

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

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

Date: 14/05/2022

Call for Proposals for Establishing Centers for Advanced Research for Bone Marrow Transplantation/ Hematopoietic Cell Transplantation (BMT/HCT)

I. Background:

HCT/BMT is an advanced therapeutic intervention that is required for a number of malignant and non-malignant conditions such as haemoglobinopathies, hematological cancers, aplastic anemia, primary immunodeficiency disorders and many such disorders, often for critically ill patients. There is no denial that there has been a steady rise in the number of HSCT centres and the number of transplants being done in the country. However, majority of these are in the private sector restricting access to the poor and marginalized. Another major limiting factor for the availability of BMT/HCT in India is the high cost of setting and running the required infrastructure. ICMR recognizes and would like to address these constraints to enhance access and encourage regionally relevant research in this area. The need of the hour is to make bone marrow transplant services easily available, accessible and affordable to the diseased and vulnerable population of the country, and as an output of the same, conduct context specific and regionally relevant translational research from bed to bench and bring it back to the bed to improve the outcome of bone marrow transplantation. As ICMR functions with the mandate of promoting biomedical research and implementing it for the benefit of society, it envisages to creating Centers for Advanced Research (CAR) in hospitals across the country and making this essential treatment safe and accessible to the masses. This is a research model that creates and unites multiple research centers with the goal of expediting and providing safe and affordable BMT in all the 6 regions of India (north, south, east, west, north-east and central). Through this nation-wide effort, the goal is to contribute to the development of BMT/HCT, improve access to this established SOC (Standard of Care) and improve its outcome.

ICMR invites application to set up Centers for Advanced Research for Bone Marrow Transplantation in tertiary care hospitals of India.

Key research areas:

Applications may include, but are not limited to proposals addressing the following research areas in BMT/HCT:

- Graft-versus-host disease
- Graft manipulation
- Prevention of infectious complications
- Management of long-term issues
- Immune-based therapies
- Disease recurrence
- Precision Medicine

II. Assessment/Evaluation Criteria:

The proposal will be evaluated based on the following criteria:

- 1. Strength and Expertise of Principal Investigator (PI)
- 2. Expertise, facilities, and track record and ability of the BMT team to achieve the research goals as depicted by no. of Team BMT Bone Marrow Transplants done by the team and the hospital/institute till date
- 3. Potential regional impact of the project
- 4. Need assessment and disease burden in the region
- 5. Scientific and technical merit of the proposal
- 6. Proposal formulation (Precision in the objective, adequacy, and completeness of literature review, preliminary work done, methodology and work plan, resources requested for this purpose, effectiveness of planning and resource management, etc.)
- 7. Critical Mass of the institute/hospital
- 8. Capacity building
- 9. Human Resource Development
- 10. Model for sustainability after five years

III. Key dates/Timelines

Call start date: 14th May 2022

Call end date: 05th June, 2022, 17:00 IST

Declaration of Results: Before 30th August, 2022

The proposals which are not submitted through EPMS portal and received after due date will

not be entertained.

IV. Eligibility/Who Can Apply:

Faculties working in the tertiary care hospitals and research institutes (valid DSIR/SIRO certificate), with sound scientific & technical backgrounds and relevant publications in the proposed areas can submit projects proposals. CAR is usually established around a scientist of eminence (40-55 yrs) already established in the area of expertise as evidenced by publications in peer reviewed journals. The primary objective is to support the researcher for pursuing the proposed leads and ideas to their logical conclusions. This support is for 5 years for staff (Scientific, Technical & Supportive), equipments & contingency. Please refer to Guidelines for Extramural Research Program of ICMR (https://main.icmr.nic.in/sites/default/files/extramural/Extramural_Projects_Guidelines.pdf).

- 1. The applying Institution should have facilities for performing BMT on a routine basis with all the ancillary medical and laboratory services for the same.
- 2. The BMT services will be performed in compliance with the National Guidelines for Hematopoietic Cell Transplantation Guidelines, 2021.

