Expression of Interest (EoI)

No: EMDR/NHRP/2025/TERIIP-Phase2 **Date: 30.10.2025**

Request for Expression of Interest (EOI)

Expression of Interest (EOI): ICMR's Taskforce on Establishment of Reference Intervals in Indian Population (TERIIP Phase II): A Multicentric Observational Cross-Sectional Study among Child and Adolescent Population (<18 years)

Overview

The most common decision support tool used for interpretation of numerical laboratory reports is the **Reference Interval (RI)**. Laboratory results are interpreted by comparison with these intervals. Hence, the **quality of reference intervals is as important as the quality of the test results themselves**.

Reference intervals must be **established or verified for each analyte and specimen source** (e.g., blood, urine, CSF) for a specific **population group**.

The currently used Reference Intervals in India are **not derived from the Indian population**, particularly not from child and adolescent cohorts. Most reference intervals are based on data from **Western populations** (USA and/or Europe) or from **small, non-representative Indian samples**. This reliance limits the accuracy and clinical relevance of test interpretations for children and adolescents in India.

The current Taskforce plans to address this critical gap. The results of this effort will **equip clinicians with age- and sex-specific, population-based RIs**, improving diagnostic accuracy and patient management for Indian children and adolescents.

Purpose of the call

ICMR is inviting **Expressions of Interest (EOI)** from interested researchers to **establish robust, age- and sex-stratified reference intervals** for routine blood parameters in the **Indian Child and Adolescent Population (<18 years)** through a **multicentric, population-based approach**. The study will ensure **inclusion of diverse geographic, and socio-economic groups**.

Scope of Work

The exercise will include the following components:

1. **Identification of Reference Individuals** from a healthy child and adolescent population
2. Collection of **socio-demographic and anthropometric data**
3. **Sample collection and transportation**
4. **Sample analysis** in NABL-accredited laboratories
5. Review and validation of results
6. **Establishment of Bharat Specific Reference Intervals**

Age Stratification Requirement

Participating centres are required to conduct the study in all of the following age sub-study groups:

i. **Neonates:** 0 ≤ age ≤ 28 days
ii. **Infants:** >28 days to <1 year
iii. **Under 5:** ≥1 year to <5 years
iv. **Children:** ≥5 years to <10 years
v. **Early Adolescents:** ≥10 years to <14 years
vi. **Late Adolescents:** ≥14 years to <18 years

Note:

- *All age group-specific studies must be conducted simultaneously and under a unified standard protocol.*
- *Participating institutions must demonstrate the capacity to recruit healthy volunteers from each of the specified age groups to ensure the comprehensive implementation of the study.*
- *At least 25% of participants recruited in each age-group should be from rural population.*

Expected Outcomes

The following outcomes are expected from the research project that shall be developed and implemented by the team under the guidance of ICMR:

- Bharat Specific Reference Intervals for routine biochemistry, immunology, and haematology parameters in Indian children.
- Age- and Sex-specific Reference Intervals, if justified based on results
- Creation of a national paediatric dataset to support **diagnostic standardization**.
- Contribution to global data on paediatric laboratory values.

Outline of the study:

Design*:* Direct sampling is envisaged from healthy **reference individuals <18 years** from the general population. Samples collected will be used to establish RIs for all analytes listed in **Annexure-I**.

Target Population*:* Native Indian **children and adolescents** from six geographical zones: **North, West, South, Central, East, and North-East India.**

Interested research teams may submit the EOI with the following details in an additional document (in addition to the essential submissions):

A. **<u>Checklist for applicant centres while submitting EoI for participating:</u>**

- NABL Accreditation in scope for all tests (list as provided in Annexure-I)
    - If NABL Accreditation is not available, is the applicant institute able and willing to collaborate with an NABL-accredited laboratory that has the scope of tests mentioned in Annexure-I?

1. Is the participating lab a Tertiary level/Large lab (as per CEA)?

2. Equipment and method to be used for each test (as per Annexure A).
3. Inter-instrument accuracy checks are to be conducted before starting the processing of actual samples. Declaration/consent for the activity.

