AMENDMENT NO. 1 TO SUBCONTRACT NUMBER 43339-BLDE
BY AND BETWEEN
EMORY UNIVERSITY
AND
BLDE (Deemed to be UNIVERSITY), INDIA
UNDER
USC (BMGF) AWARD 18-3594 (OP1110043)

EMORY PI: Argeseanu, Solveig
AWARD No.: 0000043339
SUBRECIPIENT PI: Patil, Shailaja

This Amendment (the "Amendment") to the Subaward Agreement dated October 4th, 2018 between Emory University ("EMORY") and BLDE (Deemed to be University), India ("SUBRECIPIENT") is made and entered into on RECITALS

A. WHEREAS, EMORY and SUBRECIPIENT entered into that certain Subaward Agreement (the "Agreement") regarding conduct of a Project, as identified in the Agreement with funding from the Prime Agency identified in the Agreement.

B. AND, WHEREAS EMORY and SUBRECIPIENT now desire to amend the Agreement as set forth below;

NOW, THEREFORE, in consideration of the foregoing and the mutual promises herein contained, the parties agree to amend the Agreement as follows:

12. SUBAWARD PERIOD OF PERFORMANCE
The subaward period of performance is extended through March 31, 2020.

13. SUBAWARD AMOUNT
Additional funding is provided to the SUBRECIPIENT to continue to perform the work in support of the SUBAWARD, in the amount of $44,024 per the attached budget. The total funding obligated to date to the SUBAWARD is modified from $56,259 to $100,283.
Automatic carryover of funds from one budget period to another budget period is permitted.
Email invoices to katherine.carey@emory.edu.

Prime Award: The Prime Sponsor Continuation Notice of Award is attached and incorporated in the amendment.

The Subawardee shall continue to perform the specified services as outlined in the original subaward. All other terms and conditions remain the same.

Other than the changes, modifications and additions specifically articulated in this Amendment, the provisions of the original Agreement by and between EMORY and SUBRECIPIENT remain in effect and

are still binding on and against EMORY and SUBRECIPIENT. Unless expressly modified or added in this Amendment, the terms and conditions of the original Agreement are expressly incorporated into this Amendment as if restated.

IN WITNESS WHEREOF, the respective Parties have executed this Amendment effective as of the date of last signature below.

Emory University	BLDE (Deemed to be University), India
Maggie Hassan Associate Director Office of Sponsored Programs	DR S P GUGGARIGOUDAR. PRINCIPAL BLDE (Deemed to be University) Shri B. M. Patil Medical College Hospital & Research Centre, VIJAYAPUR-586103
April 22, 2019 Date	Date 21-03-2019

DFC Competitive Grants Program Budget Worksheet: Year 2

Project Begin Date:	
Project End Date:	
Number of years:	1

Total Dollar Amount: $ 44,024

PERSONNEL

Name	Title	% Effort	Months	Annual Salary	Total Salary	Total Fringe Benefits	Total Cost
Dr.Shalaja Patil	Co-Investigator	35%	4.20	$ 10,262.00	$ 10,262.00	$ 307.86	$ 10,569.86
TBN	Project coordinator	100%	12.00	$ 6,792.00	$ 6,792.00	$ 203.76	$ 6,995.76
TBN	Budget manager /assistant	100%	12.00	$ 938.00	$ 938.00	$ 28.14	$ 966.14
TBN	Computer assistant / data e	100%	6.00	$ 2,250.00	$ 1,125.00	$ 33.75	$ 1,158.75
TBN	Field supervisor (1)	100%	6.00	$ 2,813.00	$ 2,813.00	$ 84.39	$ 2,897.39
TBN	Field staff (interviewer) (4)	100%	6.00	$ 2,438.00	$ 1,219.00	$ 36.57	$ 5,022.28
TBN	Research Assitant			$ 3,500.00	$ 3,500.00		$ 3,500.00
				$ -	$ -	$ -	$ -
				$ -	$ -	$ -	$ -
					PERSONNEL SUBTOTAL		$ 31,110

EQUIPMENT (Cost > 5,000.00 USD)

Equipment Name/Description:	Justification:	Quantity:	Cost per unit	Total	Additional Notes:
			$ -	$ -	
			$ -	$ -	
			$ -	$ -	
			$ -	$ -	
				EQUIPMENT SUBTOTAL	$ -

SUPPLIES (Cost < 5,000.00 USD)

Supplies Name/Description	Justification:	Quantity:	Cost per unit:	Total	Additional Notes:
recurring stationery expenses	office use	12	$ 50.00	$ 600.00	
phone charges/internet/sim cards	field work coordination	6	$ 28.00	$ 168.00	
Monthly Internet WIFI rental charges	Office internet use, skype calls etc.,	12	$ 24.00	$ 288.00	
antivirus	protection of data in computer	1	$ 48.00	$ 48.00	
			$ -	$ -	
			$ -	$ -	
			$ -	$ -	
			$ -	$ -	
			$ -	$ -	
			$ -	$ -	
				SUPPLIES SUBTOTAL	$ 1,104

TRAVEL

Destination:	Justification:	Quantity:	Cost per unit:	Total	Additional Notes:
Local Travel and Field Work	vehicle hiring for field work	0.5	$ 8,555.00	$ 4,277.50	
Travel to meetings inside country	state level food supply officers and policy peopl			$ 250.00	
			$ -	$ -	
			$ -	$ -	
			$ -	$ -	
				TRAVEL SUBTOTAL	$ 4,528

OTHER EXPENSES (Other Than Supplies)

Expense:	Justification:	Quantity:	Cost per unit:	Total	Additional Notes:
Incentives(Participant)	participation in data collectior	800	$ 4.00	$ 3,200.00	
Hard disk	to store data as back up	1	$ 80.00	$ 80.00	
			$ -	$ -	
			$ -	$ -	
			$ -	$ -	
				OTHER EXPENSES SUBTOTAL	$ 3,280

TOTAL DIRECT EXPENSES	$	40,022
INDIRECT (10%)	$	4,002
GRAND TOTAL	$	44,024

Subaward Amendment

Prime Awardee	Subawardee
Institution/Organization ("UNIVERSITY") Name: University of South Carolina Address: Office of Sponsored Awards Management 1600 Hampton Street, Suite 414 Columbia, South Carolina 29208 PI: Christine Blake	Institution/Organization ("COLLABORATOR") Name: Emory University 1599 Clifton Road Atlanta, Georgia 30322 PI: Dr. Solveig Argeseanu Cunningham
Prime Award No. OPP1110043	Subaward No. 18-3594 (11540-KA56)
PO No. 2000038671	Amendment No. One

Amendment(s) to Original Terms and Conditions

The purpose of this amendment is to extend the end date and increase the budget.

Emory University agrees to perform the work supportive of Grant No. OPP1110043 for the performance period of January 1, 2018 to March 31, 2020.

Compensation is hereby increased by $129,708 for the budget period January 1, 2019 to March 31, 2020 as indicated in Attachment A. The maximum amount to be reimbursed under this subaward is $270,000. Invoices referencing PO No. 2000038671 shall be submitted to Dr. Blake not more often than monthly. The final invoice must be submitted within forty-five (45) days after the expiration of this subaward.

All other terms and conditions of the agreement remain unchanged.

By an Authorized Official of UNIVERSITY: 11/8/18 Name: Nida Reid-Williamson Date Title: Team Leader, SPA Sponsored Awards Management	By an Authorized Official of COLLABORATOR: 11/8/18 Name: Janette Hannam Hayes Date Title: Associate Director for Research

SUBAWARD AGREEMENT
BY AND BETWEEN
EMORY UNIVERSITY
AND
BLDE (Deemed to be UNIVERSITY) , INDIA

This SUBAWARD Agreement, entered into this 4th day of October 2018, by and between Emory University (hereinafter "EMORY") and BLDE (Deemed to be University) , India (hereinafter "SUBRECIPIENT") is for the purpose of conducting work related to the Project defined below for which EMORY has received prime funding by the PRIME AGENCY identified below.

1.	**EMORY SUBAWARD/PO NUMBER:**	43339-BLDE
2.	**SUBRECIPIENT NAME AND ADDRESS:**	BLDE (Deemed to be University) Shri B M PMCH&RC, Vijayapura, Smt. Bangaramma Sajjan Campus, Solapur Road, Vijayapura, Karnataka, INDIA 586103
3.	**SUBRECIPIENT DUNS NUMBER:**	N/A
4.	**SUBRECIPIENT ADMINISTRATIVE CONTACT:**	Dr. Shailaja S. Patil, shailaja.dr@gmail.com, 08352262770 extn2111 91-9448820464
5.	**PRIME AGENCY:**	University of South Carolina (under a grant from Bill & Melinda Gates Foundation)
6.	**PRIME AWARD NUMBER:**	18-3594 (OP1110043)
7.	**PRIME AWARD DATE**	January 1, 2018
8.	**PROJECT TITLE:**	Food choices in Indian households during the Nutrition Transition
9.	**A. EMORY PRINCIPAL INVESTIGATOR:**	Argeseanu,Solveig
	B. SUBRECIPIENT PRINCIPAL INVESTIGATOR:	Patil, Shailaja S.
10.	**EMORY ADMINISTRATIVE CONTACT:**	Maggie Hassan Office of Sponsored Programs Emory University 1599 Clifton Road NE, 4th Floor 1599-001-1BA Atlanta, GA 30322

11.	**EMORY INVOICE CONTACT (NAME; PHONE; E-MAIL):**	_Katherine Carey katherine.carey@emory.edu, (470)259-0297
12.	**SUBAWARD PERIOD OF PERFORMANCE:**	From January 1, 2018 Through December 31, 2018
13.	**SUBAWARD AMOUNT (FUNDS OBLIGATED THIS ACTION):**	
14.	**AGREEMENT TYPE:**	☒ Cost-reimbursement ☐ Fixed Fee
15.	**RESEARCH & DEVELOPMENT SUBAWARD?**	☒ Yes ☐ No

16. **SUBAWARD PURPOSE AND PROJECT PERSONNEL:** The purpose of this Agreement is to support SUBRECIPIENTS's participation in the Project identified in Article 8, above. A description of the Project is attached as Exhibit A, "Statement of Work," and incorporated herein by reference. The SUBRECIPIENT shall supply all the necessary personnel, equipment, and materials (except as otherwise may be provided herein) and shall use all reasonable effort to perform the research tasks set forth in the Statement of Work described in Appendix A, which is attached and made a part hereof, which is an integral part of the PRIME AWARD attached in APPENDIX D hereto.

SUBRECIPIENT has been selected to participate in this Project at EMORY'S discretion. SUBRECIPIENT may not make any statement or otherwise imply to donors, investors, media or the general public that it is a direct grantee of the Bill & Melinda Gates Foundation ("Foundation") or the Department for International Development of the United Kingdom of Great Britain and Northern Ireland ("DFID") (Funders). SUBRECIPIENT may state that University of South Carolina is the Foundation and DFID's grantee and that SUBRECIPIENT IS a sub grantee, subcontractor or subawardee of EMORY for the Project.

The EMORY Principal Investigator ("PRINCIPAL INVESTIGATOR"), who is the technical representative of EMORY, is identified in Article 9A above. PRINCIPAL INVESTIGATOR shall retain the responsibility for supervision of this Project. PRINCIPAL INVESTIGATOR must approve any change in the Statement of Work, in writing.

The scientific and technical direction of SUBRECIPIENT's portion of the Project as set forth in the Statement of Work shall be under the direction of SUBRECIPIENT Principal Investigator ("SUBRECIPIENT INVESTIGATOR") as identified in Article 9B above.

SUBRECIPIENT INVESTIGATOR is considered to be essential to the work performed hereunder. In the event this person leaves SUBRECIPIENT or is reassigned to another program, SUBRECIPIENT shall notify EMORY immediately in writing. In addition, any individual(s) appointed to replace SUBRECIPIENT INVESTIGATOR must have the prior written approval of EMORY. If any individual(s) is/are not acceptable to EMORY, EMORY shall issue a modification terminating this Agreement. SUBRECIPIENT will be reimbursed for its costs properly incurred through such termination date.

17. **TERM:** The term of this Agreement is as specified in Article 12, SUBAWARD Period of Performance, above. Any change of the SUBAWARD Period of Performance, including extensions, requires written modification to this Agreement, signed by both parties. No expenses that are incurred prior to the effective date or subsequent to the termination date of the SUBAWARD Period of Performance will be reimbursed.

18. **AWARD AMOUNT, INVOICING AND PAYMENT:** Funds provided for SUBRECIPIENT's involvement in this Agreement shall not exceed the amount specified in Article 13 above. All award funds specified are in U.S. dollars. A line item budget for these funds is attached as Appendix B, which is attached and made a part hereof.

Invoices submitted under this Agreement must be accompanied by copies of general ledger printouts, labor distribution and/or payroll reports, as applicable, for expenses requested for reimbursement. Failure to submit such supporting documentation will delay payment. Emory reserves the right to request further detailed expenditure documentation in its sole discretion.

SUBRECIPIENT shall invoice EMORY quarterly. All invoices must be in U.S. dollars. When converting local currency to U.S. dollars for submission of an invoice, SUBRECIPIENT shall use the currency exchange rate in effect on the last date of the invoicing period. EMORY reserves the right to request detailed expenditure documentation from SUBRECIPIENT. A sample invoice is attached as Appendix C, which is attached and made a part hereof. All invoices must reference the EMORY SUBAWARD/PO Number specified in Article 1. Invoices that do not reference this number may be returned to SUBRECIPIENT for correction prior to payment.

