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अनुसंधान नीति विषयक बोर्ड

RESEARCH ETHICS BOARD RIMS

REGIONAL INSTITUTE OF MEDICAL SCIENCES

Lamphelpat, Imphal, Manipur - 795004

(Reg. No. ECR/1105/INST/MN/2018 as per the provisions of Rule 122DD of the Drugs and Cosmetics Rules, 1945)

REG. NO. EC/NEW/INST/2025/MA/0679 as per the NECRBHR, DHR

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CIRCULAR ADMINISTRATIVE SOP ADDENDUM 27th October, 2026

Ref. No.: A/206/REB/RIMS/C/2026: Amendment of Annexure I, Section IV of REB SOP Manual (Version 4.0): Participant Information and Informed Consent Documents (**Reference:** CDSCO Query No. 3.5; Application File No. EC/RENEW/INST/2026/21227; CDSCO File No. EC/26/000292)

Pursuant to the administrative requirements for institutional re-registration with the Central Drugs Standard Control Organization (CDSCO), and following a comprehensive review of the participant information and informed consent formats under the applicable REB SOP amendment procedures, the following administrative addendum to Annexure I, Section IV of the REB SOP Manual (Version 4.0) is hereby adopted with immediate effect:

1. Replacement of Legacy Templates:

- The existing participant information and informed consent templates contained within Annexure I, Section IV of the active REB RIMS Standard Operating Procedures (SOP Version 4.0) manual are hereby superseded and replaced in their entirety by the updated annexure enclosed herewith (*Revised Annexure I, Section IV (Parts A-C)*). Earlier versions shall be archived as superseded controlled records and shall not be deployed for new protocol submissions after the effective date.

2. Scope and Application:

- Standard Framework.** The revised annexure provides a standardized operational framework for all biomedical and health research reviewed by the REB, including postgraduate thesis research.
- Protocol Adaptation:** Principal Investigators shall adapt the Master Participant Information Sheet (PIS) and Informed Consent Form (ICF) to align with their specific approved protocol, study population, language preferences, and risk profile.
- CDSCO-Regulated Trials:** Mandatory provisions prescribed under Table 3 of the Third Schedule of the New Drugs and Clinical Trials Rules (NDCTR), 2019—including non-conditional sponsor liabilities for free medical management, financial compensation, and nominee registration—shall apply strictly to CDSCO-regulated clinical trials. Non-applicable trial-specific clauses shall not be imposed automatically on non-interventional or observational academic research.

3. Operational Responsibilities:

- Investigators:** Must submit protocol-specific PIS/ICF versions with exact version numbers and dates, certified local language translations where applicable, and separate parental/LAR permission and child assent forms when enrolling special populations.
- REB Reviewers:** Shall systematically verify applicable consent elements using Part A of the revised annexure, document any non-applicability, and ensure full compliance prior to issuing formal protocol approval.
- REB Secretariat:** Shall circulate the approved addendum, update the controlled master SOP manual, and maintain version control records and evidence of authorization.
- Safeguards & Waivers:** Provisions regarding consent waiver, alteration, re-consent, impartial witness attestation, and vulnerable population safeguards shall adhere strictly to active REB SOPs, ICMR Ethical Guidelines, and statutory regulatory requirements.

Issued under the collective authority of the Research Ethics Board, RIMS, Imphal.



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REVISED ANNEXURE I, SECTION IV

PART A: CHECKLIST FOR PARTICIPANT INFORMATION SHEET (PIS) AND INFORMED CONSENT FORM (ICF)

Instructions: For CDSCO-regulated clinical trials, check the applicable provisions of Table 3, Third Schedule, NDCTR 2019 and the prescribed consent format. For other research, apply the ICMR ethical guidelines and relevant law. Record "N/A" only with a reason; this checklist is a review aid, not a substitute for the Rules.

