



भारतीय आयुर्विज्ञान अनुसंधान परिषद
स्वास्थ्य अनुसंधान विभाग, स्वास्थ्य एवं परिवार
कल्याण मंत्रालय, भारत सरकार

Indian Council of Medical Research
Department of Health Research, Ministry of Health
and Family Welfare, Government of India

No: 55/1/2022/BMS/BIO

Date: 09/10/2023

Request for Expression of Interest (EOI)

For ICMR's Taskforce on Establishment of Reference Intervals in Indian Population (TERIIP)

Overview

The most common decision support tool used for interpretation of numerical laboratory reports are the Reference Intervals. Laboratory results are interpreted by comparison with these intervals. Hence, quality of the reference intervals is as important as the quality of the result itself.

The reference intervals must be established or verified for each analyte and specimen source (e.g., blood, urine, CSF) for a specific Population.

Unfortunately, the currently used Reference Intervals in the country are not derived from our population. Most of the available in use Reference Intervals are either based on studies conducted in USA and/or Europe, or they are based on studies with very small sample sizes. In this scenario, the correctness of the Reference Intervals, and the management of the patients based on these values, becomes circumspect.

The current Taskforce plans to address this fallacy and bridge the gap. The results of this exercise will give renewed confidence to our clinicians in managing their patients based on population specific Reference Intervals.

Purpose of the call

ICMR is looking to partner with interested researchers to implement the exercise of Establishment of Reference Intervals in Indian Population. The exercise will include the following elements:

1. Establishment of common SOP for the exercise
2. Identification of Reference Individual
3. Collection of socio-demographic data of participants
4. Collection of anthropometric data
5. Sample collection and transport
6. Sample analysis in NABL Accredited laboratory
7. Review of laboratory results, and determination of reference intervals for each parameter.

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
- Population specific Reference Intervals, if justified based on results
- Geography specific Reference Intervals, if justified based on results

Outline of the study:

Design: Direct sampling is envisaged in Reference Individuals from the population. The collected samples will be used to establish Reference Intervals for all analytes, as mentioned in Annexure-I.

Target Population: Native Indians in the six geographical areas, viz. North, West, South, Central, East & North-East India.

Setting: Both rural and urban settings will be covered in this setting.

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

A. Checklist for applicant centres while submitting EOI for participating:

- NABL Accreditation in scope for all tests (list as provided in Annexure-I)
 - If NABL Accreditation not available, is the applicant institute able and willing to collaborate with an NABL accredited lab having scope of tests as mentioned in Annexure-I ?
- Is the participating lab Tertiary level/Large lab (as per CEA)?
- Equipment and method to be used for each test.
- Inter-instrument accuracy checks to be conducted before starting the processing of actual samples. Declaration/consent for the activity.
- List departments which will be part of the exercise.
- Demonstrated expertise and manpower to identify the reference individuals, sample collection, transport & analysis. Please provide details.
- Consent form.
- 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 have to describe the geographical area from where the recruitment of the subjects will be done. 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. Also, highlight the skill set and expertise the members shall bring to the research team for developing the final protocol and research project implementation. The participating institutes should have the

demonstrated expertise and workforce to identify the reference individuals, sample collection, transport & analysis.

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

Operational feasibility would be the key to this research study. The EoI should describe the existing or proposed outreach centres in the areas where the recruitment of reference individuals is proposed to be undertaken.

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:

What is the next step?

The shortlisted teams will be invited to collaborate and develop one single detailed proposal to be implemented in all the selected sites and will be coordinated through ICMR HQ. A two day workshop is envisaged 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 developed in consultation with ICMR HQ.

Who can submit the EOI?

The EOI can be submitted through ONLINE MODE ONLY by the Principal Investigator on behalf of the proposed team of Scientists/ professionals who have a regular employment in Medical Institutes/ Research Institutes/ Universities/ Colleges/ recognized Research & Development laboratories/ Government and semi-government organizations and Non-Governmental Organisations. The research team should have credentials for relevant skills, experience and demonstrated ability to solve health problems under consideration.

An eligible co-Principal Investigator should be included in the project i.e. a regular employee in the PI's organization.