Invoices must also include the following certification: "By signing this report, I certify to the best of my knowledge and belief that the report is true, complete, and accurate, and the expenditures, disbursements and cash receipts are for the purposes and objectives set forth in the terms and conditions of the Federal award. I further certify that payment made by EMORY under this Agreement shall not duplicate reimbursement of costs and services which are received from other sources. I am aware that any false, fictitious, or fraudulent information, or the omission of any material fact, may subject me to criminal, civil or administrative penalties for fraud, false statements, false claims or otherwise.

Invoices for payment shall be sent via e-mail as a PDF attachment to the EMORY Invoice Contact identified in Article 11, above. The final invoice of expenditures, clearly marked as "FINAL," shall be sent no later than sixty (60) days after the SUBAWARD Period of Performance end date as specified in Article 12 above. Final invoices received after sixty (60) days following the termination date of this Agreement shall be honored for payment at the discretion of EMORY unless another date for submission is agreed upon in advance by EMORY and
SUBRECIPIENT.

Final payment under this Agreement shall be predicated upon receipt and acceptance by EMORY of all services, reports, and/or supplies called for hereunder. EMORY reserves the right to withhold final payment until receipt and acceptance of all services, reports, and/or supplies called for hereunder. All services, reports, and/or supplies called for hereunder must meet all specifications as set forth herein and be to EMORY's reasonable satisfaction.

Questions regarding invoices and payment should be directed to the EMORY Invoice Contact identified in Article 11, above.

19. **REBUDGETING OF FUNDS:** It is understood that SUBRECIPIENT's budget as set forth in Appendix B is an estimate and there may be need to depart from it to meet certain unanticipated requirements of the Project. Any Budget cost category change of more than 10% must be approved in writing by EMORY in advance. SUBRECIPIENT must submit a request for the Rebudgeting of funds that require prior approval to EMORY for forwarding to PRIME AGENCY for approval. SUBRECIPIENT may not use the funds to reimburse any expenses incurred prior to the Start Date.

20. **EQUIPMENT:** Title to real property, equipment, and supplies acquired under this Agreement shall vest upon acquisition, in SUBRECIPIENT. EMORY reserves the right to require transfer of items of equipment (including title) having a unit acquisition cost of $ 5,000 or more if the Project for which the SUBRECIPIENT acquires the equipment is acquired is transferred to another subrecipient.

21. **AUDIT AND RECORD RETENTION:** The accounting for funds provided under this Agreement shall be in accordance with generally accepted accounting principles consistently applied. SUBRECIPIENT shall maintain records to support identifiable charges to this Agreement. All costs reimbursed for the performance of this Agreement will be subject to audit by either EMORY or the PRIME AGENCY, and SUBRECIPIENT agrees to allow auditors access to its records pertinent to this Agreement during normal business hours. SUBRECIPIENT's financial records for this Agreement shall be retained for a period of three (3) years, beginning from the date of the receipt of payment of the final invoice.

    SUBRECIPIENT assumes sole responsibility for reimbursement to EMORY of a sum of money equivalent to the amount of any expenditure disallowed, should EMORY, the PRIME AGENCY or any authorized agency rule through audit exception, or some other appropriate means, that expenditures from funds allocated to SUBRECIPIENT through EMORY for direct and/or indirect costs were not made in compliance with the terms of this Agreement or the regulations of the Prime Agency of this Agreement. In addition, SUBRECIPIENT is responsible for repayment of any monies required to be returned to Prime Agency as a result of SUBRECIPIENT breach of this Agreement.

22. **TECHNICAL REPORTING PROCEDURES:** SUBRECIPIENT will be required to keep clear and accurate records of the procedures conducted and data collected through the SUBAWARD Period of Performance so that the progress of the study may be readily evaluated at any time by the EMORY PRINCIPAL INVESTIGATOR designated in Article 9A above. In addition, SUBRECIPIENT shall submit a final technical report within sixty (60) days of expiration or termination of this Agreement.

23. **PUBLICATIONS:** All research reports and other publications relating to the work under this Agreement shall be prepared in consultation with the EMORY PRINCIPAL INVESTIGATOR designated in Article 9A above. At a minimum, for any publication or press release describing research that has been funded in whole or in part by the Drivers of Food Choice Competitive Grants Program, under this Agreement shall:
    A. Bear proper acknowledgement as follows:
        i) Publication: This research has been funded by the Drivers of Food Choice (DFC) Competitive Grants Programs, which is funded by the UK Government's Department for International Development and the Bill & Melinda Gates Foundation, and managed by the

University of South Carolina, Arnold School of Public Health, USA; however, the views expressed do not necessarily reflect the UK Government's official policies.

ii) Press release: This research has been funded by the Drivers of Food Choice (DFC) Competitive Grants Programs, which is funded by the UK Government's Department for International Development and the Bill & Melinda Gates Foundation, and managed by the University of South Carolina, Arnold School of Public Health, USA.

B. Be submitted to the EMORY PRINCIPAL INVESTIGATOR designated in Article 9A above in the form of advance copies for review and comment prior to publication to ensure appropriate coordination of research results.

SUBRECIPIENT further grants to EMORY an irrevocable, royalty-free, non-transferable, non-exclusive right and license to use, reproduce, make derivative works, display, and perform publicly any copyrights or copyrighted materials (including any computer software and its documentation and/or databases) first developed and delivered under this Agreement for the purpose of and to the extent required to meet EMORY's obligations under its PRIME AWARD.

24. **DATA RIGHTS:** Subject to its legal ability to do so, the SUBRECIPIENT shall grant to EMORY the right to use data created in the performance of this Agreement for the purpose of education and research or to the extent required to meet EMORY's obligations under its PRIME AWARD.

25. **TERMINATION**: Either SUBRECIPIENT or EMORY may terminate this Agreement for any reason upon thirty (30) days prior written notice to the other party. EMORY reserves the right to terminate this Agreement within five (5) days written notice if EMORY determines SUBRECIPIENT to be in significant breach of this Agreement. If at any time EMORY's PRIME AWARD is terminated by PRIME AGENCY, this Agreement shall also be terminated immediately upon receipt by SUBRECIPIENT of written notice to that effect from EMORY. SUBRECIPIENT shall be reimbursed for all allowable costs and any non-cancelable obligations properly incurred prior to the date of termination, provided that such costs shall not exceed the amount allowed under this Agreement and that a report of progress to date of termination has been submitted to EMORY. Nothing in this article is intended to abrogate the Parties' right to mutually terminate this Agreement on such other terms as may be agreed upon.

26. **REGULATORY DATA:** All administrative and regulatory data required by PRIME AGENCY shall be applicable to this Agreement as appropriate. All conditions referenced in the PRIME AWARD to EMORY by PRIME AGENCY shall become binding upon SUBRECIPIENT. A copy of the award terms and conditions, and any applicable regulatory requirements, are included in Appendix D, which is attached and made a part hereof.

27. **INDEMNIFICATION:** SUBAWARDEE agrees to indemnify, defend and hold harmless EMORY and the FOUNDATION from and against any and all liability, loss, expense (including reasonable attorney's fees) or claims for injury or damages arising out of or resulting from, or alleged to arise out of or result from, the actions or omissions by SUBAWARDEE or by any of SUBAWARDEE's officers, agents, employees, subgrantees, contractors or subcontractors with respect to this Agreement or the PROJECT. SUBAWARDEE also agrees to assume responsibility for all liability for damages and injuries (including reasonable attorney's fees) which may arise or result from the actions or

omissions of SUBAWARDEE's lower-tier subawardees and contractors or any of their officers, agents or employees.

SUBAWARDEE acknowledges and agrees that any activities by EMORY or the FOUNDATION in association with this Agreement or the PROJECT, such as the review or proposal of suggestions to the PROJECT, or any other activity in association with this Agreement or the PROJECT, will not modify, or constitute the basis for any claim of waiver by SUBAWARDEE of, Emory's or the FOUNDATION's rights under this paragraph.

28. HUMAN SUBJECTS: If human subjects are used in the conduct of the work supported by this Agreement, SUBAWARDEE warrants by the execution of this Agreement that SUBAWARDEE is in compliance with the applicable laws, regulations, and policies applicable to research involving human subjects. EMORY and SUBAWARDEE agree that both the Institutional Review Board (IRB) for EMORY and the IRB and/or Ethics Committee (EC) for SUBAWARDEE will review and have continuing oversight for the PROJECT. This review and continuing oversight will meet the human subjects' protection requirements of any and all applicable laws governing the IRB of EMORY and IRB/EC of SUBAWARDEE. Such review and continuing oversight also shall satisfy the requirements of the IRB of EMORY and the IRB/EC of SUAWARDEE. SUBAWARDEE agrees to provide annual certification to EMORY that an institutional committee has reviewed and approved the procedures that involve human subjects. SUBAWARDEE further agrees to provide notification to EMORY if the procedures that involve human subjects have been amended or modified, as well as when adverse events are reported. SUBAWARDEE shall bear full responsibility for the proper and safe performance of all work and services involving the use of human subjects under this Agreement.

28.1 EMORY and SUBAWARDEE agree that Emory's IRB and SUBAWARDEE IRB/EC will review and have continuing oversight over the PROJECT. This review and continuing oversight will meet the human subjects' protection requirements of all applicable laws. In addition, the review and continuing oversight will meet any requirements of EMORY or SUBAWARDEE'S Human Research Protections Program. At a minimum, this review and continuing oversight shall ensure compliance with the following requirements for any research conducted pursuant to this Agreement: 28.1.1 Determining that protections for human research subjects are adequate.

28.1.2 Ensuring that legally effective informed consent is obtained. Such consent shall include information on what care and/or referrals will be available through participation in the
PROJECT.

28.1.3 Ensuring that, when identifiable protected health information (PHI) is used, proper means, including subject authorization, are in place for gaining access to, using and/or disclosing the information under the U.S. Health Insurance Portability and Accountability Act (HIPAA) regulations (45 CFR Part 164) if the PHI is used or disclosed in the United States at an Emory unit or other entity that is a covered entity under applicable HIPAA regulations.

28.1.4 Ensuring that changes to the PROJECT are reviewed and approved, modified or disapproved, by Emory's and SUBAWARDEE'S pertinent IRBs as appropriate.

28.1.5 Ensuring that adequate documentation of IRB review activities, including minutes of meetings at which any pertinent protocols are discussed, are maintained at Emory's

IRB and SUBAWARDEE'S IRB, as applicable, with copies of relevant portions of such documentation being provided upon request by SUBAWARDEE to Emory, or vice-versa.

28.1.6 Ensuring that each reviewing IRB, in accordance with its procedures, reports its findings and actions regarding the PROJECT to the Administrative Contact officials for both Emory and SUBAWARDEE.

28.1.7 Reporting the following items to the Administrative Contact officials for EMORY and SUBAWARDEE:

28.1.7.1 Any serious or continuing non-compliance by persons involved in the PROJECT at EMORY's or SUBAWARDEE's facilities;

28.1.7.2 Any suspension or termination of IRB approval of the PROJECT;

28.1.7.3 Any injuries to human subjects caused by the PROJECT.

28.1.7.4 Any unanticipated problems involving risks to subjects or others from the PROJECT.

28.1.7.5 Any IRB-reviewed and approved changes in the PROJECT.

28.2 SUBAWARDEE acknowledges and agrees that funds from the Award have not been set aside to provide care and/or referrals to any human subject participants or employees of SUBAWARDEE who are injured as a result of participation in this PROJECT.

29. **SUBJECT CONFIDENTIALITY (HIPAA):** EMORY and SUBRECIPIENT agree to comply with the restrictions in any subject Authorization (as defined below) regarding the use, disclosure and confidentiality of any individually identifiable health information and further agree to comply with all applicable federal and state laws and regulations governing the security and privacy of the individually identifiable health information, including HIPAA, to the extent required by such federal and state laws and regulations, including HIPAA. .

Prior to participation of any human subject in the Project, SUBRECIPIENT will ensure that a properly executed written consent and authorization approved by its IRB or other designated IRB/Privacy Board (the "Authorization") is obtained from each human subject or the subject's authorized representative to document the subject's express written Authorization for the use by SUBRECIPIENT, and the disclosure to and use by EMORY, when applicable, of protected health information when required under HIPAA. SUBRECIPIENT and EMORY will cooperate in the amendment of the Authorization or other documents as may be necessary from time to time, to comply with HIPAA to the extent HIPAA applies to SUBRECIPIENT or EMORY to ensure the Project data may be used by SUBRECIPIENT or EMORY for the purposes specifically identified in this Agreement and the Authorization.

30. **ANIMAL SUBJECTS RESEARCH:** No live vertebrate animals are used in the conduct of the work supported by this Agreement.

31. **RECOMBINANT DNA RESEARCH OUTSIDE OF THE U.S:** Recombinant DNA research must be in compliance with the U.S. guidelines and laws, unless the country in which such research is being carried out has adopted guidelines comparable to those of the U.S. and EMORY has approved such guidelines.

32. **ASSIGNMENT AND SUBCONTRACTING:** SUBRECIPIENT shall not assign, transfer or subcontract its interests or obligations hereunder without the written consent of EMORY. Any such assignment, transfer, or subcontract shall be null and void automatically. In the case that the SUBRECIPIENT is approved to subcontract, the SUBRECIPIENT is responsible for flowing down the terms of this agreement to lower tier subcontractors. Any agreements with lower tier subcontractors SUBRECIPIENT engages to assist with the Project must include the following language: "Your organization has been selected to participate in this Project at the discretion of the University of South Carolina, and Emory University. You may not make any statement or otherwise imply to donors, investors, media or the general public that you are a direct grantee of the Bill & Melinda Gates Foundation ("Foundation") or the Department for International Development of the United Kingdom of Great Britain and Northern Ireland ("DFID")."

