

**DIVISION OF CLINICAL RESEARCH & TRAINING**

**SJRI**

19<sup>th</sup> October, 2024

Dear Dr.Shailaja Patil,

Subject : MoU for ICRA-2 ICMR CAR Cross Sectional Study – BLDE DU's Shri B.M. Patil Medical College Hospital and Research Centre, Vijayapur, Karnataka.

Please find enclosed two copies of the final MoU for your signatures.

We request you and your Institute head to kindly sign & date with seal on page no. 08 and initial all the pages of the agreements.

Please keep one original signed MoU at your site and courier us 2<sup>nd</sup> signed MoU to us.

Thanks & Kind Regards,



Freeda Xavier  
Program Manager  
Division of Clinical Research and Training  
St. John's Research Institute  
Bengaluru

Encl: 1) 2 copies of signed MoU



1. Annexure I: Self-Assessment Checklist for contents of MOA/MOA

SI #	CONTENT	YES/ NO	CLAUSE/ ARTICLE	PAGE No.
1	The official Logo/emblem of all Parties	Yes		1
2	Preamble of all Parties is stated	Yes		2 & 3
3	Purpose/Objective of the MOA is explicitly Stated	Yes	I	3
4	Scope of Co-operation is mentioned	Yes	II	3
5	Modalities of Cooperation are stated	Yes	III	3
6	Funding arrangements, if applicable, are mentioned	Yes	IV	3
7	Mutual topics of collaboration, if any, are identified and stated	NA	-	-
8	Modalities for governing or managing the scope of cooperation are stated	Yes	V	4
9	Ownership/ authorship issues related to Intellectual property rights (IPR), commercialization and Publications are carefully worked out and stated	Yes	VI	4 & 5
10	Conditions to use the name, logo and/or official emblem of the other Party	Yes	VI	4 & 5
11	Maintenance of Confidentiality of the Other Party	Yes	VII	5
12	Terms and conditions related to the Ethical issues/ transfer of biological material/data sharing, if applicable, have been worked out between the Parties and stated in the MOA	Yes	VIII	5
13	Mechanism of dispute resolution is stated	Yes	IX	5 & 6
14	The MOA is not prohibitive on any Party with respect to undertaking/conducting similar programmers/ research/academic activities with any other <<site name>>/organization	Yes	X	6
15	Obligations on each Party have been worked out and stated in the MOA	Yes	XI	6
16	Duration of validity is mentioned	Yes	XII	6
17	Policy of amendment is mentioned	Yes	XIII	7
18	Conditions of termination are mentioned	Yes	XIV	7
19.	Force majeure	Yes	XV	7
20	MOA recognizes the authorized signatories	Yes	PIs are signatories	8 & 9

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सत्यमेव जयते

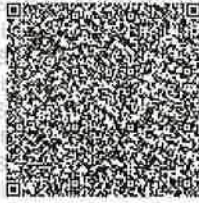
INDIA NON JUDICIAL

Government of Karnataka

Rs. 500

e-Stamp

Certificate No. : IN-KA20100215503160W  
 Certificate Issued Date : 20-Sep-2024 02:42 PM  
 Account Reference : NONACC (FI)/ kacrsfl08/ KORAMANGALA1/ KA-JY  
 Unique Doc. Reference : SUBIN-KAKACRSFL0888656599283084W  
 Purchased by : ST JOHNS RESEARCH INSTITUTE BENGALURU  
 Description of Document : Article 5(J) Agreement (in any other cases)  
 Property Description : MEMORANDUM OF AGREEMENT  
 Consideration Price (Rs.) : 0  
 (Zero)  
 First Party : ST JOHNS RESEARCH INSTITUTE BENGALURU  
 Second Party : BLDE DUS SHRI BM PATIL MEDICAL COLLEGE VIJAYAPURA  
 Stamp Duty Paid By : ST JOHNS RESEARCH INSTITUTE BENGALURU  
 Stamp Duty Amount(Rs.) : 500  
 (Five Hundred only)



Please write or type below this line

MEMORANDUM OF AGREEMENT

Between

Name of PARTY 1 (St. Johns Research Institute, Bengaluru)