***Certificate issued by Department of Scientific and Industrial Research (DSIR)**

- a. Public funded institutions do not require DSIR certificate for applying.
- b. Private academic institutions with valid UGC/AICTE/PCI or NMC approved Medical colleges also do not require DSIR certificate for applying.
- c. All other institutions must submit DSIR certificate.

Timeline

Activities	Date
Release of Call	9 th October 2023
Webinar	16 th October 2023
End of Call	20 th November
Selection of centres	5 th December 2023
SOP Development Workshop	14 th -15 th December 2023
Last date for submission of codals	To be notified
Disbursal of funds	To be notified

Interested PIs can join the webinars that will be organized by ICMR in a week after the release of call (tentatively 16th October 2023). If required, another webinar will be scheduled one week before the last date of submission of projects, (tentatively 14th November 2023) to discuss related queries.

How to apply:

1. Before proceeding to submit the proposal, it is suggested to read user manual and ICMR Extramural Research Program guidelines; and make ready all relevant information, documents and research plan.
2. 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.
3. Project proposal submission is three steps process in e-PMS:
 - Step 1: PI registration/ Login
 - Step 2: Verify email ID and complete/ update PI profile
 - Step 3: Proposal submission
4. Click on “LOGIN” and select “Register” for new registration OR if already registered, provide details to login and enter into e-PMS portal.
5. Verify your registered email and complete the PI profile.
6. After completing mandatory section of PI profile, click on “Proposal submission → Submit.
7. It is advised to carefully read the budget provision available under Guidelines for Extramural Research Programme of ICMR and submit the budget in prescribed format.
8. Including at least one Co-PI from PI’s institute is mandatory.

9. PIs are advised to submit proposal well ahead of the last date, since 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
Dr. Pulkit Verma Scientist D and Program Officer Division of BMI, ICMR Headquarters, V Ramalingaswami Bhawan, Ansari Nagar, New Delhi-110029 <i>Email: po.epms@icmr.gov.in</i>	Dr. Nilesh Chandra, Scientist-E Discovery Research Division, ICMR Headquarters, V Ramalingaswami Bhawan, Ansari Nagar, New Delhi-110029 Email: chandra.nilesh@icmr.gov.in

Final list of all tests to be conducted:

S. no.	Parameter	Unit
1.	Hb	g/dL
2	PCV	%
3	TRBC	Million/mm ³
4	MCH	pg
5	MCV	fL
6	MCHC	g/dL
7	RDW	%
8	TLC	Thousand/mm ³
	Differential count	
9	Neutrophil	%
10	Eosinophil	%
11	Basophil	%
12	Monocyte	%
13	Lymphocyte	%
14	Total Platelets	Thousand/mm ³
15	MPV	fL
16	Abs Neutrophil Count	Thou/mm ³
17	Abs Basophil Count	Thou/mm ³
18	Abs Eosinophil Count	Thou/mm ³
19	Abs Lymphocyte Count	Thou/mm ³
20	Abs Monocyte Count	Thou/mm ³
21	Reticulocyte count	%

LFT	Total Bilirubin Direct Bilirubin Indirect Bilirubin	
	ALT/SGPT AST/SGOT	
	ALP	
	Total Protein	
	Albumin	
	γ-GGT	
KFT	Urea	
	Creatinine	
	Uric Acid	
Serum Electrolytes	Na+	
	K+	
Glucose	Glucose HbA1c	

Lipid Profile	T. Cholesterol	
	LDL-Cholesterol	
	HDL-Cholesterol	
	Triglyceride	
Cardiac Bio Maker	CK MB	
	Total CK	
	Troponin (cTropI)	
Thyroid Profile	TSH Total T3, Free T3 Total T4, Free T4 Thyroglobulin Ab TPO	
Others	Amylase	
	Calcium	
	Phosphorus	
	Lipase	
	Vit D	
Fertility hormones	LH FSH Prolactin Testosterone Estrogen Progesterone	

Additional test for verification of CBC:

- Iron
- Ferritin
- PBS
- Tfr saturation
- serum transferrin receptor
- AGP
- TIBC
- B-12/ Cyanocobalamin
- Erythrocyte Folate levels
- CRP/hsCRP
- ESR
- Minerals