Please provide CV as per format attached (Annexure 1).

V. How to Apply:

Applicants may submit full-length proposal online on EPMS portal of ICMR. Please submit proposal as per format attached (Annexure 2-6)

VI. Review and Assessment of Proposal:

Upon receipt of the detailed proposal, the same will be reviewed by an Internal Screening Committee. Incomplete applications and those which do not fulfill eligibility criteria will not be considered. Shortlisted applications that are complete administratively and responsive will be evaluated for scientific and technical merit by an Expert Group/ Committee. The project investigators may be invited to make a detailed presentation before the committee. The decision of the committee on a proposal will be final and communicated to the investigator.

FURTHER INFORMATION CONTACTS

Dr. Geeta Jotwani,
Scientist G,
Division of Basic Medical Sciences
Indian Council of Medical Research
V. RamalingaswamiBhavan
Ansari Nagar, New Delhi- 110029
Email: jotwanig.hq@icmr.gov.in

Tel: +91-11-26589272 Fax: +91-11-26589791

Annexure 1: CV of PI/Co-PI

1. Name:
2. Date of Birth:
3. Sex (M/F):
4. Designation:
5. Department:
6. Institute/University:
7. Address:
PIN : e-mail:
8. Specialization/Research Areas:
9. Education Details (Post-graduation onwards & Professional Career)
10. Employment Details: Position and Employment (Starting with the most recent employment)
11. Awards/Honors Details
12. Details of ongoing/completed projects.
13. Publications of the last 5 years in relevant areas
14. Specific Training in BMT:
15. No. of transplants done / assisted in: (Auto/Allo/Hanlo)

Annexure 2:

- 1. Project Title:
- 2. Key Research Area:
- 3. Region of India being catered to:
- 4. Assessment of Need and Disease Burden:
- 5. Novelty/Innovation:
- 6. Rationale:
- 7. Project Summary:
- 8. Introduction:
- 9. Aims and Objectives: The proposal should dwell on the below mentioned aspects:
 - i. Capacity Building
 - ii. Hypothesis driven research projects (minimum 5)
 - iii. Human Resource Development
- 10. Work done in the area/region till date:
- 11. Review and status of Research and Development in the subject:
- 12. Work Plan/Methodology:
- 13. Timelines/Milestones:
- 14. Suggested Plan of action for utilization of research outcome expected from the project)
- 15. Model of sustainability after 5 years
- 16. Mention the preliminary work done by the applicant, if any.
- 17. Previous experience of working in this area of research and study area
- 18. Collaborating institutes and justification:
- 19. Institutional support (up to 200 words): Mention the institutional support in terms of basic infrastructure, Manpower, departments and laboratories with equipment required for the proposed research work. The organizations should have basic infrastructure, skilled manpower preferably prior experience in doing bone marrow transplantation, Commitment of time of Principal Investigator (PI) and co-principal investigator (Co-PI) will be considered as one of the key factors while short listing the proposals. (Please fill annexure 3)
- 20. Budget estimates Please fill annexure 4)
- 21. Endorsement from the Head of Institution: (Please fill annexure 5)
- 22. Certificate from the investigator: (Please fill Annexure 6)
- 23. Undertaking from the Head of Institution: (Please fill Annexure 7)