33. **INSURANCE:** Each Party certifies that it has and shall maintain sufficient insurance or a program of self-insurance at levels sufficient to support its obligations assumed under this Agreement. Each Party agrees to provide the other Party written certification of such insurance or self-insurance coverage upon written request.

34. **TRADE CONTROL LAWS:** SUBRECIPIENT acknowledges that this Agreement and the performance thereof are subject to compliance with any and all applicable U.S. and non-U.S. trade control laws, regulations, or orders, including but not limited to the economic sanctions programs administered by the United States Department of Treasury Office of Foreign Assets Control and the export control regulations administered by the U.S. Office of the Directorate of Defense Trade Controls and/or the U.S. Bureau of Industry and Security. SUBRECIPIENT acknowledges that the export, re-export or transfer of certain commodities, software, source code, technical data or services may require a license from the relevant regulating agency of the U.S. or other government. In particular, SUBRECIPIENT agrees it will not disclose, transfer, export or re-export any commodities, software, source code, technical data or services received under this Agreement to any countries for which the United States government requires an export license or other supporting documentation at the time of export or transfer, unless SUBRECIPIENT has obtained the required license or other prior written authorization from the appropriate U.S. authority responsible for such matters. While EMORY agrees to cooperate in securing any license that the regulating agency deems necessary in connection with this Agreement, EMORY cannot guarantee that such licenses will be granted.

    The parties represent, warrant, and agree that they have not taken, and will not take, any action related to or arising out of this Agreement, which in any way violates, or aids or abets any violation of, the United Kingdom Bribery Act, the United States Foreign Corrupt Practices Act, or the applicable anti-corruption laws of any country. Specifically, and not in limitation of the foregoing, the parties represent, warrant, and agree that they have not, and will not, in connection with this Agreement, directly or indirectly request, give, pay, offer or promise to give or pay, or authorize another party to give or pay any money or anything of value to any person (whether or not such person is a government official), for the purpose of influencing any act or decision of such entity or person or inducing such person to take or omit to take any action in order to secure a business advantage or any improper advantage.

    SUBRECIPIENT will promptly notify Emory of any event which interferes or threatens to materially interfere with the successful implementation of the Project, including credible suspicion of or actual, fraud, corruption or any other financial irregularity or impropriety related to the Project (collectively,

"Fraud"). In such event, SUBRECIPIENT will notify EMORY. SUBRECIPIENT will take timely and appropriate action to investigate credible allegations of Fraud, and cooperate fully with investigations into such matters, whether led by Emory, PRIME AGENCY, DFID or the Bill and Melinda Gated Foundation.

In the event of any credible indications that SUBAWARD funds may have been subject to Fraud, the Emory may, at any time during the Grant Period and for a period of up to five (5) years thereafter, arrange for additional Fraud investigations, on-the-spot checks and/or inspections of Project records to be carried out. If Fraud is established by such investigations, SUBRECIPIENT agrees to work with Emory and use its reasonable best efforts to recover the amount of funds subject to Fraud and restore them to the Project account or, at the direction of Emory, directly to them. During such period(s) of investigation,

SUBRECIPIENT acknowledges and accepts the right of Emory to suspend, withhold or terminate funding in accordance with the terms and conditions of this Grant Agreement.

35. **ANTI-TERRORIST COMPLIANCE:** SUBRECIPIENT hereby agrees that all funds, including SUBAWARDs to subrecipients, will be used in compliance with all applicable U.S. anti-terrorist financing and asset control laws, regulations, rules, and executive orders. SUBRECIPIENT will use reasonable efforts to ensure that it does not support or promote terrorist activity or related training, or money laundering. Further, SUBRECIPIENT will assure itself that the SUBAWARD funds will not be made available, either directly or indirectly, to or for the benefit of, persons, groups or entities listed in European Council Regulation EC/2580/2001 (as amended) and/or the Terrorism (United Nations Measures) Orders 2009 of the United Kingdom, or contravene the provisions of those and that of any subsequent applicable anti-terrorism legislation.

36. **LOCAL LAWS AND REGULATIONS**: SUBRECIPIENT hereby represents and warrants that it is duly organized and appropriately registered in INDIA to fulfill its responsibilities and conduct all activities under the Agreement.

    SUBAWARDEE further represents and warrants that all activities conducted under this Agreement shall be conducted in compliance with all local, regional and national laws, as applicable, including, but not limited to laws related to research involving human subjects and the transport of specimens and/or other data under this Agreement.

37. **DISSEMINATION, DATA SHARING AND INTELLECTUAL PROPERTY:** Information about research funded through the Drivers for Food Choice (DFC) Competitive Grants Program will be made available on the public DFC website (http://www.driversoffoodchoice.org). SUBRECIPIENT will be asked to collaborate with the DFC team on research uptake and dissemination activities, which may include, among others, presentations at seminars and conferences, blogs, interviews and opinion pieces. SUBRECIPIENT will be expected to disseminate the results of their research as widely as possible, based on the premise that publicly-funded research data are a public good, produced in the public interest, and should be made openly available to other researchers in a timely manner to the maximum extent possible. As well as scientific communication, emphasis is placed by the funder on engagement with potential users and beneficiaries of research, and the route to

application of its outcomes. Consideration of possible pathways to impact will form an important element of the assessment of proposals.

The DFC Competitive Grants Program will utilize the free Dataverse Network project to facilitate public access to datasets. The "Dataverse Network project develops software, protocols, and community connections for creating research data repositories that automate professional archival practices, guarantee long-term preservation, and enable researchers to share, retain control of, and receive web visibility and formal academic citations for their data contributions." Further information about this service can be found here: http://thedata.orp·/home. Datasets will be finalized for public access within six months after the end of each grant funding period. Datasets will not be made available for public access until 12 months after the end of each grant funding period. During this 12-month period, the SUBRECIPIENT will have exclusive use of the data for publications and reports. After 12 months, the data will be available for public access. Extensions up to 18 months may be requested by the SUBRECIPIENT and must be authorized by the DFC

Competitive Grants Program. Users must be requested by the SUBRECIPIENT and must be authorized by the DFC Competitive Grants Program. Users must have extensive previous experience in making data-use agreements and have a template to use to initiate agreements. In cases where grantees have pre-existing agreements or legal constraints that preclude providing full access to data, they will be required to identify these limitations in the Data Access Plan.

Consultation with the DFC Competitive Grants Program staff and the Bill & Melinda Gates Foundation will be necessary to come to agreement on what data will and will not be made publicly available and how these limited data are to be shared prior to receipt of funding. SUBRECIPIENT must contact EMORY prior to any contact with the DFC Competitive Grants Program staff or the Bill & Melinda Gates Foundation.

All intellectual property rights for all material (including but not limited to reports, data, designs, whether or not electronically stored, and technologies) produced by the investigator(s) or the investigators' personnel, and arising from research funded through this Subaward Agreement will be the property of the investigators' institution(s). The investigators' institution(s) will grant to the funders of the program, if requested, a world-wide, non- exclusive, irrevocable, royalty-free license to use all such material. If investigator(s) wish to apply for a patent for a particular application arising out of the information, however, they may request that publication of data is withheld until the patent application has been made. After that time, the data must be made freely available. The funders should be consulted about any request of this kind at an early stage, and any license(s) granted must be managed in a way that is consistent with the core principles of Global Access, i.e., that the findings of the research would be disseminated promptly and broadly, and that products and technologies arising from the knowledge gained would be made available and accessible at reasonable cost to people most in need in developing countries.

Notwithstanding the foregoing, The SUBRECIPIENT grants to EMORY an irrevocable, world-wide, royalty-free, non-transferable, non-exclusive right and license to use any copyrights or copyrighted material (including any computer software and its documentation and/or databases) delivered or

developed under this Agreement for the purpose of its own education and research and for meeting EMORY's obligation under its PRIME AWARD.

38. **PRIVACY AND NON-CONFIDENTIALITY NOTICE:** The Bill & Melinda Gates Foundation is required by the U.S. Internal Revenue Service to publish a list of its grants. The Bill & Melinda Gates Foundation also provides a general description of the grants it awards on their web sites, in press releases, and in other marketing materials. Subject to the Bill & Melinda Gates Foundation's Privacy Policy, the foundation may also share SUBRECIPIENT's proposal, reports, and related materials with third parties, including external reviewers, key partners and co funders. This document is subject to the foundation's Terms of Use.

39. **DISPUTES:** Resolution of disputes of a technical nature shall be resolved through good faith negotiations to the greatest possible extent. Any dispute arising under or related to this Agreement shall be resolved, to the maximum possible extent, through good faith negotiations and settlement. Failing settlement, despite reasonable efforts by both parties, any such unresolved issues shall be presented to EMORY whose decision will be reduced to writing with a copy furnished to the SUBRECIPIENT. Within 30 days after the date of receipt of such copy, the SUBRECIPIENT may notify EMORY in writing of its appeal of the decision, and, in the absence of such notice, EMORY's decision shall be final. In the event of notice from the

    SUBRECIPIENT of its appeal, the SUBRECIPIENT may pursue any right or remedy it may have at law or in equity in any court of competent jurisdiction. Pending such appeal, the SUBRECIPIENT shall proceed diligently with the performance of this Agreement and in accordance with EMORY's decision. All disputes under this Agreement shall be resolved and conducted, regardless of the means or authority, in the English language.

40. **GOVERNING LAW AND JURISDICTION:** This Agreement shall be governed, construed and enforced for all purposes in accordance with the laws of the State of Georgia, United States, without regard to principles of conflicts of law, provided that, insofar as the terms of this Agreement (including without limitation any specific U.S. or international regulatory or professional standards adopted by or incorporated into this Agreement) may contradict or be inconsistent with such law, then the terms of this Agreement shall prevail and be enforced. In addition, matters arising out of or concerning this Agreement or SUBRECIPIENT relationship with EMORY, SUBRECIPIENT hereby consents to jurisdiction and venue in DeKalb County, Georgia, U.S.A. and agrees to submit itself to the jurisdiction of the appropriate state, federal, and local courts therein.

41. **NOTICES:** Any notices to be given under this Agreement shall be submitted to the SUBRECIPIENT Administrative Contact, identified in Article 4 above, or the EMORY Administrative Contact, identified in Article 10 above, as appropriate.
42. **WAIVER AND SEVERABILITY:** No delay, failure or waiver of either Party's exercise or partial exercise of any right or remedy under this Agreement will operate to limit, impair, preclude, cancel, waive or otherwise affect such right or remedy. No waiver of any provision of this Agreement will constitute a waiver of any other provision or of the same provision on another occasion. If any provision of this Agreement is held by a court of competent jurisdiction to be illegal, invalid or

unenforceable, the remaining provisions will remain in full force and effect, provided that the surviving portion materially comports with the original intent of the Parties.

43. **INDEPENDENT CONTRACTOR:** In the performance of this Agreement, SUBRECIPIENT shall be deemed to be an independent contractor and, as such, no employee or staff of SUBRECIPIENT shall be entitled to any benefits applicable to employees of EMORY

44. **USE OF NAME:** Neither party shall use the name of the other party, nor the name of any faculty member, employee, or student of the other party, in connection with any product, service, promotion, news release, or other publicity without the prior written permission of the other party and, if an individual's name is used, of that individual.

45. **GOVERNING LANGUAGE:** In the event that a translation of this Agreement is prepared and signed by the parties, and a conflict arises between the English version and other language version, this English language version shall be the official version and shall govern and control.

46. **MODIFICATION OF CONTRACT:** This Agreement may only be changed or modified by mutual written agreement, signed by both parties. No modifications or addition will be binding until signed by both parties.

47. **FORCE MAJEURE:** Neither party shall be in violation of this Agreement, and neither party shall be liable to the other for damages in the event either is prevented from performing any of the obligations hereunder for a reason beyond its reasonable control, including without limitation, natural disaster, epidemic, act of God, declared war, strike, governmental restrictions and controls or production or maintenance delays.

48. **ENTIRE AGREEMENT:** This Agreement constitutes the entire understanding and agreement between the parties with regard to SUBRECIPIENT'S participation in the Project. SUBRECIPIENT acknowledges and agrees that participation in the Project shall be governed by this Agreement, unless mutually agreed by the parties in writing.

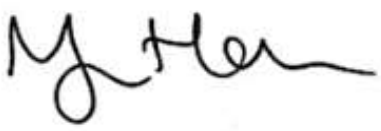
49. **HEADINGS:** The headings to the various sections of this Agreement have been inserted for convenience of reference only and shall not modify, define, limit or expand the express provisions of this Agreement. No provision of this Agreement is to be interpreted for or against either party because that party or that party's legal representative drafted such provision.

50. **COUNTERPARTS:** This Agreement may be executed in any number of counterparts, each of which shall be deemed an original, and all of which counterparts together shall constitute but one and the same instrument.

IN WITNESS WHEREOF the respective Parties have executed this Agreement effective as of the date of last signature below. By signing below, in addition to executing this Agreement on behalf of the SUBRECIPIENT, SUBRECIPIENT's authorized representative also individually and personally makes the certifications, representations and assurances contained herein and as shown in Appendix D.