AND

Name of PARTY 2 (BLDE DU's Shri B. M. Patil Medical College Hospital and Research Centre, Vijayapura)

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**PREAMBLE**

**This Memorandum of Agreement (hereinafter referred to as 'MOA') is made between**

St. Johns Research Institute, Bengaluru  
(Hereinafter referred to as "Central Coordinating Centre or CCC")

**AND**

(BLDE DU's Shri B. M. Patil Medical College, Hospital and Research  
Centre, Vijayapura, Karnataka - 586103)  
(Hereinafter referred to as BLDE (DU) SBMPMC)

**WHEREAS CBCI Society for Medical Education, ("CBCI") (PAN – AAATC0773E)** established and registered under the Karnataka Societies Registration Act, 1980, having its address at St. John's National Academy of Health Sciences, John Nagar, Sarjapur Road, Koramangala, Bengaluru -560034, Karnataka, India, represented by its Secretary -and-**St. John's Research Institute, ("SJRI")** a unit of the Society, having its address at St. John's National Academy of Health Sciences, John Nagar, Sarjapur Road, Koramangala, Bengaluru-560034, Karnataka, India represented by its Dean. **Dr. Denis Xavier**, Professor and HOD, Department of Pharmacology, St. Johns Medical College & Head – Division of clinical research and training (DCRT), St. John's Research Institute, Bengaluru, for the said Project, will act as the **Principal Investigator for the MOA on behalf of Party 1.**

**WHEREAS, BLDE DU's Shri B. M. Patil Medical College, Hospital and Research Centre, Vijayapura, (PAN –AAAAB7055P),** at Smt. Bangaramma Sajjan Campus, Sholapur Road, Vijayapura – 586103, Karnataka, India (BLDE (DU) SBMPMC) represented by Dr. R.V. Kulkarni Registrar, BLDE (DU) Vijayapura, hereinafter the "Participating center". **Dr. Shailaja S Patil, Prof. Community Medicine, SBMPMC, Vijayapura** is the 'site investigator' and referred to as BLDE (DU) SBMPMC, PI.

BLDE (DU) SBMPMC & BLDE (DU) SBMPMC, PI is collectively referred as "**Party 2**"

The "Party 1" and "Party 2" are hereinafter individually referred to as 'Party' collectively referred to as "Parties" to this MOA,

**WHEREAS, Central Coordinating Centre (CCC)** coordinates with BLDE DU's Shri B. M. Patil Medical College, Hospital and Research Centre, Vijayapura, Karnataka in the performance of the Study entitled: Assessment of individual and health system factors for cardiovascular disease risk reduction at diverse regions and facilities in India – A cross sectional study hereinafter referred as "**Project**")

**WHEREAS, the Project is funded through ICMR Centre for Advanced Research (CAR) 2024-**

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29 grant offer Ref: ICMRCAREP-2023-0000165 per Appendix-I. (hereinafter referred as "Project Sponsor")

**NOW THEREFORE**, the undersigned Parties have agreed upon the rights and obligations set forth below, which shall apply between them in connection with the services and

**HAVE REACHED THE FOLLOWING AGREEMENT:**

#### **ARTICLE I: PURPOSE/OBJECTIVE**

To collaborate and work together in the research project titled "Assessment of individual and health system factors for cardiovascular disease risk reduction at diverse regions and facilities in India – A cross sectional study" technically approved by the Indian Council of Medical Research (ICMR). **Dr. Denis Xavier**, Professor and HOD, Department of Pharmacology, St. Johns Medical College & Head – Division of clinical research and training (DCRT), St. John's Research Institute, Bengaluru, for the said Project, will act as the Principal Investigator **for the MOA on behalf of Party 1.**

**Dr. Shailaja S Patil**, Prof. Community Medicine, SBMPMC for the said Project, will act as BLDE (DU) SBMPMC, PI **for the MOA on behalf of Party 2.**

#### **ARTICLE II: SCOPE OF COOPERATION**

The work related to the said project, shall be carried out by both parties, broadly described as following-:

1. Obtaining Ethics Committee Approval from respective Institute Human Ethics Committee,
2. Completion of all Codal Formalities as required by the Indian Council of Medical Research (ICMR)
3. Obtaining and submission of Utilization Certificate and Statement of Expenditure as required by the Indian Council of Medical Research (ICMR)
4. Technical and scientific work as described in the approved Study Protocol .

