribute of study files.
4. To schedule and organize IEC-I meetings.
5. To prepare and maintain meeting agenda and minutes.
6. To maintain IEC-I documentations and to archive them.
7. To communicate with the IEC-I members and applicants/ investigators.
8. To notify the Principal Investigator regarding IEC-I decisions related to the submitted research proposal.
9. To prepare for and respond to audits and inspections
10. To ensure completeness of documentation at the time of receipt and timely inclusion in agenda for EC review.
11. To assess the need for expedited review/ exemption from review or full review.
12. To assess the need to obtain prior scientific review, invite independent consultant, patient or community representatives.
13. To ensure quorum during the meeting and record discussions and decisions.
14. To perform the task of site monitoring.
15. To arrange for training of personnel and IEC-I members.
16. To organize the preparations, review, revision and distribution of SOPs and guidelines.
17. To provide necessary administrative support for IEC-I related activities to the Chairperson.
18. To provide updates on relevant and contemporary issues to ethics in health research as well as relevant contemporary literature to the committee members.
19. To receive fees and issue official receipts for the same.
20. To delegate various responsibilities to appropriate and authorized individuals.
21. To ensure adherence of IEC-I functioning as per SOPs.
22. To maintain confidentiality of the documents and deliberations of IEC-I meetings.
23. To declare any conflict of interest.
24. To sign the Confidentiality/ Conflict of Interest Agreements regarding meeting, deliberations, applications, information on research participation, and related matters.

You are expected to comply with the Standard Operating Procedures (SOPs) of the IEC of Seth GS Medical College and KEM Hospital, Mumbai.

XXXXXXXX
Dean, Seth GSMC & KEMH.

xxxx

To,

XXXXX.
(Affiliated)

Sub: Appointment letter and tenure of responsibilities and membership as '**Member (Joint Member Secretary) of IEC-I**'.

Dear xxxx,

You have been appointed on the Institutional Ethics Committee–I (IEC-I) as a Member (**Joint Member Secretary**) for the period of three years from xxxx to xxxx.

You will have to carry out the following activities as a Member (Basic Medical Scientist):

1. To attend IEC-I meetings and participate in discussions and deliberations so that appropriate decisions can be arrived at.
2. To review, discuss and consider research Proposals submitted for evaluation.
3. To monitor Serious Adverse Event reports and recommend appropriate action(s).
4. To review the progress reports and monitor ongoing studies as appropriate.
5. To evaluate final reports and outcomes.
6. To maintain confidentiality of the documents and deliberations of IEC-I meetings.
7. To declare any conflict of interest.
8. To sign the Confidentiality/Conflict of Interest Agreements regarding meeting, deliberations, applications, information on research participation, and related matters.
9. To participate in continuing education activities in biomedical ethics and biomedical research.
10. To provide information and documents related to training obtained in biomedical ethics and biomedical research to the IEC-I secretariat.
11. To provide an updated CV when requested for by the IEC-I secretariat.
12. To carry out the work delegated by Chairperson and Member-secretary.
13. To assist Chairperson and Member-secretary in carrying out IEC-I work as per SOPs.
14. To perform the task of site monitoring.
15. To Scientific and ethical review with special emphasis on the intervention, benefit-risk analysis, research design, methodology and statistics, continuing review process, SAEs, protocol deviation, progress and completion report
16. For clinical trials to review the drug safety and pharmacodynamics.
17. To perform the same functions of member secretary in her absence.

You are expected to comply with the Standard Operating Procedures (SOPs) of the IEC of Seth GS Medical College and KEM Hospital, Mumbai.

xxxxxxx
Dean, Seth GSMC & KEMH.

xxxx
To,
Xxxxxxxxxxxxxxx
Affiliated / Non affiliated

Sub: Appointment letter and tenure of responsibilities and membership as '**Member (Clinician) of IEC-I**'.

Dear xxxxx,

You have been appointed on the Institutional Ethics Committee–I (IEC-I) as a Member for the period of three years from xxxx to xxxxx.

You will have to carry out the following activities as a Member.

1. To attend IEC-I meetings and participate in discussions and deliberations so that appropriate decisions can be arrived at.
2. To review, discuss and consider research Proposals submitted for evaluation.