Emory University

Signature:



Name: Maggie Hassan

Title: Associate Director, OSP

Date: 10/04/2018

BLDE (Deemed to be University)

Signature:

Name: Dr. S P Guggarigoudar

Title: Dean, Faculty of Medicine and Principal, BLDE (Deemed to be University), Shri B M Patil Medical College, Hospital & Research Center, Vijayapura

PRINCIPAL
BLDE (Deemed to be University)
Shri B. M. Patil Medical College
Hospital & Research Centre,
VIJAYAPUR-586103

Date: 06-10-2018

APPENDIX A

STATEMENT OF WORK/PROJECT DESCRIPTION

BLDE (Deemed to be University) Subcontract Scope of Work

Dr. Shailaja S. Patil, MD will be responsible for scientific leadership, adherence to program vision, coordination of the study at the site, quality control, and financial accountability. She will work with her PI and Co-PIs in developing proposal lead the survey implementation and participate in presentation and writing manuscripts

Project Coordinators, Research Assistants at BLDE (Deemed to be University) will assist Dr. Patil in coordinating all aspects of the project, including, hiring, training and coordination of field staff, execution and monitoring of field work, human subjects approval and adherence, and monitoring of data entry and coordinate financial transactions and maintain timeline of progress of the project .the salary is calculated on the basis of assumptions made referring the salaries of similar positions in other external funded projects in the local institute. Designated computer and data entry personnel will be responsible for data entry and data management, extracted from each study form, along with checking for accuracy and security of study data at all times. The field staff/interview team at BLDE (Deemed to be University) will be responsible for conducting interviews, obtaining prior consents, and coordination of study participant appointments.

APPENDIX B

BUDGET (COST-REIMBURSEMENT)

DFC Competitive Grants Program Budget Worksheet: Year 1 (BLDE (Deemed to be University)

Project Begin Date: 1/2/2018
Project End Date: 1/31/2020
Number of years: 2

Grand Total Dollar Amount: $ 56,259

PERSONNEL

Name	Title	% Effort	Months	Annual Salary	Total Salary	Total Fringe Benefits	Total Cost
Dr.Shaiaja Patil	CO-PI	35%	4.20	$ 10,262.00	$ 10,262.00	$ 307.86	$ 10,569.86
TBN	Project coordinator	100%	12.00	$ 6,792.00	$ 6,792.00	$ 203.76	$ 6,995.76
TBN	Budget manager /assistant	100%	12.00	$ 938.00	$ 938.00	$ 28.14	$ 966.14
TBN	Computer assistant / data er	100%	6.00	$ 2,250.00	$ 1,125.00	$ 33.75	$ 1,158.75
TBN	Field supervisor (1)	100%	9.00	$ 2,813.00	$ 2,813.00	$ 84.39	$ 2,897.39
TBN	Field staff (interviewer) (4)	100%	9.00	$ 2,438.00	$ 1,828.50	$ 54.86	$ 7,533.42
TBN	Research Assistant			$ 3,500.00	$ 3,500.00	$ -	$ 3,500.00
						$ -	$ -
						$ -	$ -
					PERSONNEL SUBTOTAL		$ 33,621

EQUIPMENT (Cost > 5,000.00 USD)

Equipment Name/Description:	Justification:	Quantity:	Cost per unit	Total	Additional Notes:
				EQUIPMENT SUBTOTAL	$ -

SUPPLIES (Cost < 5,000.00 USD)

Supplies Name/Description	Justification:	Quantity:	Cost per unit:	Total	Additional Notes:
printring modules for data collection	data collection instruments	80000	$ 0.04	$ 3,200.00	*field work supplies for 6people (4 interviewers, 1 supervisors and 1 project coordinator, i resaerch assistant) *phone charges / internet WIFI rent @ office for 1000 Rs/month and Sim card with monthly top up for 6 people for 9 monthsin year 1 .
field work supplies*	bag/badge/stationeryincludin g	8	$ 7.80	$ 62.40	
Recurring stationery expenses	office use	12	$ 50.00	$ 600.00	
phone chargest/sim cards*	field work coordination	6	$ 28.00	$ 168.00	
Printing colour laminated flash cards and	For food group selection required for data collection	860	$ 0.50	$ 430.00	
Monthly Internet WIFI rental charges	Office internet use, skype calls etc..	12	$ 24.00	$ 288.00	
antivirus	protection of data in computer	$ 1.00	$ 48.00	$ 48.00	
				SUPPLIES SUBTOTAL	$ 4,796

TRAVEL

Destination:	Justification:	Quantity:	Cost per unit:	Total	Additional Notes:
Local Travel and Field Work	vehicle hiring for field work	0.75	$ 8,555.00	$ 6,416.25	
preperatory phase for meeting , permissi	iring for preperatory work rela	2	$ 80.00	$ 160.00	
			$ -	$ -	
			$ -	$ -	
			$ -	$ -	
				TRAVEL SUBTOTAL	$ 6,576

OTHER EXPENSES (Other Than Supplies)

Expense:	Justification:	Quantity:	Cost per unit:	Total	Additional Notes:
Incentives(Participant)	participation in data collection	800	$ 4.00	$ 3,200.00	800 plus survey instruments include Aim 1 , 2 & 3for translation and back translation charges (approx @ 60 Rs /module)
lation and Backtranslation of survey instru	for local language use	800	$ 1.00	$ 800.00	
during first quarter of study for IHMS clear	ance (paper work, phone charges , copying e		$ 300.00	$ 300.00	
digital cameras for field work	r food database and documen	2	$ 100.00	$ 200.00	
Training expenses	s stationary during training of interviewers		$ 100.00	$ 100.00	
computer	ta entry/storage/communicati	$ 1.00	$ 938.00	$ 938.00	
printer/copier/fax	comunication	$ 1.00	$ 313.00	$ 313.00	
cupboards with locks	storage of data in hard copy	$ 1.00	$ 300.00	$ 300.00	
				OTHER EXPENSES SUBTOTAL	$ 6,151
				TOTAL DIRECT EXPENSES	$ 51,145
				INDIRECT (10%)	$ 5,114
				GRAND TOTAL	$ 56,259

Budget justification, BLDE (Deemed to be University) (Sub Contract) Personnel:

- ***Shailaja S. Patil, MD, Co- Principle Investigator*** (4.20 calendar-months in year 1 & 4.20 in year 2), is Professor, Department of Community Medicine, Sri. B. M. Patil Medical College, BLDE (Deemed to be University). She will be responsible for scientific leadership, adherence to program vision, coordination of the study at the site, quality control, and financial accountability. She will work with her PI and Co-PIs in developing proposal lead the survey implementation and participate in presentation and writing manuscripts. Total salary is calculated considering she will work 35% of her time @ unit cost rate for each month based on the base salary of the investigator at her working institution.
- **(*TBH) Project Coordinator*** (24 .00 calendar-months), will be a MSc graduate / PhD trainee will assist Dr. Patil in coordinating all aspects of the project, including, hiring, training and coordination of field staff, execution and monitoring of field work, human subjects approval and adherence, and monitoring of data entry and coordinate financial transactions and maintain timeline of progress of the project .the salary is calculated on the basis of assumptions made referring the salaries of similar positions in other external funded projects in the local institute.***Project Coordinator*** will be full time (100% time) for this project.
- (TBN**) Research Assistant** (7.20 calendar-months), A junior faculty / a Ph.D trainee who will be helping in all aspects of the project to Dr.Patil , the consolidated salary is calculated on the basis of assumptions made referring the salaries of similar positions in the local institute.
- *(TBH**) Budget Coordinator*:** (24.00 calendar-months) It will be a person from finance section of the university who will be arranging the salary payments of all project staff at BLDE (Deemed to be University) including the tax deduction, maintaining receipts and financial transactions related papers. Getting the audit done for the project amount utilization at the end of first year and after completion of the project and maintaining and filing all the finance related documents. The salary is estimated based on the salaries of similar positions in other external funded projects carried out in the local institute depending on part time involvement.
- *(TBH)* ***Computer assistant/data entry personnel:*** (6.00 calendar months in 1st and 6.00 calendar months in 2nd year) the person will be a graduate or diploma in computer application, trained in data entry and data management. Will input data from interview forms, check data entered for accuracy, clean data, ensure that data is secure, and produce status reports as needed he will also maintain the error log book. The salary is estimated based on the payments made to similar position in the previous projects.
- *(TBH**) Field Supervisor 1*(FS)** (9.00 calendar months in 1st and 6.00 calendar months in 2nd year) she/he will be responsible for day to day monitoring of field

work, can also participate as field interviewer when required along with other field staff. She/he will monitor the interviewers to ensure that study protocol and human subjects' guidelines are being adhered to, check data for completeness and accuracy, and collect data sheets for delivery to the study coordination office. **FS** will arrange for day to day logistics needed for field work, plan and coordinate the travel for each day during data collection and ensure the availability of all the materials required for the data collection with the checklist, and has alternative plan for multiple visits if required and check all the survey instruments at the end of day and informs the project coordinator on daily basis. Salary is calculated based on the payments made to similar position in our previous projects.

- ***(TBH) Field staff / interviewers (4)*** (9.00 calendar months in 1st and 6.00 calendar months in 2nd year) (2 teams of 2 each).They will be a graduates or Medico-Social Workers. They will be responsible for conducting the interviews, taking prior consents and appointments of the study participants by phone and planning the day to day visits and re-visits in close coordination with field supervisor and project coordinator. They will adhere to human subject protocols during interview. Salary is estimated based on the previous payments made to similar positions made in our projects.

Supplies:

- *Printing modules for data collection*: 80000 printed sheets are required for collection of data from approximately 1600 study participants including the consent forms. Cost is generated by calculating @ 2 INR **(Indian Rupee)**for printing of single sheet.
- *Field works supplies*: It's a kit that contains Bag, Identity card/badge laminated for each interviewer and project staff and stationery required for field work. Cost is generated by calculating each field kit @ 500 INR approximately.
- *Recurring stationery expenditure*: Includes materials required for office use and field work like pen, pencil, paper etc. Totaling @ 2000 INR per month approximately.
- *Phone charge/ sim card:* All the 4 interviewers and 1 supervisor , 1Project coordinator will be provided with a Sim card in the beginning of the study and every month it will be recharged with top-up for the period of data collection, for communication with the project coordinator and for contacting the study participants etc., totaling @ 1800 INR per month approximately.
- *Flash cards and health education materials:* Approximately 250, they will be color printed and laminated. Cost is generated at @70 INR per card including lamination.
- *Monthly Internet WIFI rental charges:* Includes WIFI recharge at the project office for communication /Skype calls etc. with Emory University and elsewhere. It is calculated considering @ 1500 INR per month total for 24

months.

- *Computer:* it will be based at the project office to be used for data entry, data management, and analysis. BLDE **(Deemed to be University)** does not provide a restricted access computer for entering and storing data. **The computer** will be used for the sole purpose of this project, password protected, and stored in a secure cabinet. Cost is calculated based on the present rate of the standard company desktop sets available at the market.
- *Printer/copier/fax:*Used for printing and copying of questionnaires, information sheets, consent forms, training manuals, and other project related materials. Cost is calculated based on the present rate of the standard company printer/ copier/fax sets available at the market.
- *Antivirus:*Used for protection of compiled and analyzed data entered in the desktop.Cost is calculated based on the present rate of the standard company antivirus available at the market for two years.

Travel:

- *Local travel and field work:*It includes van rental including fuel charges accommodating minimum 6-7 people excluding the driver for travel of field teams, project staff for 9 months in 1st year and 6months in 2nd year. Calculated @ 1520INR per day (Hiring charges and Fuel) approximately.

Other expenses:

- *Translation/back translation of the survey instrument*: Translation of study forms and documents into Kannada (local language) and back-translation into English to ensure accuracy of translation. It is calculated @ 30 INR per module of approximately.
- *Incentives for the participants:* Incentives will be given to all the study participants @ 500 INR per participants/ approximately for 2-3 visits in 2 years.

APPENDIX C

SAMPLE INVOICE

APPENDIX C
SAMPLE INVOICE

YOUR INSTITUTION
ADDRESS
TELEPHONE/FAX

TO: EMORY UNIVERSITY
Via E-mail: invoices@emory.edu
ATLANTA, GA 30322

INVOICE DATE:
(YOUR ACCOUNT IDENTIFIER):
INVOICE#:

CONTACT/AWARD NO: _____38963NIH-Armenia/R01 TW010664

REIMBURSABLE EXPENSES FROM: _____ THRU _____

AMOUNT FOR THE CURRENT PERIOD $_____

EXPENSES	CURRENT EXPENSES	CUMULATIVE
SALARY/WAGES		
FRINGE BENEFITS (Rate: %)		
CONSULTANTS		
COMMUNICATIONS		
SUPPLIES		
TRAVEL		
EQUIPMENT		
PATIENT CARE		
OTHER	_____	_____
TOTAL DIRECT COSTS		
INDIRECT COST (Rate: %)	_____	_____
TOTAL EXPENSES	_____	_____

By signing this report, I certify to the best of my knowledge and belief that the report is true, complete, and accurate, and the expenditures, disbursements and cash receipts are for the purposes and objectives set forth in the terms and conditions of the Federal award. I further certify that payment made by EMORY under this Agreement shall not duplicate reimbursement of costs and services which are received from other sources. I am aware that any false, fictitious, or fraudulent information, or the omission of any material fact, may subject me to criminal, civil or administrative penalties for fraud, false statements, false claims or otherwise. (U.S. Code Title 18, Section 1001 and Title 31, Sections 3729–3730 and 3801–3812).