No.	Consent Element	Location	Check / Remarks
1	Research nature, purpose and expected duration	B1	☐ Yes ☐ No ☐ N/A
2	Procedures, experimental interventions and randomisation/allocation, if applicable	B2	☐ Yes ☐ No ☐ N/A
3	Participant responsibilities	B3	☐ Yes ☐ No ☐ N/A
4	Foreseeable risks/discomforts, including pregnancy-related risks where relevant	B4	☐ Yes ☐ No ☐ N/A
5	Reasonably expected benefits or absence of direct benefit	B5	☐ Yes ☐ No ☐ N/A
6	Appropriate alternative procedures or treatments	B6	☐ Yes ☐ No ☐ N/A
7	Confidentiality and authorised access to original records	B7	☐ Yes ☐ No ☐ N/A
8	Free medical management and financial compensation for trial-related injury/death, as applicable	B8	☐ Yes ☐ No ☐ N/A
9	Payments/reimbursement and additional costs	B9	☐ Yes ☐ No ☐ N/A
10	Voluntary participation and withdrawal without loss of entitled care	B10	☐ Yes ☐ No ☐ N/A
11	Foreseeable circumstances for investigator/sponsor termination	B11	☐ Yes ☐ No ☐ N/A
12	New findings that may affect willingness to continue	B12	☐ Yes ☐ No ☐ N/A
13	Approximate number of participants	B13	☐ Yes ☐ No ☐ N/A
14	Investigator and REB contacts; trial injury contacts	B14	☐ Yes ☐ No ☐ N/A
15	Participant/LAR, person obtaining consent, impartial witness when required; dated signatures	C	☐ Yes ☐ No ☐ N/A
16	Nominee details and prescribed declarations for regulated trials	C	☐ Yes ☐ No ☐ N/A
17	Parental/LAR permission and child assent, where applicable	Separate forms	☐ Yes ☐ No ☐ N/A



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PART B: PARTICIPANT INFORMATION SHEET (PIS)

Instructions for Principal Investigators:

Replace all bracketed placeholder text [] with protocol-specific, lay language (8th-grade reading level). Non-applicable options may only be removed following formal REB approval. Local language translations (e.g., Manipuri/Meiteilon) must be submitted for REB review prior to deployment.

Do not issue this uncompleted master template to study participants.

1. **Study Title:** [Insert Full Protocol Title]
2. **Sponsor / Funding Institution:** [Insert Sponsor Name]
3. **Study Site:** Regional Institute of Medical Sciences (RIMS), Imphal
4. **Principal Investigator (PI):** [Insert PI Name, Designation & Dept.]
5. **PI Contact Details:** [Insert Phone Number & Email]

B1. Invitation, purpose and duration

You are invited to take part in a research study. This study is being done to [plain-language purpose]. Your participation will last about [duration], including [visits/follow-up]. This is research, not routine treatment.

B2. Procedures and allocation

If you agree, you will [describe each visit, tests, samples, questionnaires, interventions and follow-up]. Procedures that are experimental or additional to usual care are [specify]. [If randomised: explain random allocation, chance of receiving each group/treatment, placebo and blinding in understandable terms.]

B3. Your responsibilities

If you participate, you will be asked to [visits, medication, diaries, safety reporting, restrictions]. Explain what happens if visits are missed.

B4. Risks and discomforts

Possible risks, side effects, discomforts or privacy risks include [study-specific details and their likelihood where known]. [Describe pregnancy, fetus, nursing infant and contraception-related issues if relevant]. There may be risks that are not yet known.

B5. Possible benefits

You may [describe realistic potential direct benefit], but benefit is not guaranteed. [Or: You may not benefit directly.] Findings may help [others/science].

B6. Alternatives

You may choose not to participate. Available alternatives, including routine care, are [describe; if not relevant, explain why].

B7. Privacy and access to records

Your study information will be identified by [code] and stored securely for [period], accessible to [study team and authorised persons]. Reports will not normally identify you. For regulated trials, authorised monitors, auditors, the REB and regulatory authorities including CDSCO may inspect relevant original records to verify the study, subject to applicable safeguards. Explain any data sharing, transfer or future use.