3. To monitor Serious Adverse Event reports and recommend appropriate action(s).
4. To review the progress reports and monitor ongoing studies as appropriate.
5. To evaluate final reports and outcomes.
6. To Review medical care, facility and appropriateness of the principal investigator, provision for Medical care, management and compensation.
7. Thorough review of protocol, investigators brochure (if applicable) and all other protocol details and submitted documents.
8. To perform the task of site monitoring.
9. To maintain confidentiality of the documents and deliberations of IEC-I meetings.
10. To declare any conflict of interest.
11. To sign the Confidentiality/Conflict of Interest Agreements regarding meeting, deliberations, applications, information on research participation, and related matters.
12. To participate in continuing education activities in biomedical ethics and biomedical research.
13. To provide information and documents related to training obtained in biomedical ethics and biomedical research to the IEC-I secretariat.
14. To provide an updated CV when requested for by the IEC-I secretariat.
15. To carry out the work delegated by Chairperson and Member-secretary.
16. To assist Chairperson and Member-secretary in carrying out IEC-I work as per SOPs.

You are expected to comply with the Standard Operating Procedures (SOPs) of the IEC of Seth GS Medical College and KEM Hospital, Mumbai.

XXXXXX,
Dean, Seth GSMC & KEMH.

xxxxxxx
To,
xxxxxxxxxxx
Psychologist.

Sub: Appointment letter and tenure of responsibilities and membership as **'Member (Social scientist) of IEC-I'.**

Dear xxxxx,

You have been appointed on the Institutional Ethics Committee–I (IEC-I) as a Member **(Social scientist)** for the period of three years from xxxxx to xxx.

You will have to carry out the following activities as a Member.

1. To attend IEC-I meetings and participate in discussions and deliberations so that appropriate decisions can be arrived at.
2. To review, discuss and consider research Proposals submitted for evaluation.
3. Ethical review of the proposal, ICD along with the translations, to assess impact on community involvement, socio–cultural context, religious or philosophical context, if any. To serve as a patient/participant/ societal / community representative and bring in ethical and societal concerns.
4. To monitor Serious Adverse Event reports and recommend appropriate action(s).
5. To review the progress reports and monitor ongoing studies as appropriate.
6. To evaluate final reports and outcomes.
7. To Review medical care, facility and appropriateness of the principal investigator, provision for Medical care, management and compensation.
8. Thorough review of protocol, investigators brochure (if applicable) and all other protocol details and submitted documents.
9. To perform the task of site monitoring.
10. To maintain confidentiality of the documents and deliberations of IEC-I meetings.
11. To declare any conflict of interest.

12. To sign the Confidentiality/Conflict of Interest Agreements regarding meeting, deliberations, applications, information on research participation, and related matters.
13. To participate in continuing education activities in biomedical ethics and biomedical research.
14. To provide information and documents related to training obtained in biomedical ethics and biomedical research to the IEC-I secretariat.
15. To provide an updated CV when requested for by the IEC-I secretariat.
16. To carry out the work delegated by Chairperson and Member-secretary.
17. To assist Chairperson and Member-secretary in carrying out IEC-I work as per SOPs.

You are expected to comply with the Standard Operating Procedures (SOPs) of the IEC of Seth GS Medical College and KEM Hospital, Mumbai.

Dr. Sangeeta Ravat,
Dean, Seth GSMC & KEMH.

xxx
To,
xxxxx.

Sub: Appointment letter and tenure of responsibilities and membership as **'Member (Legal Expert)'.**

Dear xxxxx,

You have been appointed on the Institutional Ethics Committee–I (IEC-I) as a Member (**Legal Expert**) for the period of three years from xxxx to xxxxx.
You will have to carry out the following activities as a Member.

1. To attend IEC-I meetings and participate in discussions and deliberations so that appropriate decisions can be arrived at.
2. To review, discuss and consider research Proposals submitted for evaluation.
3. Ethical review of the proposal, ICD along with translations, MoU, Clinical Trial Agreement (CTA), regulatory approval, insurance document, other site approvals, researcher's undertaking, protocol specific other permissions, such as, stem cell committee for stem cell research, HMSC for international collaboration, compliance with guidelines etc.
4. Interpret and inform EC members about new regulations if any.
5. To monitor Serious Adverse Event reports and recommend appropriate action(s).
6. To review the progress reports and monitor ongoing studies as appropriate.
7. To evaluate final reports and outcomes.
8. To Review medical care, facility and appropriateness of the principal investigator, provision for Medical care, management and compensation.
9. Thorough review of protocol, investigators brochure (if applicable) and all other protocol details and submitted documents.
10. To perform the task of site monitoring.
11. To maintain confidentiality of the documents and deliberations of IEC-I meetings.
12. To declare any conflict of interest.
13. To sign the Confidentiality/Conflict of Interest Agreements regarding meeting, deliberations, applications, information on research participation, and related matters.
14. To participate in continuing education activities in biomedical ethics and biomedical research.
15. To provide information and documents related to training obtained in biomedical ethics and biomedical research to the IEC-I secretariat.
16. To provide an updated CV when requested for by the IEC-I secretariat.
17. To carry out the work delegated by Chairperson and Member-secretary.
18. To assist Chairperson and Member-secretary in carrying out IEC-I work as per SOPs.