Annexure 3: Institutional Support

Broad Area	Facilities	Availability
Innationt weit	Class single hadded reams with isolation canability	Availability
Inpatient unit	Clean single-bedded rooms with isolation capability Intensive care unit	
Ancillary		
medical	- Emergency room service	
services	Gastroenterology and pulmonary service	
Outpatient clinic	-Single patient examination rooms	
Blood bank	– Twenty-four hour on-site blood bank service: ABO	
	typing and cross match, RBC, and platelets for	
	transfusion	
	 Irradiation and leukocyte depletion of blood products 	
Laboratory	 Hematology cell count and chemistry lab 	
	 Serology for viral screen 	
	 Microbiology for basic bacterial and fungal cultures 	
	– CMV PCR or antigenemia	
	 Access to CSA/tacrolimus levels 	
HLA typinglab	-Access to ASHI or similarly accredited HLA typing lab	
Stem cell	 PBSC apheresis capability 	
collection	 Bone marrow harvesting facility and expertise for 	
	matched sibling donor	
Stem cell	– FACSCD34 enumeration	
processing	 Refrigerator for blood and bone marrow 	
facility	 Controlled cryopreservation capability for freezing of 	
,	autologous stem cell product	
	 Equipment and expertise to process ABO-mismatched 	
	cellularproduct	
Radiology	 Routine x-ray radiology ,ultrasound,and CTscanner 	
	 Placement of central venous catheters 	
Pharmacy	 Availability of conditioningchemotherapydrugs 	
	 Availabilityofantimicrobialagents(broad- 	
	spectrumantibiotics,antiviral,andantifungaldrugs)	
	 AvailabilityofimmunosuppressiveagentsforGVHDprophyl 	
	axisandtreatment	
Human	– Medical director: Licensed physician with adequate	
resources/Critical Mass	training and experience in HSCT	
IVIGSS	- Nursingstaffwithtraininginchemotherapyadmini	
	stration,infectioncontrol,andhandling of stem	
	cell products	
	 Clinical laboratory director: Clinical pathology trained. 	
	– Appropriately trained lab scientist and technicians	
	 Multidisciplinarymedicalstaff(radiology,pathology,I 	
	CU,surgery,gastroenterology,pulmonary)	
Outcome database	-Monitor patient demographics, treatment, and outcomes (levell data reporting)	
Quality	- Written institutional protocols/guidelines	
management	Regular audits ofvarious HSCT procedures andpatient	
	treatment outcomes	
	 Systemtodetecterrorsoradverseeventsforcorrectiveorpr 	
	eventativeactions	
	eventativeactions	

Equipment available with the Institute	Deep Freezer – 80°C Plasma thawing water bath Apheresis Machine including CMC for 3 years High Flow Oxygen Delivery System Electric five function ICU type Hospital Beds ECG Machine Defibrillator Infusion Pump Syringe Pump Transport Stretcher Bed Multi-Parameter Monitors with central monitoring facility Fully automatic Donor couch Class II Type A2 & Type B1 Biosafety Cabinet Blood irradiator	
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Annexure 4: Budget Estimates: Summary

	Item BUDGET			(in			
							Rupees)
		1 st Year	2 nd Year	3 rd year	4 th year	5 th Year	Total
A.	Recurring						
	 Salaries/wages 						
	2. Consumables						
	3. Travel						
	4. Other costs						
B.	Equipment						
	Grand Total (A+B)						

a. Budget for Salaries/Wages (As per ICMR rule. Please visit ICMR project staff recruitment rule at https://main.icmr.nic.in/sites/default/files/basic_page/Guidelines_for_recruitment.pdf)

Designation & number of	Monthly Emoluments	BUDGET			(in Rupees)		
persons							
		1 st Year	2 nd Year	3 rd year	4 th year	5 th Year	Total
Total							

Justification for the manpower requirement:

b. Budget for Travel

		BUDGET				
	1 st Year	2 nd year	3 rd year	4 th year	5 th Year	Total
Travel (Only						
inland travel)						

Justification for intensive travel, if any:

c. Budget for Other Costs/ Contingencies

SI. No.	Other costs/ Contingency costs			BUDGET			(in Rupees)
		1 st Year	2 nd Year	3 rd year	4 th year	5 th Year	Total

Justification for specific costs under other costs, if any:

d. Budget for Equipment

Sl. No.	Generic name of the Equipment along with make & model	Imported/ Indigenous	Estimated Costs	Spare time for other users (in %)

Justification for the proposed equipment:

Annexure 5: Endorsement from the Head of Institution

(To be given on letter head)