- List of departments that will be part of the exercise.
- Demonstrated expertise and staff to identify the reference individuals, sample collection, transport and analysis. Please provide details.
- Informed Consent and Assent:

  All participants will be enrolled only after obtaining:
  - **Written informed consent** from parents/legal guardians,
  - **Oral Assent** from children above 7 years of age and **Written Assent** from children above 10 years of age.
- IEC.
- Sample Banking facility (details) to be provided for reanalysis and additional tests. Samples to be stored till the completion of the analysis and publication of results.
- Declaration for not using the samples for any other activity.

a. Catchment Area

The investigators must describe the geographical area from which the subjects will be recruited. Details should include State, District, City/Town, and specific address of collection centres, if already identified/functional.

B. Research team (<500 words)

Summarize and justify the composition of the research team based on the expertise of the individual team members in designing and implementing the project, especially experience in large-scale paediatric or adolescent research. Additionally, highlight the skill set and expertise that the members will bring to the research team for developing the final protocol and implementing the research project. The participating institutes should have demonstrated expertise and a workforce capable of identifying reference individuals, collecting samples, transporting them, and performing analysis.

C. Established Relationships with the community (<500 words)

EOIs must explain the **operational feasibility** of community engagement for recruiting child and adolescent participants, and describe:

- Existing or proposed outreach centres
- Linkages with paediatric care providers, schools, or health departments (if applicable)

D. Additional documents

One-page CV of the principal investigator and other key investigators in a single PDF

Please provide a one-page CV of the PI and key investigators from each identified area. Each CV should include:

a. Academic and professional qualifications
b. Current position and affiliation
c. Up to five most relevant previous research grants
d. Up to five most relevant previous publications

Review process:

The shortlisted teams will be invited to collaborate and develop a single, detailed proposal to be implemented at all the selected sites, which will be coordinated through ICMR HQ. A two-day workshop will be conducted to draft and finalize the SOPs for each activity planned within the study. An expert group will evaluate the developed proposal for the technical and operational aspects. The budget will be prepared in consultation with ICMR HQ.

Who can submit the EOI?

The EOI can be submitted through ONLINE MODE ONLY by the Principal Investigator. Indian Scientists/ Professionals who have regular employment in the Medical College, Research Institute, University, Recognized Research and Development Laboratory, Govt., and Semi-Govt. Organizations and NGOs. An eligible co-Principal Investigator should be included in the project, i.e., a regular employee in the PI's organization. For more details, refer to pt. 26 under II. Guidelines for the operation of projects. ICMR scientists are also eligible to apply under this call.

***Certificate issued by the Department of Scientific and Industrial Research (DSIR)**
a. Public-funded institutions do not require a DSIR certificate for applying.
b. Private academic institutions with valid UGC/AICTE/PCI or NMC-approved Medical colleges also do not require a DSIR certificate for applying.
c. All other institutions must submit a DSIR certificate.

Timeline

Activities	**Date**
Release of Call	30.10.2025
Webinar	06.11.2025
End of Call	15.12.2025 (till 1700 hours)
Selection of centres	15.02.2026
Last date for submission of codal documents	30.04.2026
Disbursal of funds	30.06.2026

Interested PIs can join the webinars that ICMR will organize in a week after the release of the call (tentatively 06.11.2025). If necessary, another webinar will be scheduled one week prior to the final project submission date (tentatively 08.12.2025) to address any related queries.

How to apply:

- Before proceeding to submit the proposal, it is suggested to read the user manual and ICMR Extramural Research Program guidelines, and make ready all relevant information, documents, and research plan.

- Open the ICMR Electronics Project Management System (e-PMS) portal http://epms.icmr.org.in. The user manual of e-PMS (under Guidelines → e-PMS manual) is available on the portal.

- Project proposal submission is a three step process in e-PMS:
  - Step 1: PI registration/ Login
  - Step 2: Verify email ID and complete/ update PI profile
  - Step 3: Proposal/ EoI submission

- Click on "Login" and select "Register" for new registration, and verify your registered email and complete the PI profile. Or if already registered, login with the credentials.

- After completing the mandatory section of the PI profile, click on EoI under Proposal submission → Click on the **+ blue tab** under EoI proposal list.

- PIs are advised to submit proposals well in advance of the last date, as servers may be overloaded and slow to respond near the end dates.