You are expected to comply with the Standard Operating Procedures (SOPs) of the IEC of Seth GS Medical College and KEM Hospital, Mumbai.

xxxxxxxxxxx
Dean, Seth GSMC & KEMH.

xxxxx
To,
Xxxx
Non affiliated

Sub: Appointment letter and tenure of responsibilities and membership as '**Member (Lay Person)**'.
Dear xxxxx,

You have been appointed on the Institutional Ethics Committee–I (IEC-I) as a Member (**Lay Person**) for the period of three years from xxx to xxx.

You will have to carry out the following activities as a Member.

1. To attend IEC-I meetings and participate in discussions and deliberations so that appropriate decisions can be arrived at.
2. To review, discuss and consider research Proposals submitted for evaluation.
3. Ethical review of the proposal, ICD along with the translations, to assess impact on community involvement, socio–cultural context, religious or philosophical context, if any. To serve as a patient/participant/ societal / community representative and bring in ethical and societal concerns.
4. To monitor Serious Adverse Event reports and recommend appropriate action(s).
5. To review the progress reports and monitor ongoing studies as appropriate.
6. To evaluate final reports and outcomes.
7. To Review medical care, facility and appropriateness of the principal investigator, provision for Medical care, management and compensation.
8. Thorough review of protocol, investigators brochure (if applicable) and all other protocol details and submitted documents.
9. To perform the task of site monitoring.
10. To maintain confidentiality of the documents and deliberations of IEC-I meetings.
11. To declare any conflict of interest.
12. To sign the Confidentiality/Conflict of Interest Agreements regarding meeting, deliberations, applications, information on research participation, and related matters.
13. To participate in continuing education activities in biomedical ethics and biomedical research.
14. To provide information and documents related to training obtained in biomedical ethics and biomedical research to the IEC-I secretariat.
15. To provide an updated CV when requested for by the IEC-I secretariat.
16. To carry out the work delegated by Chairperson and Member-secretary.
17. To assist Chairperson and Member-secretary in carrying out IEC-I work as per SOPs.

You are expected to comply with the Standard Operating Procedures (SOPs) of the IEC of Seth GS Medical College and KEM Hospital, Mumbai.

XXXXXXXXXXXX
Dean, Seth GSMC & KEMH.

Template for Acceptance letter of IEC member

Date: xxxxxxxxxxxx

To,

xxxxxxxx,

Dean / Head of the institute,

Seth GSMC & KEMH,

Pare, Mumbai.

Ref: Appointment letter XXXXXXXX.
Sub: Consent to be a member of Institutional Ethics Committee-I.

Sir / Madam,

In response to your letter stated above, I give my consent to become a Member of IEC for the tenure xxxxx to xxxxx. I shall regularly participate in the IEC meetings to review and give my unbiased opinion regarding the ethical issues. I shall not keep any literature or study related documents with me after the discussion and final review. I shall maintain all the research project related information confidential and shall not reveal the same to anybody other than project related personnel.
Thanking you,
Yours Sincerely,

XXXXXX,

Prepared by **Signature with date**	Reviewed by **Signature with date**	Approved by **Signature with date**	Accepted by **Signature with date**
8/5/23 **Dr. Raakhi Tripathi** **Member Secretary,** **IEC-I**	9. May. 23 **Dr. Nithya Gogtay** **Joint-Member Secretary,** **IEC-I**	10/5/2023 **Dr. Manju Sengar** **Chairperson,** **IEC-I**	Institutional Ethics Committee (IEC-I) Established In 1985 Seth G.S. Medical College & K.E.M. Hospital Parel, Mumbai-400 012. **Institutional Ethics Committee-I, Seth GSMC & KEMH, Mumbai.**