Institutional Ethical Review Committee (IERC)

Application for Ethical Review

This form is an application for ethical review only. The IERC does not award or administer research funding. Submit the signed form with all required documents to the IERC Secretariat [e-mail]. Read the IERC Policy and SOPs (LMRC/ORIC/IERC/POL-01) before applying.

For office use

IERC reference no.	
Date received	
Date complete submission received	
Review category assigned	☐ Exemption (E__) ☐ Expedited (X__) ☐ Full board
Assigned by (Chairperson / Acting Chairperson)	

Section 1: Study details

Title of the research project	
Planned start and end dates	
Study site(s)	
Participating institution(s) / department(s)	
Total budget (PKR) and source of funding	
Sponsor / funder (national or international)	

Section 2: Investigators

Principal Investigator: name, qualification, designation, institution, phone, e-mail	
Co-Investigator(s): name, qualification, designation, institution	
Supervisor (for students and trainees)	
Research ethics training of PI and Co-Investigators (course, year) – attach certificates	

Section 3: Type of submission

☐ New proposal ☐ Resubmission ☐ Amendment ☐ Continuing review ☐ Request for exemption

Section 4: Review category requested

The final category is decided by the Chairperson (Policy Section 10). Researchers may not decide for themselves that a study is exempt.

Exemption: ☐ E1 ☐ E2 ☐ E3 ☐ E4 ☐ E5 ☐ E6

Expedited: ☐ X1 ☐ X2 ☐ X3 ☐ X4 ☐ X5 ☐ X6 ☐ X7

☐ **Full board**

Section 5: Screening questions

Does the study involve:	Answer
A clinical trial, investigational drug, vaccine, biologic or device, experimental invasive procedure, ionising radiation, stem cells or fetal material? **The LMRC IERC does not review clinical trials or these types of research (Policy Section 2.7). If yes, the application will be returned without review.**	☐ Yes ☐ No
Children, pregnant women or other vulnerable persons?	☐ Yes ☐ No
Human genetic / genomic analysis?	☐ Yes ☐ No
Storage of samples or data for future use (biobanking)?	☐ Yes ☐ No
Residual diagnostic samples?	☐ Yes ☐ No
Forensic samples or DNA profiles?	☐ Yes ☐ No
Audio or video recording of participants?	☐ Yes ☐ No
Transfer of samples or data outside LMRC or Pakistan?	☐ Yes ☐ No
International funding or collaboration, or more than one province (NBC-R approval needed)?	☐ Yes ☐ No
Is any investigator the Patron, a Director of LMRC or an IERC member? (Policy Sections 10.3.2–10.3.3)	☐ Yes ☐ No

Section 6: Other approvals

☐ NBC-R ☐ Parent institution ethics committee ☐ Institutional Biosafety Committee ☐ None

Section 7: Documents attached

Document	Attached
Research Protocol (Annex 2)	☐ Yes
Informed consent form in Urdu and English (Annex 3A); parental permission and child assent forms (Annexes 3B, 3C) where applicable	☐ Yes ☐ N/A
Budget (Annex 4)	☐ Yes
Request for Exemption Certificate (Annex 5)	☐ Yes ☐ N/A
Conflict of interest declaration (Annex 6, Part B)	☐ Yes
Questionnaires, interview guides and recruitment materials (Urdu and English)	☐ Yes ☐ N/A

Document	Attached
CVs and research ethics training certificates of investigators	☐ Yes
MoU and parent-institution ethics approval (external researchers)	☐ Yes ☐ N/A
Material Transfer / data-sharing agreement (Annex 12)	☐ Yes ☐ N/A

Section 8: Declaration by the Principal Investigator and Co-Investigators

I/We confirm that the information provided is accurate; that the study will not start until all required approvals have been received; that it will be conducted as approved and in accordance with the LMRC IERC Policy; that amendments will not be implemented without prior approval; that adverse events, deviations and progress will be reported within the stated timelines; and that study records will be made available to the IERC and to authorised representatives of NBC on request.

Principal Investigator Name: Signature: Date:	**Co-Investigator** Name: Signature: Date:	**Supervisor (if applicable)** Name: Signature: Date:

Certification by Head of Department / Institution: I certify that the facilities required for this study are available and will be made available to the investigators.

Head of Department / Institution Name: Signature: Date:

Institutional Ethical Review Committee (IERC)

Ethical Approval Letter

Ref. No.: LMRC/IERC/[year]/[number]	**Date:** ____ / ____ / _____

To:

[Name of Principal Investigator]

[Designation, Department, Institution]

Subject: Ethical approval of research project

Title of the project	
Principal Investigator	
Co-Investigator(s)	
Study site(s)	
Type of review	☐ Exemption (category E__) ☐ Expedited (category X__) ☐ Full board (meeting dated ____)
Decision	☐ Approved ☐ Approved after minor modifications (verified on ____)
Date of approval	
Approval valid until	____ / ____ / _____ (maximum one year from the date of approval)

The IERC of Lahore Medical Research Center has reviewed the above project in accordance with its Policy and Standard Operating Procedures (LMRC/ORIC/IERC/POL-01), the guidance of the National Bioethics Committee (NBC) Pakistan, and the Declaration of Helsinki. The IERC is pleased to grant ethical approval for the project as described in the following documents:

#	Document	Version	Date
1	Research protocol		
2	Informed consent form (Urdu)		
3	Informed consent form (English)		
4	Parental permission / child assent forms (if applicable)		
5	Questionnaire / data collection tools		
6	Other (specify)		

Conditions of approval. This approval is subject to the following conditions:

1. The study must be conducted in accordance with the approved documents. No change may be made without prior IERC approval, except to eliminate an immediate hazard to participants, which must be reported within 5 working days.
2. Informed consent must be obtained, and documented, as approved, before any study procedure.
3. Serious adverse events must be reported to the IERC within 24 hours of the study team becoming aware of them, with a full report within 7 calendar days. Major protocol deviations and breaches of confidentiality must be reported within 7 working days (Annex 7).
4. A progress report (Annex 8) must be submitted at least 30 days before this approval expires if the study is to continue. Continuing the study after expiry without renewed approval is not permitted.
5. A final report (Annex 8) must be submitted within 3 months of completion or early termination of the study.
6. Study records, consent forms and data must be kept securely for at least 5 years after completion or publication, and made available to the IERC or NBC on request.
7. This approval does not replace any other approval required for the study (for example NBC-R or the approval of another institution), which must be obtained before the study begins.
8. The IERC may monitor the study, and may suspend or withdraw approval if these conditions are not met.

[Additional conditions, if any:] _____

Members with a conflict of interest in this project did not take part in its review or decision.

Chairperson / Acting Chairperson Name: Signature: Date: Institutional Ethical Review Committee, LMRC	**Member-Secretary** Name: Signature: Date: Institutional Ethical Review Committee, LMRC

IERC NBC Registration No.: _____

Copy to: Head of Institution (Patron), LMRC; study file.