CERTIFIED CORRECT BY:

_____
NAME
TITLE

APPENDIX D

PRIME AWARD

Subaward Agreement – Non-Federal

Prime Awardee	Subawardee
Institution/Organization ("UNIVERSITY") Name: University of South Carolina Address: Sponsored Awards Management 1600 Hampton Street, Suite 414 Columbia, SC 29208 Principal Investigator: Dr. Christine Blake	Institution/Organization ("COLLABORATOR") Name: Emory University Address: 1599 Clifton Road Atlanta, Georgia 30322 Principal Investigator: Dr. Solveig Argeseanu Cunningham

Prime Award No.	Subaward No.	Purchase Order No.
OPP1110043	18-3594	2000038671

Sponsor

University of South Carolina

Subaward Period of Performance	Amount Funded this Action	Est. Total (if incrementally funded)
January 1, 2018 to December 31, 2018	140,292	129,708

Project Title: "Food Choice in Indian Households in the Context of the Nutrition Transition"

Reporting Requirements [Check here if applicable: X See Attachment 1]

Terms and Conditions

1) University hereby awards a cost reimbursable subaward, as described above, to Collaborator. The statement of work and budget for this subaward are shown in Attachment 4. In its performance of subaward work, Collaborator shall be an independent entity and not an employee or agent of University.
2) University shall reimburse Collaborator not more often than monthly for allowable costs. All invoices shall be submitted using Collaborator's standard invoice, but at a minimum shall include current and cumulative costs (including cost sharing), subaward number, purchase order number and certification as to truth and accuracy of invoice. *Invoices that do not reference University's subaward and purchase order numbers shall be returned to Collaborator.* Invoices and questions concerning invoice receipt or payments should be sent to the appropriate party's Principal Investigator, as shown in Attachment 2.
3) A final statement of cumulative costs incurred, including cost sharing, marked "FINAL," must be submitted to University's Principal Investigator NOT LATER THAN forty-five (45) days after subaward end date. The final statement of costs shall constitute Collaborator's final financial report.
4) All payments shall be considered provisional and subject to adjustment within the total estimated cost in the event such adjustment is necessary as a result of an adverse audit finding against the Collaborator.
5) Matters concerning the technical performance of this subaward should be directed to the appropriate party's Principal Investigator, as shown in Attachment 2. Technical reports are required as shown above, "Reporting Requirements."
6) Matters concerning the request or negotiation of any changes in the terms, conditions, or amounts cited in this subaward agreement should be directed to the appropriate party's Administrative Contact, as shown in Attachment 2. Any such changes made to this subaward agreement require the written approval of each party's Authorized Official, as shown in Attachment 2.
7) Each party shall be responsible for its negligent acts or omissions and the negligent acts or omissions of its employees, officers, or directors, to the extent allowed by law.
8) Either party may terminate this agreement with thirty days written notice to the appropriate party's Administrative Contact, as shown in Attachment 2. University shall pay Collaborator for all allowable, noncancellable obligations in the event of termination.
9) No-cost extensions require the approval of the University. Any requests for a no-cost extension should be addressed to and received by the Administrative Contact, as shown in Attachment 2, not less than thirty days prior to the desired effective date of the requested change.
10) The Subaward is subject to the terms and conditions of the Prime Award and other special terms and conditions, as identified in Attachment 1.

By an Authorized Official of UNIVERSITY:	By an Authorized Official of COLLABORATOR:
Brandi K. Boniface, Associate Director Sponsored Awards Management Date: 3/12/18	Viraj Parmar Digitally signed by Viraj Parmar DN: cn=Viraj Parmar, o, ou, email=viraj.k.parmar@emory.edu, c=US Date: 2018.03.19 14:44:03 -04'00' Date

Attachment 1
Research Subaward Agreement
Terms and Conditions

Special terms and conditions:

1. ***This project is incrementally funded contingent upon USC receiving payment from Funder and there is automatic carry forward.***
2. ***All term and conditions indicated in the RFA are applicable.***

3. ***Human Subjects***
   If human subjects are used in the conduct of research the protocol must be approved annually by the appropriate Institutional Review Boards. Subrecipient may not conduct research on humans unless there is evidence of an approved assurance of regulatory compliance and evidence of the annual review of the of the human subjects protocol.

4. ***Continuation of Terms and Condition is attached.***

Continuation of Attachment 1

Terms and Conditions to be applied as applicable.

Your organization has been selected to participate in this Project at our discretion. You may not make any statement or otherwise imply to donors, investors, media or the general public that you are a direct grantee of the Bill & Melinda Gates Foundation ("Foundation") or the Department for International Development of the United Kingdom of Great Britain and Northern Ireland ("DFID") (Funders). You may state that University of South Carolina is the Foundation and DFID's grantee and that you are a subgrantee, subcontractor or subawardee of University of South Carolina for the Project.

Charitable Purpose of the Grant. The charitable purpose of this grant is to gain a deep understanding of the drivers of food choice among the poor in developing countries in South Asia and Sub-Saharan Africa in order to guide on-going and future programs and research activities to improve food and nutrition security in poor countries and to foster a community of practice in food choice research in developing countries, as described in your attached proposal (the "Proposal") and budget.

Use of Grant Funds. Grant funds may only be used for the Project. Any grant funds unexpended or uncommitted at the end of the Grant Period must be promptly returned to the University of South Carolina. Any Budget cost category change of more than 10% must be approved in writing by the University of South Carolina in advance. You may not use the grant funds to reimburse any expenses you chose to incur prior to the Start Date.

Political Campaign/Lobbying Activity. Foundation Funds may not be used to influence the outcome of any election for public office or to carry on any voter registration drive. There is no agreement, oral or written, permitting the Foundation Funds to be directed to or earmarked for lobbying activity or other attempts to influence local, state, federal, or foreign legislation. Subgrantee confirms that the amount of funds received from the Foundation, via a Subgrant from the University of South Carolina, will not exceed the amount budgeted each year for nonlobbying activities. Subgrantee agrees to comply with lobbying, gift and ethics rules applicable to the Project under local, state, federal or foreign law.

Anti-Terrorism. Subgrantee confirms that it is familiar with the U.S. Executive Orders and laws prohibiting the provision of resources and support to individuals and organizations associated with terrorism and the terrorist related lists promulgated by the U.S. Government. Subgrantee will use reasonable efforts to ensure that it does not support or promote terrorist activity or related training, or money laundering. Further, Subgrantee will assure itself that the Grant Funds will not be made available, either directly or indirectly, to or for the benefit of, persons, groups or entities listed in European Council Regulation EC/2580/2001 (as amended) and/or the Terrorism (United Nations Measures) Orders 2009 of the United Kingdom, or contravene the provisions of those and that of any subsequent applicable anti-terrorism legislation.

Fraud and Anti-Corruption. The University of South Carolina, and Subgrantee have a zero tolerance approach towards fraud and fraudulent behavior that may lead to the misuse of Grant Funds. The University of South Carolina, and Subgrantee will promptly inform each other of any event which interferes or threatens to materially interfere with the successful implementation of the Project, whether financed in full or in part by DFID or the Foundation, including credible suspicion of or actual, fraud, corruption or any other financial irregularity or impropriety related to the Project (collectively, "Fraud"). In such event, Subgrantee will notify University of South Carolina. Subgrantee will take timely and appropriate action to investigate credible allegations of Fraud, and cooperate fully with investigations into such matters, whether led by University of South Carolina, DFID or the Foundation.

In the event of any credible indications that Grant Funds may have been subject to Fraud, the University of South Carolina may, at any time during the Grant Period and for a period of up to five (5) years thereafter, arrange for additional Fraud investigations, on-the-spot checks and/or inspections of Project records to be carried out. If Fraud is established by such investigations, Subgrantee agrees to work with the University of South Carolina and use its reasonable best efforts to recover the amount of funds subject to Fraud and restore them to the Project account or, at the direction of University of South Carolina,
directly to them. During such period(s) of investigation, Subgrantee acknowledges and accepts the right of University of South Carolina to suspend, withhold or terminate funding in accordance with the terms and conditions of this Grant Agreement.

Subgrants and Subcontracts. Subgrantee is responsible for flowing down the terms of this agreement to lower tier subgrantees and subcontractors. Any agreements with lower tier subgrantees and subcontractors Subgrantee engages to assist with the Project must include the following language: "Your organization has been selected to participate in this Project at the University of South Carolina's discretion. You may not make any statement or otherwise imply to donors, investors, media or the general public that you are a direct grantee of the Bill & Melinda Gates Foundation ("Foundation") or the Department for International Development of the United Kingdom of Great Britain and Northern Ireland ("DFID"). You may state that University of South Carolina is the Foundation and DFID's grantee and that you are a subgrantee or subcontractor of University of South Carolina for the Project."

Due Diligence. In utilizing the Grant Funds, Subgrantee will exercise the same care in the discharge of its functions under this Grant Agreement as it exercises with respect to the administration and management of its own resources and affairs. Subgrantee will cooperate fully to resolve any due diligence issues raised by University of South Carolina or a Funder (or a Funder's delegate(s)) regarding Subgrantees internal controls and systems, and agrees to notify the University of South Carolina of any material changes to Subgrantees procedures, controls or operating environment that are relevant to the Project during the Grant Period. In addition, Subgrantee will assess the internal controls and systems of any lower tier subgrantees or subcontractors of the Project prior to disbursing funds to such entities, and at regular intervals throughout the Grant Period, as appropriate given the amount of the Grant Funds and risks of the Project. Such assessments should address: (1) the reliability and integrity of the organization's financial controls, systems and processes; (2) the effectiveness and efficiency of its Project operations; (3) its procedures for safeguarding Project assets; and (4) its compliance with applicable law. Upon request, Subgrantee will share the results of such assessments with the Funders.

Reporting. Subgrantee is required to submit two reports regarding the expenditure of Grant Funds and its progress on the Project. The first report is due February 15, 2019, which is 45 days after the end of year one. Subgrantee also agrees to submit other reports that University of South Carolina may reasonably request.

Communications. Subgrantee agrees to be in regular communication with the University of South Carolina throughout the Grant Period regarding Subgrantee's progress and to notify the University of South Carolina in writing promptly of any major development that is likely to have a material impact on Subgrantee's ability to achieve the Project objectives.

Record Maintenance and Inspection. The University of South Carolina requires that Subgrantee maintain adequate records for the Project to enable the University of South Carolina to easily determine how the Grant Funds were expended. Subgrantees's books and records must be made available for inspection by University of South Carolina or its designee at reasonable times to permit such Funder to monitor and conduct an evaluation of operations under this grant.

Compliance. If (a) Funder or University of South Carolina is not reasonably satisfied with Subgrantee's progress on the Project; (b) significant leadership or other changes occur that University of South Carolina believes may threaten the Project; or (c) Subgrantee fails to comply with any term or condition of this Grant Agreement, the University of South Carolina will notify Subgrantee of the concerns and provide Subgrantee with a reasonable period of time to address them. If no resolution satisfactory to University of South Carolina is reached within that time period, University of South Carolina may, at its discretion, terminate its support of the Project and/or grant. If University of South Carolina determines that the cause of its concerns cannot be remedied, University of South Carolina may immediately terminate, suspend, or withhold payment of Grant Funds to the grant. On termination, if requested by the University of South Carolina, Subgrantee agrees to promptly return to University of South Carolina any unspent and uncommitted funds (as of the date of termination).

Indemnification. Subgrantee will indemnify, defend, and hold harmless the University of South Carolina and the Funders and their trustees, employees, and agents ("Indemnified Parties") from and against any and all demands, claims, actions, suits, losses, damages (including property damage, bodily injury, and wrongful death), arbitration and legal proceedings, judgments, settlements, or costs or expenses (including reasonable attorneys' fees and expenses) (collectively, "Claims") arising out of or relating to the acts or omissions, actual or alleged, of the Subgrantee or its employees, lower tier subgrantees, lower tier subcontractors, contingent workers, agents, and affiliates with respect to the Project or this Agreement. Subgrantee agrees that any activities by the University of South Carolina in connection with the Project, such as its review or proposal of suggested modifications to the Project, will not modify or waive the University of South Carolina or Funders' rights under this paragraph. An Indemnified Party may, at its own expense, employ separate counsel to monitor and participate in the defense of any Claim. The Subgrantee's indemnification obligations are limited to the extent permitted or precluded under applicable federal, state or local laws, including federal or state tort claims acts, the Federal Anti-Deficiency Act, state governmental immunity acts, or state constitutions. Nothing in this Agreement will constitute an express or implied waiver of your governmental and sovereign immunities.

Dissemination, Data Sharing, and Intellectual Property. Information about research funded through the DFC Competitive Grants Program will be made available on the public DFC website (http://www.driversoffoodchoice.org). Subgrantees will be asked to collaborate with the DFC team on research uptake and dissemination activities, which may include, among others, presentations at seminars and conferences, blogs, interviews and opinion pieces. Subgrantees will be expected to disseminate the results of their research as widely as possible, based on the premise that publicly-funded research data are a public good, produced in the public interest, and should be made openly available to other researchers in a timely manner to the maximum extent possible. As well as scientific communication, emphasis is placed by the funder on engagement with potential users and beneficiaries of research, and the route to application of its outcomes. Consideration of possible pathways to impact will form an important element of the assessment of proposals.

The DFC Competitive Grants Program will utilize the free Dataverse Network project to facilitate public access to datasets. The "Dataverse Network project develops software, protocols, and community connections for creating research data repositories that automate professional archival practices, guarantee long-term preservation, and enable researchers to share, retain control of, and receive web visibility and formal academic citations for their data contributions." Further information about this service can be found here: http://thedata.org/home. Datasets will be finalized for public access within six months after the end of each grant funding period. Datasets will not be made available for public access until 12 months after the end of each grant funding period.

During this 12 month period, the Subgrantee will have exclusive use of the data for publications and reports. After 12 months the data will be available for public access. Extensions up to 18 months may be requested by the Subgrantee and must be authorized by the DFC Competitive Grants Program. Users

have extensive previous experience in making data-use agreements and have a template to use to initiate agreements. In cases where grantees have pre-existing agreements or legal constraints that preclude providing full access to data, they will be required to identify these limitations in the Data Access Plan. Consultation with the DFC Competitive Grants Program staff and the Bill & Melinda Gates Foundation will be necessary to come to agreement on what data will and will not be made publicly available and how these limited data are to be shared prior to receipt of funding.