For any queries related to the call, please contact

Proposal submission related query	**Program related query**
Mail to: po.epms@icmr.gov.in	**Dr. Nilesh Chandra,** Scientist-E Discovery Research Division, ICMR Headquarters, V RamalingaswamiBhawan, Ansari Nagar, New Delhi-110029 Email: chandra.nilesh@icmr.gov.in

ANNEXURE-A

List of analytes to be covered under TERIIP (Phase II) and Analytical Methods

S. no.	**Parameter**	**Unit**	**Analytical Method**
1	Hb	g/dL	SLS Hb method
2	PCV	%	Electrical Impedance
3	TRBC	Million/ µL	Electrical Impedance
4	MCV	fL	Electrical Impedance
5	MCH	pg	Electrical Impedance
6	MCHC	g/dL	Electrical Impedance
7	RDW	%	Electrical Impedance
8	TLC	Thousand/ µL	Fluorescence Flow Cytometry, Optical method (Light Scatter analysis)
Differential Leucocyte count			Fluorescence Flow Cytometry, Optical method (Light Scatter analysis)
9	Neutrophil	%	Fluorescence Flow Cytometry, Optical method (Light Scatter analysis)

10	Lymphocyte	%	Fluorescence Flow Cytometry, Optical method (Light Scatter analysis)
11	Monocyte	%	Fluorescence Flow Cytometry, Optical method (Light Scatter analysis)
12	Eosinophil	%	Fluorescence Flow Cytometry, Optical method (Light Scatter analysis)
13	Basophil	%	Fluorescence Flow Cytometry, Optical method (Light Scatter analysis)
14	Platelet count	Thousand/ µL	Electrical Impedance, Optical method (Light Scatter analysis), Fluorescence Flow Cytometry
15	MPV	fL	Electrical Impedance, Optical method (Light Scatter analysis), Fluorescence Flow Cytometry
16	Abs Neutrophil Count	Thousand/ µL	Fluorescence Flow Cytometry, Optical method (Light Scatter analysis)
17	Abs Basophil Count	Thousand/ µL	Fluorescence Flow Cytometry, Optical method (Light Scatter analysis)
18	Abs Eosinophil Count	Thousand/ µL	Fluorescence Flow Cytometry, Optical method (Light Scatter analysis)
19	Abs Lymphocyte Count	Thousand/ µL	Fluorescence Flow Cytometry, Optical method (Light Scatter analysis)
20	Abs Monocyte Count	Thousand/ µL	Fluorescence Flow Cytometry, Optical method (Light Scatter analysis)
21	Reticulocyte count	%	Fluorescence Flow Cytometry, Optical method (Light Scatter analysis)

LFT	Total Bilirubin Direct Bilirubin Indirect Bilirubin	Diazonium salt/ Jendrassik
	ALT/SGPT AST/SGOT	U V Kinetic with & without P-5-P IFCC Reference Method
	ALP	PNP AMP Kinetic IFCC Reference Method
	Total Protein	Biuret
	Albumin	BCG / BCP
	ϒ-GGT	Modified IFCC
KFT	Urea	Urease / GLDH
	Creatinine	Jaffe's kinetic (Alkaline Picrate) Uncompensated Jaffe's

		Creatininase (enzymatic)
	Uric Acid	Uricase
Serum Electrolytes	Na^+	Direct / Indirect ISE
	K^+	Direct / Indirect ISE
	Cl^-	Direct / Indirect ISE
Glucose	Glucose HbA1c	GOD-POD / Hexokinase HPLC
Lipid Profile	T. Cholesterol	CHO- POD
	LDL-Cholesterol	Direct Method
	HDL-Cholesterol	Direct Method
	Triglyceride	GPO, POD Trinder Without Serum Blank
Thyroid Profile	TSH Total T3, Free T3 Total T4, Free T4 Thyroglobulin Ab TPO	CLIA / ECLIA
Others	Amylase	CNPG3 & CNPG7 IFCC reference method
	Calcium	OCPC / Arsenazo III / BAPTA
	Phosphorus	Phosphomolybdate complex
	Lipase	Colorimetric
	Iron	Colorimetric/MS
	Ferritin	CLIA

	LH FSH Prolactin Testosterone (For age groups 10-14 & 14-18)	CLIA/ECLIA

Additional tests for verification of CBC:

- PBS
- Transferrin saturation
- TIBC
- Vitamin B-12
- Folate
- CRP
- Vitamin D
- Minerals (Cu, Mg, Zn)