



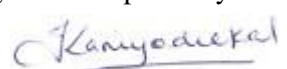




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Document name:	Initial Full Board Review of New Research Study Protocols
Document Number:	IHEC/SOP-08A/V1
Number of Pages:	10
Issue No:	01
Issue Date:	20/08/2025
Revision Date	20/08/2026
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**Initial Full Board Review of New Research
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AMENDMENT SHEET

Sl. No	Sec no. & page No.	Details of amendment	Signature



1. Purpose

The purpose of this Standard Operating Procedure (SOP) is to describe how the Institutional Human Ethics Committee (IHEC) members will perform an initial review on a new research study protocol using the Assessment Form.

2. Scope

This SOP applies to the initial review and assessment of all research study protocols submitted for review and approval from the IHEC. All research studies presented with more than minimal risk and which do not qualify for exemption (See IHEC/SOP-8C/V1) or expedited review (See IHEC/SOP-8B/V1), are covered in this SOP.

3. Responsibility

The Member Secretary is responsible, after categorization of the studies (as per IHEC/SOP-08/V1), to forward the studies to the Secretariat.

The IHEC Secretariat is responsible for creation of a study specific file, distribution of the packages along with study assessment forms to the IHEC members for review (If the study is categorized for Full Board review), and communicate the review results to the investigators.

IHEC members (including Member Secretary) will be responsible for reviewing the research protocols and related documents within the given time frames.

It is the responsibility of all the IHEC members to fill the Assessment form along with comments and recommendation they have after reviewing each study protocol.

The IHEC members are responsible for attending and participating actively in the discussion at the full Board Meeting

The Member Secretary is responsible for setting up the Full Board Meeting (IHEC/SOP-08A/V1)

The IHEC Secretariat is responsible for recording and filing the decision, relevant points and deliberation about a specific protocol, including the reasons for that decision.

The Chairperson is responsible to sign and date the decision in the IHEC Decision Form ANX-03/IHEC/SOP-8A/V1.

4. Detailed instructions

4.1 Appointment of reviewers

The Member Secretary/Chairperson will appoint one primary reviewer or one secondary reviewer for each study on the basis of expertise in the related field and experience. They should include one clinician and one non-technical person as applicable. More than two may be appointed if necessary.



4.2 Distribute the protocol package

The Secretariat will send a packet (*hard*) to the IHEC members.

- Letter to IHEC Members requesting Initial Review and specifying their role
- Study Submission Application Form *ANX-01/IHEC/SOP-07/V1*
- Protocol and related documents
- Study assessment form *ANX-02/IHEC/SOP-8A/V1* to the Primary reviewer and secondary reviewer. The same form will be given to all members for facilitating the review process.

4.3 Receive the distributed protocol package

- The IHEC members will receive the protocol package with the Study Application Form *ANX-01/IHEC/SOP-07/V1* as hard copy.
- Designated reviewers will also receive the Study Assessment Forms *ANX-02/IHEC/SOP-8A/V1*

4.4 Review by the IHEC members

Review of the protocol

- The protocol will be reviewed by each member as per guidelines
 - Scientific design and conduct of the study
 - Risks and potential benefits
 - a) Selection of study population and recruitment of research participants
 - Inducements, financial benefits and financial costs
 - 6. Protection of research participants' privacy and confidentiality
 - Community considerations
 - Qualifications of Investigators and assess adequacy of study sites
 - Disclosure or declaration of potential conflicts of interest
 - Recruitment strategy (Direct recruitment of potential study participants/ in-hospital Advertisements, flyers, information sheets, and notices/referrals from non-investigator health care providers).

The IHEC member will consider the following criteria when performing the review of the Informed Consent Document Annexure (*ANX-08/SO- 8A /V1*- checklist for reviewing Informed Consent may be used).