Project Title:	
Certified that the Institute welcomes participation of Dr Principal Investigator and Dr The property of the pr	as the Principal Co-Investigator for
the project and that in the unforeseen event of discontinual Principal Co-Investigator will assume the responsibility of the due information to ICMR).	•
2. Certified that the equipment and other basic facilities as other administrative facilities as per terms and conditions of investigator(s) throughout the duration of the project.	
3. Institute assumes to undertake the financial and other project.	management responsibilities of the
Date:	
Name and Signature of Head of Institution	
Place:	

Annexure 6: Certificate from the Investigator

Project Title:				
1. I/ We agree to abide by the terms and conditions of the ICMR research grant.				
2. I/ We did not submit the project proposal elsewhere for financial support.				
3. I/ We have explored and ensured that equipment and basic facilities (enumerated at Annexure 3) will actually be available as and when required for the purpose of the projects. II We shall not request financial support under this project, for procurement of these items.				
Date:				
Place:				
Name and Signature of Principal Investigator:				
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Annexure 7

TERMS AND CONDITIONS FOR THE ESTABLISHMENT OF

CENTRE FOR ADVANCED RESEARCH AND EXCELLENCE

1. Basic Facilities for Research

- i) All Basic facilities for the conduct of the research such as office space, basic equipment and ordinary laboratory, chemicals, glass are, furniture and other assistance, as may be required for the smooth working of the advanced centre, shall be provided by the host institution. The Council will provide financial assistance for special equipment and salaries of research staff. The equipment purchased out of the research grant would be the property of the Council and could be transferred elsewhere after the termination of the centre.
- ii) Grants for carrying out research are provided to investigators to supplement the resources put at their disposal by the institution in which they are working. The grant should not be used as a subversion towards the normal work of the institution but should be exclusively utilised for the advanced centre for which it has been sanctioned.

2. Research Staff

- i) Temporary posts on consolidated pay/pay scales for scientists and technicians will be provided. The designation and the scale of pay and allowances will be the same as prevalent for corresponding categories of the staff in the institute where the advanced centre has been located. The research staff will be recruited and appointed according to the rules and procedure of the host institution. If there is no corresponding post in an institute, the ICMR scale of pay and allowances, and not those of the Institutes concerned, will be admissible. The persons appointed at the advanced centre will not be treated as the employees of the Council. They will, for all intents and purposes, be governed by the rules and regulations of the institute.
- ii) Non-scientific personnel like laboratory assistant, laboratory attendant, peon and clerk, etc. are not ordinarily provided.
- iii) No person shall be appointed on deputation from any other organisation and expenditure of pension/provident fund contribution/leave salary contribution by the institution for persons, if any, appointed on deputation will not be met from the grant-in-aid provided for advanced centre.

3. Contingent Grant

i) A contingent grant is given to meet petty expenditure on purchase of chemicals, stationery. Only essential non-expendable articles or equipment, books and journals related to the fields of study can be purchased out of the grant. The amount of contingent grant would depend on the requirements and needs of the advanced centre.

4. Equipment

The Council would give assistance for purchase of special equipment required for research work at the Centre. Only Rupee funds will be given, foreign exchange, if any, required will have to be arranged for as per normal procedure. The equipment

purchased out of the Council's funds would belong to the Council and should be handed over by the host institution to ICMR on termination of the Centre.

5. Stores

- i) Normally no foreign exchange should be involved on the import of chemicals, reagents, etc.
- ii) Store items can be purchased according to the rules and procedures of the host institution.
- iii) All the store items purchased out of the grant will be the property of the Council and should not be disposed off without prior approval of the Council.