#### **ARTICLE III: MODALITIES OF COOPERATION**

Dr. Shailaja S Patil, Prof. Community Medicine, Shri B. M. Patil Medical College, Hospital and Research Centre, Vijayapura is the Site Principal Investigator for the said Project. Dr. Denis Xavier is a Professor and HOD in the Department of Pharmacology, St. Johns Medical College and Head – Division of clinical research and training (DCRT), St. John's Research Institute, Bengaluru, and Principal Investigator.

#### **ARTICLE IV: RESEARCH FUNDING AND TRANSFER OF FUNDS**

Refer to Appendix I



## ARTICLE V: GOVERNANCE AND MANAGEMENT

The work related to the said project, shall be carried out under the supervision of Principal Investigator, Dr. Denis Xavier, Professor & HOD of Pharmacology, at SJMC & DCRT, Bangalore and & BLDE (DU) SBMPMC, as site investigator at BLDE DU's Shri B. M. Patil Medical College, Hospital and Research Centre, Vijayapura, Karnataka – 586103.

Both parties will be guided by ICMR under Extramural Program.

## ARTICLE VI: INTELLECTUAL PROPERTY RIGHTS (IPR), COMMERCIALIZATION AND PUBLICATIONS INCLUDING AUTHORSHIP (IF ANY)

### Intellectual Property rights:

- The Parties shall ensure the appropriate IPR protection of each other on IPRs generated through activities arising out of mutual cooperation
- In case of research results obtained through joint activities, the grant of IPR will be sought by both the Parties jointly and once granted these rights will jointly be owned by both parties
- The Parties shall not assign any rights and obligations arising out of the IPR generated pursuant to cooperation activities under this MOA to any third party without the prior written consent of the other Party.

### Commercialization:

In case of research results obtained through joint activities under this MOA, both Parties shall apply as co-applicants and co-investigators for the protection of IPR subject to exclusive rights of both Parties to commercialize the technology or product(s).

### Publications:

The ICMR Centre for Advanced Research – ICRA-2 will be involved in multiple studies across 40 centers in about 21 states of India. There is scope for numerous publications.

A writing group comprising some of the members of Steering Committee (SC) and others who made substantial contributions, will lead or participate in different publications. This committee will be responsible for writing the primary papers. Investigators from different sites who made significant contributions will be either acknowledged or included as co-authors. The quantum of contribution will be decided by the steering committee. All study papers depending on their contribution will be sent to ICMR for approval before publication.

For subsequent publications, investigators and others, will be invited to submit proposals to the SC to lead and, or participate in manuscript preparation. Named authorship will strictly adhere to the policies of the journals to which the papers are submitted. Investigators from all participating sites who have made the required minimum contribution will be listed as investigators or co-authors as per the journal's guidelines and decisions of the steering committee.



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All publication policies and guidelines, including authorship decisions, will be approved by the SC.

#### **ARTICLE VII: CONFIDENTIALITY**

- a) During and thereafter the term of this MOA, each Party, their affiliates or employees shall not disclose any confidential information of the other Party
- b) Neither Party shall make any public announcement related to the scientific research outcome, or commercialization for work which has arisen out of the joint activities, without the prior written consent of the other Party to protect their intellectual property rights.
- c) All information and documents to be exchanged pursuant to the MOA will be kept confidential by the Parties and will be used subject to terms as each Party may specify.
- d) The Parties will not use the information for purposes other than that specified without the prior written consent of the other Party
- e) Such information shall not be transmitted or shared with any Third Party unless agreed by both or all Parties.

#### **ARTICLE VIII: ETHICAL ISSUES/ TRANSFER OF BIOLOGICAL MATERIAL/DATA SHARING**


- a) Both Parties mutually agree on the importance of the protection of human subjects in any health program/research. In recognition of this, both Parties have adopted laws and regulations on the protection of human subjects, including the transfer of data and intend to follow the same in accordance with the applicable laws, regulations, and policy of each Party.
- b) No animals will be involved in this research collaboration
- c) No transfer of biological material will be involved in this research collaboration.
- d) Both Parties agree with each other that the investigators in pursuant of the work under this MOA can share their published findings with the relevant institutions articulating how the work informs policy and practice in both the Institutes
- e) The Parties encourage the investigators in pursuant of the work under this MOA to put the data arising from the funded work into open access.