- Voluntary, non-coercive recruitment, participation/ withdrawal
- Procedures for obtaining informed consent
- Contents of the patient information sheet - title, objective, study design and procedures
- Contents and language of the informed consent document
- Translation of the informed consent document in the local languages
- Language used – plain and easy to understand by general public
- Contact persons with address and phone numbers for questions about research participants rights and study or injury
- Privacy and confidentiality
- Risks and discomforts – physical / mental / social
- Alternative treatments
- Benefits – to participants, community, institution and society
- Compensation for participation: (Whether it will act as undue inducement)
- Involvement of vulnerable participants
- Provisions for medical/ psychosocial support
- Treatment for study related injuries
- Compensation for study-related injuries: as per applicable local regulations
- Use of biological materials
- Check for provision for signatures with dates of participant, person conducting informed consent discussion, investigator and witness
- Provision for audiovisual recording of consent process in case of regulatory drug trials
- Provision for unique code number for the patients

4.5 Use of study assessment form for reviewers

- The assessment form is designed to standardize the review process.
- All reviewers will be sent a letter (ANX-01/IHEC/SOP-8A/V1) requesting initial review with study assessment form and write their comments related to review of the research proposal.
- The duly filled, signed and dated assessment forms will be returned on the day of the programme
- *The risk and benefit of the proposed study will be evaluated by using ANX-09/IHEC/SOP-8A/V1*

4.6 Gather the assessment reports

The IHEC Secretariat will collect the Assessment Forms, comments from each reviewer and file in the original study file. If the comments come as a soft copy these will be collated for discussion at the meeting.



4.7. Review by the Legal Representative

The Legal Representative will review ICD along with translations, draft Memorandum of Understanding (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, Health Ministry's Screening Committee (HMSC) for international collaboration, compliance with guidelines etc. The Legal Representative will consider the following items when reviewing the Clinical Trial Agreement.

- Statement of work
- Obligations and Responsibilities of the Principal Investigator
- Obligation and Responsibilities of the Institute
- Obligation and Responsibilities of the Sponsor
- Financial compensation for trial related injury such as injury or death as per the notification of the Drug Controller General of India (DCGI) & Government of India
- Undertaking and Representation of Principal Investigator
- Undertaking and Representation of Institute
- Undertaking and Representation of Sponsor
- Administration
- Trial Drug; Materials Transfer; Records Retention; Inspection
- Representation and Warranties
- Confidentiality
- Return of Confidential Information
- Trial Results and Inventions
- Payment
- Screen Failures/ Drop-outs
- Set-Up Fees
- Hospitalization costs
- Institutional Ethics Committee Fees
- Payments by Sponsor to Institute



- Tax deduction
- Use of other parties' names
- No joint venture etc
- Insurance and Indemnification
- monitoring; audit; regulatory inspections
- Term; Waiver; Severability (The trial on its time extended)
- Effect of termination
- Recordkeeping
- Publication
- Miscellaneous
- Governing Law
- Jurisdiction
- Arbitration
- Amendment

The legal expert has to record his opinion on the CTA or other agreements or MOUs reviewed by him and it will be documented in the concerned study file. CTA or MOU or other agreements can only be signed after Ethics Committee's approval of the study and study documents including CTA or MOU or other agreements.

4.8. IHEC meeting

- During the discussion at the meeting, the primary reviewer shall brief the members about summary of the study protocol and read out the comments and evaluation provided on the assessment form.
- The comments of an independent consultant (if applicable) will be discussed by the member secretary.
- The other IHEC members shall give their comments right after the presentation.
- The investigator/sub-investigator may be called in to provide clarifications on the study protocol that he/she has submitted for review to the IHEC.
- The IHEC members will discuss and clarify the comments and suggestions.
- The Member secretary (assisted by the Secretarial staff) shall record the discussions
 - The final decision on the study will be recorded as: "Approved/
Disapproved/ Suggested recommendations or any other (as per IHEC



policy” in the meeting shall be made by voting or by majority consensus (as per the IHEC policy) and will be recorded in the IHEC Decision Form

ANX-03/IHEC/SOP-8A/V1 by the Member Secretary.

- A majority vote for approval, disapproval or request for modifications of a study suspension or termination of an ongoing study is defined as 2/3rd of the voting members present at the meeting.
- The following will not be eligible to vote
 - Member(s) of the committee who is/are listed as investigator(s) on a research proposal
 - An investigator or study team member invited for the meeting.
 - An independent consultant invited for the meeting to provide opinion
 - Specific patient groups invited for the meeting will not vote or participate in the decision making procedures of the committee.

The Committee will decide whether the query responses and (if applicable) revised protocol will go only to Member Secretary, to primary reviewers or to Full Board before final approval.