6. <u>Duration of Advanced Centres</u>

- i) The Council would normally provide assistance to the advanced centres for a period of five years. In exception cases, it can be extended after evaluation. The institution must undertake to provide the necessary basic facilities for carrying out medical research for a period of at least five years.
- ii) On completion of the tenure of the advanced centres, the institution will take over the research programmes of the advanced centres.
- iii) The concerned authorities of the host institution must undertake not to change, by transfer or otherwise, the PI/Officer-in-charge/head of the advanced centres for a period of at least five years.
- iv) The Council would have the right to post its research personnel at the advanced centres after due consultation with the Officer-in-charge. The Council may also assign its other scientific personnel for the purpose of research and training at the advanced centres.

The staff employed on the advanced centres will not undertake any private practice, and would devote their whole time and energy to research.

7. Research Programmes

- The institution selected for advanced centre will continue the tradition of high class research and should have scientists of international repute and proven ability. The programme of research to be carried out will be subject to the approval of the Council and the Scientific Advisory Committee constituted by the Council. The expert group will function as a body to identify the major thrust area for research in the discipline for which the advanced centres has been chosen. The expert group will also periodically review the progress made in the research programmes. Normally the meeting of the expert group will be held at the host institute at least once a year. Prior approval of the Council will be essential to hold such meetings. The advanced centre will also carry out research in the areas/problems identified by the Council from time to time. Work on any scheme may be discontinued as and when considered necessary by the Council.
- ii) Annual review of the progress of work conducted at the advanced centre will be done at the annual meeting of the expert group. The members of the expert group will be appointed by the Director-General, ICMR for a tenure of two years each. Apart from the review of the ongoing programme, proposals for new activities can also be assessed/considered during this meeting.

8. Report of work done

i) Reports on the progress of work done under the advanced centre will be submitted to the Council and expert group as and when called for.

9. <u>Publications</u>

- i) The assistance given by the Council should be acknowledged in any published account of work for which the grant is given.
- ii) Prior permission of the Council should be taken for publication of a paper in any journal, Indian or foreign.
- iii) Copies of reprints of all papers based on the work of the centre published in journals other than the Indian Journal of Medical Research must be sent to the Council for record.
- 10. i) The Council shall have the right to take out patents in respect of invention/discoveries made in a centre for advanced research financed by the Council.
 - ii) The Officer-in-charge or the staff employed on the research scheme shall not apply or obtain patents for any invention/discovery made by them without prior approval of the Council. All patents will be registered in the name of the Indian Council of Medical research following existing patent laws.

11. Maintenance of Accounts

- i) The grant will be released to the Head of the Institution in instalments.
- ii) A separate account for the grant received and expenditure incurred shall be maintained. The account will be subject to audit by the authorised auditor of the institution and/or by the Council's own internal auditors. Latest by the end of December following the financial year for which the grant is paid, an audit certificate from the auditors and that the money was actually spent on the objects for which it was sanctioned shall be submitted to the Council. Any unspent balance must be refunded to the Council on termination of the advanced centre. Further grants will be stopped unless audited statement of accounts and utilisation certificate are received within a period of one year after the end of the financial year for which grant was sanctioned.
- iii) Expenditure should on no account exceed the allotment sanctioned during each year.
- iv) The grant may be revoked in whole or in part at any time by Director-General of the Council.

12. <u>Termination of Advanced Centre</u>

The Director-General, ICMR, will have the rights to terminate any Advanced Centre at any time without assigning the reasons. After completion of the tenure of 5 years, the institution will take over the research programmes of the advanced centres and continue them as part of their institutional activities. At the end of five years based on the performance, ICMR can consider granting a second term of five years. Alternatively ICMR can consider granting permission for use of ICMR logo in connection with the CARE for future.

UNDERTAKING

ICMR funds all extra-mural projects on the condition that the staff employed by the project will be recruited as per the rules and procedure of the host institute. ICMR has apprised us of this rule and we have carefully noted it. It is confirmed that during the currency of the project as well as on its termination all legal liabilities relating to staff etc. will be the responsibility of the host Institute. ICMR will have no legal liabilities, what so ever, relating to staff.

Date:	Head of the Institute
	With (SEAL)