All intellectual property rights for all material (including but not limited to reports, data, designs, whether or not electronically stored, and technologies) produced by the investigator(s) or the investigators' personnel, and arising from research funded through the Grant, will be the property of the investigators' institution(s). The investigators' institution(s) will grant to the funders of the program, if requested, a world-wide, non- exclusive, irrevocable, royalty-free license to use all such material. If investigator(s) wish to apply for a patent for a particular application arising out of the information, however, they may request that publication of data is withheld until the patent application has been made. After that time, the data must be made freely available. The funders should be consulted about any request of this kind at an early stage, and any license(s) granted must be managed in a way that is consistent with the core principles of Global Access, i.e., that the findings of the research would be disseminated promptly and broadly, and that products and technologies arising from the knowledge gained would be made available and accessible at reasonable cost to people most in need in developing countries.

Privacy and Non-confidentiality Notice

The Bill & Melinda Gates Foundation is required by the U.S. Internal Revenue Service to publish a list of its grants. We also provide a general description of our grants on our web sites, in press releases, and in other marketing materials. Subject to the foundation's Privacy Policy, the foundation may also share your proposal, reports, and related materials with third parties, including external reviewers, key partners and co funders. This document is subject to the foundation's Terms of Use.

Attachment 2
Subaward Agreement

University Contacts	Collaborator Contacts
Administrative Contact Name: Natasha Dozier Sponsored Program Administrator Address: Office of Sponsored Awards Management 1600 Hampton Street, Suite 414 Columbia, SC 29208 Telephone: 803-777-5370 Email: ndozier@mailbox.sc.edu	Administrative Contact Name: Viraj Parmar Address: 1599 Clifton Road 4th Floor Atlanta, GA 30322 Telephone: 404-727-2503 Email: osp@emory.edu
Principal Investigator Name: Dr. Christine Blake Address: Arnold School of Public Health Dept. of Health Promotion, Education and Behavior Discovery One Bldg. RM 549 Columbia, SC 29208 Telephone: (803) 777-1484 Email: ceblake@mailbox.sc.edu	Principal Investigator Name: Dr. Solveig Argeseanu Cunningham Address: 1518 Clifton Road Department of Global Health Atlanta, GA 30322 Telephone: 404-727-6486 Email: sargese@emory.edu
Financial Contact Name: Gina Hambrick Address: Office of Contract and Grant Accounting 1600 Hampton Street, 6th Floor Columbia, SC 29208 Telephone: 803-777-4850 Email: hambricg@mailbox.sc.edu	Financial Contact Name: Bill Lambert Address: 1599 Clifton Road 4th Floor Atlanta, GA 30322 Telephone: 404-727-2503 Email: fgc@emory.edu
Authorized Official Name: Brandi Boniface Associate Director Address: Office of Sponsored Awards Management 1600 Hampton Street, Suite 414 Columbia, SC 29208 Telephone: 803-777-8749 Email: bonifacb@mailbox.sc.edu	Authorized Official Name: Holly Sommers Address: 1599 Clifton Road 4th Floor Atlanta, GA 30322 Telephone: 404-727-2503 Email: osp@emory.edu

Subaward Amendment

Prime Awardee	Subawardee
Institution/Organization ("UNIVERSITY") Name: University of South Carolina Address: Office of Sponsored Awards Management 1600 Hampton Street, Suite 414 Columbia, South Carolina 29208 PI: Christine Blake	Institution/Organization ("COLLABORATOR") Name: Emory University 1599 Clifton Road Atlanta, Georgia 30322 PI: Dr. Solveig Argeseanu Cunningham
Prime Award No. OPP1110043	Subaward No. 18-3594 (11540-KA56)
PO No. 2000038671	Amendment No. One

Amendment(s) to Original Terms and Conditions

The purpose of this amendment is to extend the end date and increase the budget.

Emory University agrees to perform the work supportive of Grant No. OPP1110043 for the performance period of January 1, 2018 to March 31, 2020.

Compensation is hereby increased by $129,708 for the budget period January 1, 2019 to March 31, 2020 as indicated in Attachment A. The maximum amount to be reimbursed under this subaward is $270,000. Invoices referencing PO No. 2000038671 shall be submitted to Dr. Blake not more often than monthly. The final invoice must be submitted within forty-five (45) days after the expiration of this subaward.

All other terms and conditions of the agreement remain unchanged.

By an Authorized Official of UNIVERSITY: 11/8/18 Name: Nida Reid-Williamson Date Title: Team Leader, SPA Sponsored Awards Management	By an Authorized Official of COLLABORATOR: 11/8/18 Name: Janette Hannam Hayes Date Title: Associate Director for Research

SUBAWARD AGREEMENT
BY AND BETWEEN
EMORY UNIVERSITY
AND
BLDE (Deemed to be UNIVERSITY) , INDIA

This SUBAWARD Agreement, entered into this 4th day of October 2018, by and between Emory University (hereinafter "EMORY") and BLDE (Deemed to be University) , India (hereinafter "SUBRECIPIENT") is for the purpose of conducting work related to the Project defined below for which EMORY has received prime funding by the PRIME AGENCY identified below.

1.	**EMORY SUBAWARD/PO NUMBER:**	43339-BLDE
2.	**SUBRECIPIENT NAME AND ADDRESS:**	BLDE (Deemed to be University) Shri B M PMCH&RC, Vijayapura, Smt. Bangaramma Sajjan Campus, Solapur Road, Vijayapura, Karnataka, INDIA 586103
3.	**SUBRECIPIENT DUNS NUMBER:**	N/A
4.	**SUBRECIPIENT ADMINISTRATIVE CONTACT:**	Dr. Shailaja S. Patil, shailaja.dr@gmail.com, 08352262770 extn2111 91-9448820464
5.	**PRIME AGENCY:**	University of South Carolina (under a grant from Bill & Melinda Gates Foundation)
6.	**PRIME AWARD NUMBER:**	18-3594 (OP1110043)
7.	**PRIME AWARD DATE**	January 1, 2018
8.	**PROJECT TITLE:**	Food choices in Indian households during the Nutrition Transition
9.	**A. EMORY PRINCIPAL INVESTIGATOR:**	Argeseanu,Solveig
	B. SUBRECIPIENT PRINCIPAL INVESTIGATOR:	Patil, Shailaja S.
10.	**EMORY ADMINISTRATIVE CONTACT:**	Maggie Hassan Office of Sponsored Programs Emory University 1599 Clifton Road NE, 4th Floor 1599-001-1BA Atlanta, GA 30322

11.	**EMORY INVOICE CONTACT (NAME; PHONE; E-MAIL):**	_Katherine Carey katherine.carey@emory.edu, (470)259-0297
12.	**SUBAWARD PERIOD OF PERFORMANCE:**	From January 1, 2018 Through December 31, 2018
13.	**SUBAWARD AMOUNT (FUNDS OBLIGATED THIS ACTION):**	
14.	**AGREEMENT TYPE:**	☒ Cost-reimbursement ☐ Fixed Fee
15.	**RESEARCH & DEVELOPMENT SUBAWARD?**	☒ Yes ☐ No

16. **SUBAWARD PURPOSE AND PROJECT PERSONNEL:** The purpose of this Agreement is to support SUBRECIPIENTS's participation in the Project identified in Article 8, above. A description of the Project is attached as Exhibit A, "Statement of Work," and incorporated herein by reference. The SUBRECIPIENT shall supply all the necessary personnel, equipment, and materials (except as otherwise may be provided herein) and shall use all reasonable effort to perform the research tasks set forth in the Statement of Work described in Appendix A, which is attached and made a part hereof, which is an integral part of the PRIME AWARD attached in APPENDIX D hereto.

SUBRECIPIENT has been selected to participate in this Project at EMORY'S discretion. SUBRECIPIENT may not make any statement or otherwise imply to donors, investors, media or the general public that it is a direct grantee of the Bill & Melinda Gates Foundation ("Foundation") or the Department for International Development of the United Kingdom of Great Britain and Northern Ireland ("DFID") (Funders). SUBRECIPIENT may state that University of South Carolina is the Foundation and DFID's grantee and that SUBRECIPIENT IS a sub grantee, subcontractor or subawardee of EMORY for the Project.

The EMORY Principal Investigator ("PRINCIPAL INVESTIGATOR"), who is the technical representative of EMORY, is identified in Article 9A above. PRINCIPAL INVESTIGATOR shall retain the responsibility for supervision of this Project. PRINCIPAL INVESTIGATOR must approve any change in the Statement of Work, in writing.

The scientific and technical direction of SUBRECIPIENT's portion of the Project as set forth in the Statement of Work shall be under the direction of SUBRECIPIENT Principal Investigator ("SUBRECIPIENT INVESTIGATOR") as identified in Article 9B above.

SUBRECIPIENT INVESTIGATOR is considered to be essential to the work performed hereunder. In the event this person leaves SUBRECIPIENT or is reassigned to another program, SUBRECIPIENT shall notify EMORY immediately in writing. In addition, any individual(s) appointed to replace SUBRECIPIENT INVESTIGATOR must have the prior written approval of EMORY. If any individual(s) is/are not acceptable to EMORY, EMORY shall issue a modification terminating this Agreement. SUBRECIPIENT will be reimbursed for its costs properly incurred through such termination date.

17. **TERM:** The term of this Agreement is as specified in Article 12, SUBAWARD Period of Performance, above. Any change of the SUBAWARD Period of Performance, including extensions, requires written modification to this Agreement, signed by both parties. No expenses that are incurred prior to the effective date or subsequent to the termination date of the SUBAWARD Period of Performance will be reimbursed.

18. **AWARD AMOUNT, INVOICING AND PAYMENT:** Funds provided for SUBRECIPIENT's involvement in this Agreement shall not exceed the amount specified in Article 13 above. All award funds specified are in U.S. dollars. A line item budget for these funds is attached as Appendix B, which is attached and made a part hereof.

Invoices submitted under this Agreement must be accompanied by copies of general ledger printouts, labor distribution and/or payroll reports, as applicable, for expenses requested for reimbursement. Failure to submit such supporting documentation will delay payment. Emory reserves the right to request further detailed expenditure documentation in its sole discretion.

SUBRECIPIENT shall invoice EMORY quarterly. All invoices must be in U.S. dollars. When converting local currency to U.S. dollars for submission of an invoice, SUBRECIPIENT shall use the currency exchange rate in effect on the last date of the invoicing period. EMORY reserves the right to request detailed expenditure documentation from SUBRECIPIENT. A sample invoice is attached as Appendix C, which is attached and made a part hereof. All invoices must reference the EMORY SUBAWARD/PO Number specified in Article 1. Invoices that do not reference this number may be returned to SUBRECIPIENT for correction prior to payment.

Invoices must also include the following certification: "By signing this report, I certify to the best of my knowledge and belief that the report is true, complete, and accurate, and the expenditures, disbursements and cash receipts are for the purposes and objectives set forth in the terms and conditions of the Federal award. I further certify that payment made by EMORY under this Agreement shall not duplicate reimbursement of costs and services which are received from other sources. I am aware that any false, fictitious, or fraudulent information, or the omission of any material fact, may subject me to criminal, civil or administrative penalties for fraud, false statements, false claims or otherwise.

Invoices for payment shall be sent via e-mail as a PDF attachment to the EMORY Invoice Contact identified in Article 11, above. The final invoice of expenditures, clearly marked as "FINAL," shall be sent no later than sixty (60) days after the SUBAWARD Period of Performance end date as specified in Article 12 above. Final invoices received after sixty (60) days following the termination date of this Agreement shall be honored for payment at the discretion of EMORY unless another date for submission is agreed upon in advance by EMORY and
SUBRECIPIENT.

Final payment under this Agreement shall be predicated upon receipt and acceptance by EMORY of all services, reports, and/or supplies called for hereunder. EMORY reserves the right to withhold final payment until receipt and acceptance of all services, reports, and/or supplies called for hereunder. All services, reports, and/or supplies called for hereunder must meet all specifications as set forth herein and be to EMORY's reasonable satisfaction.

Questions regarding invoices and payment should be directed to the EMORY Invoice Contact identified in Article 11, above.

19. **REBUDGETING OF FUNDS:** It is understood that SUBRECIPIENT's budget as set forth in Appendix B is an estimate and there may be need to depart from it to meet certain unanticipated requirements of the Project. Any Budget cost category change of more than 10% must be approved in writing by EMORY in advance. SUBRECIPIENT must submit a request for the Rebudgeting of funds that require prior approval to EMORY for forwarding to PRIME AGENCY for approval. SUBRECIPIENT may not use the funds to reimburse any expenses incurred prior to the Start Date.

20. **EQUIPMENT:** Title to real property, equipment, and supplies acquired under this Agreement shall vest upon acquisition, in SUBRECIPIENT. EMORY reserves the right to require transfer of items of equipment (including title) having a unit acquisition cost of $ 5,000 or more if the Project for which the SUBRECIPIENT acquires the equipment is acquired is transferred to another subrecipient.

21. **AUDIT AND RECORD RETENTION:** The accounting for funds provided under this Agreement shall be in accordance with generally accepted accounting principles consistently applied. SUBRECIPIENT shall maintain records to support identifiable charges to this Agreement. All costs reimbursed for the performance of this Agreement will be subject to audit by either EMORY or the PRIME AGENCY, and SUBRECIPIENT agrees to allow auditors access to its records pertinent to this Agreement during normal business hours. SUBRECIPIENT's financial records for this Agreement shall be retained for a period of three (3) years, beginning from the date of the receipt of payment of the final invoice.