- The response and changes carried out may be considered for discussion at a future IHEC meeting.
- If the IHEC decision is ‘Disapproved’ or any other, the decision should be made on the basis of specific reasons, which are communicated by the IHEC to the principal investigator in the letter of notification.
- The Secretariat will obtain the signature of the Chairperson of the IHEC on the IHEC Decision Form *ANX-03/IHEC/SOP-8A/V1*.
- If the study is approved, the Committee will recommend monitoring for a study if it is so determined at the meeting depending on factors like risk is high in the protocol, the PI has a history of repeated protocol violations; PI has many protocols and any other reason so deemed.
- The Secretariat will list participating members in the meeting and summarize the guidance, advice and decision reached by the IHEC members.
- With the study protocol, the Assessment Form from all members and IHEC Decision Form will be filed in the study file by the Administrative Officer.
- The Administrative Officer will return the file and the protocol to the appropriate shelves.

4.9 Final communication of the IHEC decision taken on the study to the Principal Investigator



- The Secretariat will prepare an approval letter as *ANX-04/IHEC/SOP-8A/V1* to be sent to the Principal Investigator when the study is approved at an IHEC meeting.
- The letter contains, at a minimum:
 - Study reference number
 - Study title
 - A listing of each document approved, the date set by the Committee for frequency of continuing review, and a review of other obligations and expectations from the investigator throughout the course of the study.
 - The approval is provided for the entire duration of the study or for a certain duration
 - List of IHEC members present at the meeting when the study was approved.
 - The Chairperson / Member Secretary will sign the approval letter and the Secretariat will send it to the Principal Investigator within 14 days.
- If the Committee disapproves a study, the Secretariat immediately notifies the investigator in writing about the decision and the reason/s for not approving the study within 7 working days.
- A notifying letter to the investigator should state the following:

“If you wish to appeal to this decision, please contact the IHEC and submit your appeal in writing within twelve (4) weeks of the receipt of the committee’s decision, addressed to the IHEC Chairperson with justification as to why the appeal should be granted. In absence of appeal, the study will be declared closed for the IHEC office records.”
- If the Committee requires modifications to any of the documents, the Secretariat will send a written request for carrying out specific changes to the investigator asking him or her to make the necessary changes and resubmit the documents to the IHEC. The Principal Investigator will be asked to respond to the letter of comments/queries within 10 days of the receipt of the letter by the investigator. In the absence of any response, the study will be declared closed for the IHEC office records.
- The Secretariat will verify the correctness of the wordings and spelling in all the letters and process all the above tasks within 14 days after the meeting.
- All letters should have MSMP emblem and address
- Date of the first patient recruitment should be notified to the Ethics committee.



4.10 Storage of Documents

- The Secretariat will keep a copy of the Approval letter/Query letter/Disapproval letter in the study file along with all the reviewed documents.
- The Administrative Officer will store the file on an appropriate shelf in the designated cabinet.

5. References to Other Applicable SOPs

IHEC/SOP-7/V1: Management of Research Study Protocol and Study Related Documents Submitted for Ethics Review

IHEC/SOP-08/V1: Categorization of Submitted Protocols for Ethics Review

IHEC/SOP-08B/V1: Expedited Review of Research Study Protocols

IHEC/SOP-08C/V1: Exemption from Ethics Review of Research Study Protocols

IHEC/SOP-09/V1: Agenda Preparation, Meeting Procedures and Recording of Minutes

IHEC/SOP-10/V1: Review of Amended Protocol, Protocol-related Documents and Resubmitted protocol

6. Annexures

Annexure 1 *ANX-01/SOP 8A/V1* - Letter to the IHEC Members requesting initial review with study assessment form

Annexure 2 *ANX-02/SOP-8A/V1* - Study assessment form for primary reviewer

Annexure 3 *ANX-03/SOP-8A/V1*- IHEC decision form

Annexure 4 *ANX-04/SOP-8A/V1* - Format of Interventional research study approval letter

Annexure 5 *ANX-05/SOP-8A/V1* - Format of observational research study approval letter

Annexure 6 *ANX-06/SOP-8A /V1*- Guidelines for reviewing a study protocol

Annexure 7 *ANX-07/SOP- 8A /V1*- checklist for reviewing a CTA

Annexure 8 *ANX-07/SOP- 8A /V1*- checklist for reviewing a Informed consent