B8. Research-related injury: treatment and compensation

[FOR CDSCO-REGULATED CLINICAL TRIALS: In case of injury or an adverse event during the clinical trial, free medical management will be provided as required under NDCTR 2019, including until it is established that the injury is unrelated to the trial. Financial compensation for trial-related injury or death will be provided in accordance with the applicable provisions of Chapter VI of NDCTR 2019. Identify the sponsor/party responsible and the reporting contact. Do not substitute a promise inconsistent with applicable Rules.] [FOR OTHER STUDIES: State the REB-approved arrangements for management of research-related harm, reimbursement and compensation, as applicable.]



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B9. Payments and costs

You will receive [none / amount and basis] for [reimbursement/participation], with [proration details if applicable]. Extra costs to you, if any, are []. Study-related tests/interventions paid for by [].

B10. Voluntary participation and withdrawal

Taking part is voluntary. You may refuse or withdraw at any time without penalty or loss of medical care or benefits to which you are otherwise entitled. Explain any practical limits on withdrawal of data already collected or anonymised.

B11. Early stopping

Your participation may be ended by the investigator/sponsor without your consent if [safety concerns, study closure, ineligibility, protocol non-compliance or other foreseeable circumstances]. Describe any follow-up care.

B12. New information

You will be told promptly of significant new findings that may affect your willingness to continue in the study.

B13. Number of participants

Approximately [number] people will take part in this study [at RIMS / overall].

B14. Contacts For study questions or research-related injury:

[PI name, telephone, available hours and emergency contact].

For questions about your rights: [REB Chairperson/Member Secretary, Secretariat telephone, address/email].
(You will receive a signed and dated copy of this Information Sheet and Consent Form for your records.)



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PART C: INFORMED CONSENT FORM (ICF)

Study Title: _____

1. Protocol No.: _____ ICF Version & Date: _____ Participant ID: _____
2. Participant Name: _____ Age / DOB: _____
3. Language Used for Consent: _____ Date & Time of Consent: _____

C1. Participant / parent / LAR declaration

Please initial or tick each statement after explanation:

- ☐ I have read, or had explained to me, the approved PIS in a language I understand.
- ☐ I had enough time to ask questions and received satisfactory answers.
- ☐ I understand the purpose, procedures, risks, benefits and alternatives.
- ☐ I understand participation is voluntary and I may withdraw without loss of entitled care.
- ☐ I have received, or will receive, a copy of the signed consent document and PIS.
- ☐ I understand the arrangements for privacy and authorised review of study records.
- ☐ I understand the arrangements for research-related injury, medical management and compensation as explained in the PIS.
- ☐ I agree voluntarily to participate / give permission for the person named below to participate.

C2. Signatures

1. Participant / Legally Acceptable Representative (LAR):

- Participant Name: _____

Signature / Left Thumb Impression: _____ Date & Time: _____

- Parent / LAR Name (if applicable): _____

Relationship / Legal Authority: _____

Signature: _____ Date & Time: _____

2. Person Obtaining Informed Consent:

I confirm that I have accurately explained the information sheet to the participant/LAR, answered all questions to the best of my ability, and verified that consent was given freely without coercion.

- Name of Person: _____

Signature: _____ Date & Time: _____

3. Impartial Witness (Mandatory when participant/LAR is illiterate or visually impaired):

I confirm that the information in the PIS was accurately explained to, and understood by, the participant/LAR in my presence, and that consent was given freely and voluntarily.



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- Witness Name: _____
- Contact Address & Phone: _____

Signature: _____ Date & Time: _____

C3. Regulated clinical-trial particulars (complete when applicable)

Sponsor Name: _____ Site : _____

1. Principal Investigator: _____
2. Participant Occupation: _____ Annual Income: _____
3. Nominee Details (for Compensation Administration):

a. Nominee Name: _____

b. Relationship to Participant: _____

c. Full Postal Address: _____

d. Contact Telephone / Mobile: _____

(Note: Nominee details are collected strictly for administrative routing of regulatory compensation claims under NDCTR 2019 and do not determine legal heirship).

C4. SPECIAL POPULATION

Where a child is enrolled, obtain parent/LAR permission and age-appropriate oral or written assent on a separate approved form as applicable. Respect dissent unless an ethically and legally justified exception applies. For participants unable to consent, document LAR authority and seek participant involvement to the extent possible. Follow applicable rules for audiovisual recording of consent where required.