    SUBRECIPIENT assumes sole responsibility for reimbursement to EMORY of a sum of money equivalent to the amount of any expenditure disallowed, should EMORY, the PRIME AGENCY or any authorized agency rule through audit exception, or some other appropriate means, that expenditures from funds allocated to SUBRECIPIENT through EMORY for direct and/or indirect costs were not made in compliance with the terms of this Agreement or the regulations of the Prime Agency of this Agreement. In addition, SUBRECIPIENT is responsible for repayment of any monies required to be returned to Prime Agency as a result of SUBRECIPIENT breach of this Agreement.

22. **TECHNICAL REPORTING PROCEDURES:** SUBRECIPIENT will be required to keep clear and accurate records of the procedures conducted and data collected through the SUBAWARD Period of Performance so that the progress of the study may be readily evaluated at any time by the EMORY PRINCIPAL INVESTIGATOR designated in Article 9A above. In addition, SUBRECIPIENT shall submit a final technical report within sixty (60) days of expiration or termination of this Agreement.

23. **PUBLICATIONS:** All research reports and other publications relating to the work under this Agreement shall be prepared in consultation with the EMORY PRINCIPAL INVESTIGATOR designated in Article 9A above. At a minimum, for any publication or press release describing research that has been funded in whole or in part by the Drivers of Food Choice Competitive Grants Program, under this Agreement shall:
    A. Bear proper acknowledgement as follows:
        i) Publication: This research has been funded by the Drivers of Food Choice (DFC) Competitive Grants Programs, which is funded by the UK Government's Department for International Development and the Bill & Melinda Gates Foundation, and managed by the

University of South Carolina, Arnold School of Public Health, USA; however, the views expressed do not necessarily reflect the UK Government's official policies.

ii) Press release: This research has been funded by the Drivers of Food Choice (DFC) Competitive Grants Programs, which is funded by the UK Government's Department for International Development and the Bill & Melinda Gates Foundation, and managed by the University of South Carolina, Arnold School of Public Health, USA.

B. Be submitted to the EMORY PRINCIPAL INVESTIGATOR designated in Article 9A above in the form of advance copies for review and comment prior to publication to ensure appropriate coordination of research results.

SUBRECIPIENT further grants to EMORY an irrevocable, royalty-free, non-transferable, non-exclusive right and license to use, reproduce, make derivative works, display, and perform publicly any copyrights or copyrighted materials (including any computer software and its documentation and/or databases) first developed and delivered under this Agreement for the purpose of and to the extent required to meet EMORY's obligations under its PRIME AWARD.

24. **DATA RIGHTS:** Subject to its legal ability to do so, the SUBRECIPIENT shall grant to EMORY the right to use data created in the performance of this Agreement for the purpose of education and research or to the extent required to meet EMORY's obligations under its PRIME AWARD.

25. **TERMINATION**: Either SUBRECIPIENT or EMORY may terminate this Agreement for any reason upon thirty (30) days prior written notice to the other party. EMORY reserves the right to terminate this Agreement within five (5) days written notice if EMORY determines SUBRECIPIENT to be in significant breach of this Agreement. If at any time EMORY's PRIME AWARD is terminated by PRIME AGENCY, this Agreement shall also be terminated immediately upon receipt by SUBRECIPIENT of written notice to that effect from EMORY. SUBRECIPIENT shall be reimbursed for all allowable costs and any non-cancelable obligations properly incurred prior to the date of termination, provided that such costs shall not exceed the amount allowed under this Agreement and that a report of progress to date of termination has been submitted to EMORY. Nothing in this article is intended to abrogate the Parties' right to mutually terminate this Agreement on such other terms as may be agreed upon.

26. **REGULATORY DATA:** All administrative and regulatory data required by PRIME AGENCY shall be applicable to this Agreement as appropriate. All conditions referenced in the PRIME AWARD to EMORY by PRIME AGENCY shall become binding upon SUBRECIPIENT. A copy of the award terms and conditions, and any applicable regulatory requirements, are included in Appendix D, which is attached and made a part hereof.

27. **INDEMNIFICATION:** SUBAWARDEE agrees to indemnify, defend and hold harmless EMORY and the FOUNDATION from and against any and all liability, loss, expense (including reasonable attorney's fees) or claims for injury or damages arising out of or resulting from, or alleged to arise out of or result from, the actions or omissions by SUBAWARDEE or by any of SUBAWARDEE's officers, agents, employees, subgrantees, contractors or subcontractors with respect to this Agreement or the PROJECT. SUBAWARDEE also agrees to assume responsibility for all liability for damages and injuries (including reasonable attorney's fees) which may arise or result from the actions or

omissions of SUBAWARDEE's lower-tier subawardees and contractors or any of their officers, agents or employees.

SUBAWARDEE acknowledges and agrees that any activities by EMORY or the FOUNDATION in association with this Agreement or the PROJECT, such as the review or proposal of suggestions to the PROJECT, or any other activity in association with this Agreement or the PROJECT, will not modify, or constitute the basis for any claim of waiver by SUBAWARDEE of, Emory's or the FOUNDATION's rights under this paragraph.

28. HUMAN SUBJECTS: If human subjects are used in the conduct of the work supported by this Agreement, SUBAWARDEE warrants by the execution of this Agreement that SUBAWARDEE is in compliance with the applicable laws, regulations, and policies applicable to research involving human subjects. EMORY and SUBAWARDEE agree that both the Institutional Review Board (IRB) for EMORY and the IRB and/or Ethics Committee (EC) for SUBAWARDEE will review and have continuing oversight for the PROJECT. This review and continuing oversight will meet the human subjects' protection requirements of any and all applicable laws governing the IRB of EMORY and IRB/EC of SUBAWARDEE. Such review and continuing oversight also shall satisfy the requirements of the IRB of EMORY and the IRB/EC of SUAWARDEE. SUBAWARDEE agrees to provide annual certification to EMORY that an institutional committee has reviewed and approved the procedures that involve human subjects. SUBAWARDEE further agrees to provide notification to EMORY if the procedures that involve human subjects have been amended or modified, as well as when adverse events are reported. SUBAWARDEE shall bear full responsibility for the proper and safe performance of all work and services involving the use of human subjects under this Agreement.

28.1 EMORY and SUBAWARDEE agree that Emory's IRB and SUBAWARDEE IRB/EC will review and have continuing oversight over the PROJECT. This review and continuing oversight will meet the human subjects' protection requirements of all applicable laws. In addition, the review and continuing oversight will meet any requirements of EMORY or SUBAWARDEE'S Human Research Protections Program. At a minimum, this review and continuing oversight shall ensure compliance with the following requirements for any research conducted pursuant to this Agreement: 28.1.1 Determining that protections for human research subjects are adequate.

28.1.2 Ensuring that legally effective informed consent is obtained. Such consent shall include information on what care and/or referrals will be available through participation in the
PROJECT.

28.1.3 Ensuring that, when identifiable protected health information (PHI) is used, proper means, including subject authorization, are in place for gaining access to, using and/or disclosing the information under the U.S. Health Insurance Portability and Accountability Act (HIPAA) regulations (45 CFR Part 164) if the PHI is used or disclosed in the United States at an Emory unit or other entity that is a covered entity under applicable HIPAA regulations.

28.1.4 Ensuring that changes to the PROJECT are reviewed and approved, modified or disapproved, by Emory's and SUBAWARDEE'S pertinent IRBs as appropriate.

28.1.5 Ensuring that adequate documentation of IRB review activities, including minutes of meetings at which any pertinent protocols are discussed, are maintained at Emory's

IRB and SUBAWARDEE'S IRB, as applicable, with copies of relevant portions of such documentation being provided upon request by SUBAWARDEE to Emory, or vice-versa.

28.1.6 Ensuring that each reviewing IRB, in accordance with its procedures, reports its findings and actions regarding the PROJECT to the Administrative Contact officials for both Emory and SUBAWARDEE.

28.1.7 Reporting the following items to the Administrative Contact officials for EMORY and SUBAWARDEE:

28.1.7.1 Any serious or continuing non-compliance by persons involved in the PROJECT at EMORY's or SUBAWARDEE's facilities;

28.1.7.2 Any suspension or termination of IRB approval of the PROJECT;

28.1.7.3 Any injuries to human subjects caused by the PROJECT.

28.1.7.4 Any unanticipated problems involving risks to subjects or others from the PROJECT.

28.1.7.5 Any IRB-reviewed and approved changes in the PROJECT.

28.2 SUBAWARDEE acknowledges and agrees that funds from the Award have not been set aside to provide care and/or referrals to any human subject participants or employees of SUBAWARDEE who are injured as a result of participation in this PROJECT.

29. **SUBJECT CONFIDENTIALITY (HIPAA):** EMORY and SUBRECIPIENT agree to comply with the restrictions in any subject Authorization (as defined below) regarding the use, disclosure and confidentiality of any individually identifiable health information and further agree to comply with all applicable federal and state laws and regulations governing the security and privacy of the individually identifiable health information, including HIPAA, to the extent required by such federal and state laws and regulations, including HIPAA. .

Prior to participation of any human subject in the Project, SUBRECIPIENT will ensure that a properly executed written consent and authorization approved by its IRB or other designated IRB/Privacy Board (the "Authorization") is obtained from each human subject or the subject's authorized representative to document the subject's express written Authorization for the use by SUBRECIPIENT, and the disclosure to and use by EMORY, when applicable, of protected health information when required under HIPAA. SUBRECIPIENT and EMORY will cooperate in the amendment of the Authorization or other documents as may be necessary from time to time, to comply with HIPAA to the extent HIPAA applies to SUBRECIPIENT or EMORY to ensure the Project data may be used by SUBRECIPIENT or EMORY for the purposes specifically identified in this Agreement and the Authorization.

30. **ANIMAL SUBJECTS RESEARCH:** No live vertebrate animals are used in the conduct of the work supported by this Agreement.

31. **RECOMBINANT DNA RESEARCH OUTSIDE OF THE U.S:** Recombinant DNA research must be in compliance with the U.S. guidelines and laws, unless the country in which such research is being carried out has adopted guidelines comparable to those of the U.S. and EMORY has approved such guidelines.

32. **ASSIGNMENT AND SUBCONTRACTING:** SUBRECIPIENT shall not assign, transfer or subcontract its interests or obligations hereunder without the written consent of EMORY. Any such assignment, transfer, or subcontract shall be null and void automatically. In the case that the SUBRECIPIENT is approved to subcontract, the SUBRECIPIENT is responsible for flowing down the terms of this agreement to lower tier subcontractors. Any agreements with lower tier subcontractors SUBRECIPIENT engages to assist with the Project must include the following language: "Your organization has been selected to participate in this Project at the discretion of the University of South Carolina, and Emory University. You may not make any statement or otherwise imply to donors, investors, media or the general public that you are a direct grantee of the Bill & Melinda Gates Foundation ("Foundation") or the Department for International Development of the United Kingdom of Great Britain and Northern Ireland ("DFID")."

33. **INSURANCE:** Each Party certifies that it has and shall maintain sufficient insurance or a program of self-insurance at levels sufficient to support its obligations assumed under this Agreement. Each Party agrees to provide the other Party written certification of such insurance or self-insurance coverage upon written request.

34. **TRADE CONTROL LAWS:** SUBRECIPIENT acknowledges that this Agreement and the performance thereof are subject to compliance with any and all applicable U.S. and non-U.S. trade control laws, regulations, or orders, including but not limited to the economic sanctions programs administered by the United States Department of Treasury Office of Foreign Assets Control and the export control regulations administered by the U.S. Office of the Directorate of Defense Trade Controls and/or the U.S. Bureau of Industry and Security. SUBRECIPIENT acknowledges that the export, re-export or transfer of certain commodities, software, source code, technical data or services may require a license from the relevant regulating agency of the U.S. or other government. In particular, SUBRECIPIENT agrees it will not disclose, transfer, export or re-export any commodities, software, source code, technical data or services received under this Agreement to any countries for which the United States government requires an export license or other supporting documentation at the time of export or transfer, unless SUBRECIPIENT has obtained the required license or other prior written authorization from the appropriate U.S. authority responsible for such matters. While EMORY agrees to cooperate in securing any license that the regulating agency deems necessary in connection with this Agreement, EMORY cannot guarantee that such licenses will be granted.

    The parties represent, warrant, and agree that they have not taken, and will not take, any action related to or arising out of this Agreement, which in any way violates, or aids or abets any violation of, the United Kingdom Bribery Act, the United States Foreign Corrupt Practices Act, or the applicable anti-corruption laws of any country. Specifically, and not in limitation of the foregoing, the parties represent, warrant, and agree that they have not, and will not, in connection with this Agreement, directly or indirectly request, give, pay, offer or promise to give or pay, or authorize another party to give or pay any money or anything of value to any person (whether or not such person is a government official), for the purpose of influencing any act or decision of such entity or person or inducing such person to take or omit to take any action in order to secure a business advantage or any improper advantage.

    SUBRECIPIENT will promptly notify Emory of any event which interferes or threatens to materially interfere with the successful implementation of the Project, including credible suspicion of or actual, fraud, corruption or any other financial irregularity or impropriety related to the Project (collectively,

"Fraud"). In such event, SUBRECIPIENT will notify EMORY. SUBRECIPIENT will take timely and appropriate action to investigate credible allegations of Fraud, and cooperate fully with investigations into such matters, whether led by Emory, PRIME AGENCY, DFID or the Bill and Melinda Gated Foundation.