#### **ARTICLE IX: DISPUTES AND THEIR RESOLUTION**

9.1 Any dispute arising out of the interpretation or implementation of this MOA shall be settled amicably through consultation and negotiations between the Principal Investigators as authorized by the Parties. If it fails to settle amicably after 3 rounds of talks/negotiations, the MOA can be terminated. In disputes related to the IPRs or their commercialization, both parties shall mutually decide the procedure for the appointment of an arbitrator for dispute resolution and the same shall be binding to all the parties. The place of arbitration preferably where the cause of action arises for any action, suit or proceeding (other than appeals therefrom) arising out of or relating to this Agreement, and agree not to commence any action, suit or proceeding (other than appeals therefrom) related thereto except in such courts.

9.2 The language of the arbitration shall be English and any cost arising out of the arbitration

  
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shall be borne by the investigators pursuant to joint research works under this MOA.

9.3 Any notice required shall be in writing and delivered to the addresses specified below. Delivery shall be deemed received as follows - if prior to 4:00 pm on a business day in the jurisdiction of the recipient and otherwise on the next business day by: (a) personal delivery, when delivered personally; (b) courier, upon courier's verification of delivery; successfully received transmission at recipient's location or (d) electronic mail transmission successfully received by the recipient.

**If to CCC (institution):**

The Dean, St. John's Research Institute  
a unit of CBCI Society for Medical Education  
St. John's National Academy of Health  
Sciences  
Johnnagar, Bangalore  
560 034, India  
Tel: +91 80 49467001  
Fax: +91 80 25501088  
Email: deansoffice@sjri.res.in

**If to CCC (Principal Investigator)**

Dr. Denis Xavier  
Head - Division of Clinical Research &  
Training  
St. John's Research Institute  
St. John's National Academy of Health  
Sciences  
Johnnagar, Bangalore-560 034, India  
Tel: +91 80 49466140, +91 80 4946010, +91  
80 49467080 Fax: +91 80 49467090  
Email: [denis@sjri.res.in](mailto:denis@sjri.res.in)

**If to Site (Institution)**

BLDE DU's Shri B. M. Patil Medical College,  
Hospital and Research Centre, Vijayapura,  
Karnataka - 586103.  
Tel: - +918352-262770  
Fax: - +918352-263019  
Email: registrar@bldedu.ac.in

**If to Site (Investigator):**

Dr. Shailaja S Patil, Prof. Community  
Medicine, SBMPMC  
Tel: +91 9448820464  
Fax: -  
Email: shailaja.patil@bldedu.ac.in

**ARTICLE X: EXCLUSIVITY**

The Parties understand that this relationship is not exclusive and that entering into this MOA will not prevent either Party from associating with any other Party for the purpose of conducting similar programs.

**ARTICLE XI: OBLIGATIONS**


This MOA is not intended to create a binding, legal or financial obligations between the Parties.

**ARTICLE XII: VALIDITY**

This MOA is written and signed in English in two copies. The present MOA will come into force as soon as it has been signed by the authorized representatives of the two institutions. It will remain in force till Oct 2025 (one year) from the date of execution and may be renewed for an additional one year upon mutual consent.

  
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### ARTICLE XIII: AMENDMENT

Amendments, revisions or modifications to this MOA may be proposed by either Party at any time during the term of the MOA and shall be effective from the date of the written agreement signed by both parties. These amendments shall serve as integral parts of this MOA.

### ARTICLE XIV: TERMINATION

The agreement may be terminated by the authorized official representative of either institution by written notice. Such notice must be given at least three months before it becomes effective. Such termination shall not affect the completion of any activity underway at the time or the rights of individuals exchanged under this agreement, prior to the notice of termination.

### ARTICLE XV: FORCE MAJEURE






In the event that performance of a Party's obligations are prevented by events beyond its reasonable control, including but not limited to, acts of God, regulations or acts of any governmental authority, war, civil commotion, strikes, other labor disturbances, epidemics, fire, earthquakes, storms or other catastrophes of a similar nature, the affected Party will notify the other Parties as soon as reasonably possible and the affected Party shall be relieved of its obligations for the duration and to the extent the performance of an obligation is prevented thereby. During the existence of any such condition, the affected Party shall use diligent efforts to remove the cause and resume performance of its obligations.

  
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**In Witness thereof, the Parties have signed this MOA.**

This MOA is signed in two originals in English on \_\_\_\_\_ (Date) in \_\_\_\_\_ (City, Country)

Sl no	The Parties	Signature with date
<b>For Central Coordinating Centre</b>		
1.	<b>CBCI Society for Medical Education</b> <b>Secretary</b> <i>Rev. Fr. Jesudoss Rajamanickam</i>	 18/10/24 <b>SECRETARY</b> C.B.C.I. SOCIETY FOR MEDICAL EDUCATION JOHN'S NATIONAL ACADEMY OF HEALTH SCIENCES SARJAPUR ROAD, BANGALORE - 560 034
2.	<b>Dr Tony D.S Raj</b> <b>Dean, St John's Research Institute,</b> <b>Bangalore</b>	 <b>DEAN</b> St. John's Research Institute St. John's National Academy of Health Sciences Koramangala, Bangalore - 560 034, INDIA
3.	<b>Dr. Denis Xavier</b> <b>Head, Dept. of Pharmacology</b> <b>Head, Division of Clinical Research and</b> <b>Training</b>	 24/8/2024
<b>For Participating Site</b>		
4.	<b>Institution Head</b> <b>Dr. R.V. Kulkarni, Registrar, BLDE</b> <b>(Deemed to be University)</b>	 <b>REGISTRAR</b> BLDE(Deemed to be University) Vijayapura-586103. Karnataka
5.	<b>Site Investigator</b> <b>Dr. Shailaja S Patil, Prof. Community</b> <b>Medicine, SBMPMC</b>	

On behalf of Party 1

Date: 19/0/24

Witnesses

*Prof*  
Dr. Geeta Bharti Rai  
Director of Clinical Research  
St. John's Research Institute

2.

*Niraj*  
Dr. Niraj Arimondan  
Director of Clinical  
Research & Training  
St. John's Research  
Institute

On behalf of Party 2

Date:

Witnesses

1. Dr. M. M. Patil, Director R & D Cell

2. Mr. B.S. Patil, Finance Officer (I/c)

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**Appendix -I**  
**(RESEARCH FUNDING)**

Site payments

Details	Amount (Rs)
Each site will receive after completing Cross sectional survey for 150 participants	
1. Instalment-I ( advance for 50 participant recruitment)	Rs.10,000
2. Instalment-II (After Completing 50 participants)	Rs.10,000
3. Instalment-III (After Completing 50 participants)	Rs.10,000
<b>Total</b>	<b>Rs. 30,000/-</b>
<ul style="list-style-type: none"><li>• Advance(1<sup>st</sup> Installment ) will be released on final execution of the agreement</li><li>• Above payment is inclusive of all the applicable taxes</li><li>• Subsequent installment will be released based on the target completion &amp; settlement of previous advance provided.</li></ul>	

  
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## Appendix-II

### Payment rule form

Payments will be made to only one party. <b>(ALL INFORMATION BELOW MUST BE LEGIBLE)</b>	
The following information is required in order to generate electronic payment. Incomplete information will result in no payment.	
Bank Name:	State Bank of India
Bank Address:	BLDE Campus Branch, BLDE Campus, Sholapur Road, Bijapur, Dist. Bijapur 586103
Bank SWIFT code:	SBININBBH16
IFSC Code (if applicable):	SBIN0014429
Beneficiary (Account Holder) Name:	BLDE DEEMED TO BE UNIVERSITY
Beneficiary Address:	BLDE University Ashram Road Bijapur (Karnataka)
Beneficiary Account number:	00000032093001882
Reference (if applicable):	
Contact name and email for payment notification:	Mr. B. S. Patil / Email: finance.bldeu@bldea.org
Tax ID # / GST Registration #:	29AAAAB7055P1Z9

  
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