In the event of any credible indications that SUBAWARD funds may have been subject to Fraud, the Emory may, at any time during the Grant Period and for a period of up to five (5) years thereafter, arrange for additional Fraud investigations, on-the-spot checks and/or inspections of Project records to be carried out. If Fraud is established by such investigations, SUBRECIPIENT agrees to work with Emory and use its reasonable best efforts to recover the amount of funds subject to Fraud and restore them to the Project account or, at the direction of Emory, directly to them. During such period(s) of investigation,

SUBRECIPIENT acknowledges and accepts the right of Emory to suspend, withhold or terminate funding in accordance with the terms and conditions of this Grant Agreement.

35. **ANTI-TERRORIST COMPLIANCE:** SUBRECIPIENT hereby agrees that all funds, including SUBAWARDs to subrecipients, will be used in compliance with all applicable U.S. anti-terrorist financing and asset control laws, regulations, rules, and executive orders. SUBRECIPIENT will use reasonable efforts to ensure that it does not support or promote terrorist activity or related training, or money laundering. Further, SUBRECIPIENT will assure itself that the SUBAWARD funds will not be made available, either directly or indirectly, to or for the benefit of, persons, groups or entities listed in European Council Regulation EC/2580/2001 (as amended) and/or the Terrorism (United Nations Measures) Orders 2009 of the United Kingdom, or contravene the provisions of those and that of any subsequent applicable anti-terrorism legislation.

36. **LOCAL LAWS AND REGULATIONS**: SUBRECIPIENT hereby represents and warrants that it is duly organized and appropriately registered in INDIA to fulfill its responsibilities and conduct all activities under the Agreement.

    SUBAWARDEE further represents and warrants that all activities conducted under this Agreement shall be conducted in compliance with all local, regional and national laws, as applicable, including, but not limited to laws related to research involving human subjects and the transport of specimens and/or other data under this Agreement.

37. **DISSEMINATION, DATA SHARING AND INTELLECTUAL PROPERTY:** Information about research funded through the Drivers for Food Choice (DFC) Competitive Grants Program will be made available on the public DFC website (http://www.driversoffoodchoice.org). SUBRECIPIENT will be asked to collaborate with the DFC team on research uptake and dissemination activities, which may include, among others, presentations at seminars and conferences, blogs, interviews and opinion pieces. SUBRECIPIENT will be expected to disseminate the results of their research as widely as possible, based on the premise that publicly-funded research data are a public good, produced in the public interest, and should be made openly available to other researchers in a timely manner to the maximum extent possible. As well as scientific communication, emphasis is placed by the funder on engagement with potential users and beneficiaries of research, and the route to

application of its outcomes. Consideration of possible pathways to impact will form an important element of the assessment of proposals.

The DFC Competitive Grants Program will utilize the free Dataverse Network project to facilitate public access to datasets. The "Dataverse Network project develops software, protocols, and community connections for creating research data repositories that automate professional archival practices, guarantee long-term preservation, and enable researchers to share, retain control of, and receive web visibility and formal academic citations for their data contributions." Further information about this service can be found here: http://thedata.orp·/home. Datasets will be finalized for public access within six months after the end of each grant funding period. Datasets will not be made available for public access until 12 months after the end of each grant funding period. During this 12-month period, the SUBRECIPIENT will have exclusive use of the data for publications and reports. After 12 months, the data will be available for public access. Extensions up to 18 months may be requested by the SUBRECIPIENT and must be authorized by the DFC

Competitive Grants Program. Users must be requested by the SUBRECIPIENT and must be authorized by the DFC Competitive Grants Program. Users must have extensive previous experience in making data-use agreements and have a template to use to initiate agreements. In cases where grantees have pre-existing agreements or legal constraints that preclude providing full access to data, they will be required to identify these limitations in the Data Access Plan.

Consultation with the DFC Competitive Grants Program staff and the Bill & Melinda Gates Foundation will be necessary to come to agreement on what data will and will not be made publicly available and how these limited data are to be shared prior to receipt of funding. SUBRECIPIENT must contact EMORY prior to any contact with the DFC Competitive Grants Program staff or the Bill & Melinda Gates Foundation.

All intellectual property rights for all material (including but not limited to reports, data, designs, whether or not electronically stored, and technologies) produced by the investigator(s) or the investigators' personnel, and arising from research funded through this Subaward Agreement will be the property of the investigators' institution(s). The investigators' institution(s) will grant to the funders of the program, if requested, a world-wide, non- exclusive, irrevocable, royalty-free license to use all such material. If investigator(s) wish to apply for a patent for a particular application arising out of the information, however, they may request that publication of data is withheld until the patent application has been made. After that time, the data must be made freely available. The funders should be consulted about any request of this kind at an early stage, and any license(s) granted must be managed in a way that is consistent with the core principles of Global Access, i.e., that the findings of the research would be disseminated promptly and broadly, and that products and technologies arising from the knowledge gained would be made available and accessible at reasonable cost to people most in need in developing countries.

Notwithstanding the foregoing, The SUBRECIPIENT grants to EMORY an irrevocable, world-wide, royalty-free, non-transferable, non-exclusive right and license to use any copyrights or copyrighted material (including any computer software and its documentation and/or databases) delivered or

developed under this Agreement for the purpose of its own education and research and for meeting EMORY's obligation under its PRIME AWARD.

38. **PRIVACY AND NON-CONFIDENTIALITY NOTICE:** The Bill & Melinda Gates Foundation is required by the U.S. Internal Revenue Service to publish a list of its grants. The Bill & Melinda Gates Foundation also provides a general description of the grants it awards on their web sites, in press releases, and in other marketing materials. Subject to the Bill & Melinda Gates Foundation's Privacy Policy, the foundation may also share SUBRECIPIENT's proposal, reports, and related materials with third parties, including external reviewers, key partners and co funders. This document is subject to the foundation's Terms of Use.

39. **DISPUTES:** Resolution of disputes of a technical nature shall be resolved through good faith negotiations to the greatest possible extent. Any dispute arising under or related to this Agreement shall be resolved, to the maximum possible extent, through good faith negotiations and settlement. Failing settlement, despite reasonable efforts by both parties, any such unresolved issues shall be presented to EMORY whose decision will be reduced to writing with a copy furnished to the SUBRECIPIENT. Within 30 days after the date of receipt of such copy, the SUBRECIPIENT may notify EMORY in writing of its appeal of the decision, and, in the absence of such notice, EMORY's decision shall be final. In the event of notice from the

    SUBRECIPIENT of its appeal, the SUBRECIPIENT may pursue any right or remedy it may have at law or in equity in any court of competent jurisdiction. Pending such appeal, the SUBRECIPIENT shall proceed diligently with the performance of this Agreement and in accordance with EMORY's decision. All disputes under this Agreement shall be resolved and conducted, regardless of the means or authority, in the English language.

40. **GOVERNING LAW AND JURISDICTION:** This Agreement shall be governed, construed and enforced for all purposes in accordance with the laws of the State of Georgia, United States, without regard to principles of conflicts of law, provided that, insofar as the terms of this Agreement (including without limitation any specific U.S. or international regulatory or professional standards adopted by or incorporated into this Agreement) may contradict or be inconsistent with such law, then the terms of this Agreement shall prevail and be enforced. In addition, matters arising out of or concerning this Agreement or SUBRECIPIENT relationship with EMORY, SUBRECIPIENT hereby consents to jurisdiction and venue in DeKalb County, Georgia, U.S.A. and agrees to submit itself to the jurisdiction of the appropriate state, federal, and local courts therein.

41. **NOTICES:** Any notices to be given under this Agreement shall be submitted to the SUBRECIPIENT Administrative Contact, identified in Article 4 above, or the EMORY Administrative Contact, identified in Article 10 above, as appropriate.
42. **WAIVER AND SEVERABILITY:** No delay, failure or waiver of either Party's exercise or partial exercise of any right or remedy under this Agreement will operate to limit, impair, preclude, cancel, waive or otherwise affect such right or remedy. No waiver of any provision of this Agreement will constitute a waiver of any other provision or of the same provision on another occasion. If any provision of this Agreement is held by a court of competent jurisdiction to be illegal, invalid or

unenforceable, the remaining provisions will remain in full force and effect, provided that the surviving portion materially comports with the original intent of the Parties.

43. **INDEPENDENT CONTRACTOR:** In the performance of this Agreement, SUBRECIPIENT shall be deemed to be an independent contractor and, as such, no employee or staff of SUBRECIPIENT shall be entitled to any benefits applicable to employees of EMORY

44. **USE OF NAME:** Neither party shall use the name of the other party, nor the name of any faculty member, employee, or student of the other party, in connection with any product, service, promotion, news release, or other publicity without the prior written permission of the other party and, if an individual's name is used, of that individual.

45. **GOVERNING LANGUAGE:** In the event that a translation of this Agreement is prepared and signed by the parties, and a conflict arises between the English version and other language version, this English language version shall be the official version and shall govern and control.

46. **MODIFICATION OF CONTRACT:** This Agreement may only be changed or modified by mutual written agreement, signed by both parties. No modifications or addition will be binding until signed by both parties.

47. **FORCE MAJEURE:** Neither party shall be in violation of this Agreement, and neither party shall be liable to the other for damages in the event either is prevented from performing any of the obligations hereunder for a reason beyond its reasonable control, including without limitation, natural disaster, epidemic, act of God, declared war, strike, governmental restrictions and controls or production or maintenance delays.

48. **ENTIRE AGREEMENT:** This Agreement constitutes the entire understanding and agreement between the parties with regard to SUBRECIPIENT'S participation in the Project. SUBRECIPIENT acknowledges and agrees that participation in the Project shall be governed by this Agreement, unless mutually agreed by the parties in writing.

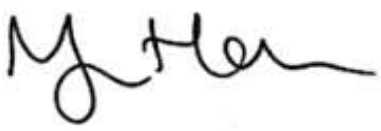
49. **HEADINGS:** The headings to the various sections of this Agreement have been inserted for convenience of reference only and shall not modify, define, limit or expand the express provisions of this Agreement. No provision of this Agreement is to be interpreted for or against either party because that party or that party's legal representative drafted such provision.

50. **COUNTERPARTS:** This Agreement may be executed in any number of counterparts, each of which shall be deemed an original, and all of which counterparts together shall constitute but one and the same instrument.

IN WITNESS WHEREOF the respective Parties have executed this Agreement effective as of the date of last signature below. By signing below, in addition to executing this Agreement on behalf of the SUBRECIPIENT, SUBRECIPIENT's authorized representative also individually and personally makes the certifications, representations and assurances contained herein and as shown in Appendix D.

Emory University

Signature:



Name: Maggie Hassan

Title: Associate Director, OSP

Date: 10/04/2018

BLDE (Deemed to be University)

Signature:

Name: Dr. S P Guggarigoudar

Title: Dean, Faculty of Medicine and Principal, BLDE (Deemed to be University), Shri B M Patil Medical College, Hospital & Research Center, Vijayapura

PRINCIPAL
BLDE (Deemed to be University)
Shri B. M. Patil Medical College
Hospital & Research Centre,
VIJAYAPUR-586103

Date: 06-10-2018

APPENDIX A

STATEMENT OF WORK/PROJECT DESCRIPTION

BLDE (Deemed to be University) Subcontract Scope of Work

Dr. Shailaja S. Patil, MD will be responsible for scientific leadership, adherence to program vision, coordination of the study at the site, quality control, and financial accountability. She will work with her PI and Co-PIs in developing proposal lead the survey implementation and participate in presentation and writing manuscripts

Project Coordinators, Research Assistants at BLDE (Deemed to be University) will assist Dr. Patil in coordinating all aspects of the project, including, hiring, training and coordination of field staff, execution and monitoring of field work, human subjects approval and adherence, and monitoring of data entry and coordinate financial transactions and maintain timeline of progress of the project .the salary is calculated on the basis of assumptions made referring the salaries of similar positions in other external funded projects in the local institute. Designated computer and data entry personnel will be responsible for data entry and data management, extracted from each study form, along with checking for accuracy and security of study data at all times. The field staff/interview team at BLDE (Deemed to be University) will be responsible for conducting interviews, obtaining prior consents, and coordination of study participant appointments.

APPENDIX B

BUDGET (COST-REIMBURSEMENT)

DFC Competitive Grants Program Budget Worksheet: Year 1 (BLDE (Deemed to be University)

Project Begin Date: 1/2/2018
Project End Date: 1/31/2020
Number of years: 2

Grand Total Dollar Amount: $ 56,259

PERSONNEL

Name	Title	% Effort	Months	Annual Salary	Total Salary	Total Fringe Benefits	Total Cost
Dr.Shaiaja Patil	CO-PI	35%	4.20	$ 10,262.00	$ 10,262.00	$ 307.86	$ 10,569.86
TBN	Project coordinator	100%	12.00	$ 6,792.00	$ 6,792.00	$ 203.76	$ 6,995.76
TBN	Budget manager /assistant	100%	12.00	$ 938.00	$ 938.00	$ 28.14	$ 966.14
TBN	Computer assistant / data er	100%	6.00	$ 2,250.00	$ 1,125.00	$ 33.75	$ 1,158.75
TBN	Field supervisor (1)	100%	9.00	$ 2,813.00	$ 2,813.00	$ 84.39	$ 2,897.39
TBN	Field staff (interviewer) (4)	100%	9.00	$ 2,438.00	$ 1,828.50	$ 54.86	$ 7,533.42
TBN	Research Assistant			$ 3,500.00	$ 3,500.00	$ -	$ 3,500.00
						$ -	$ -
						$ -	$ -
					PERSONNEL SUBTOTAL		$ 33,621

EQUIPMENT (Cost > 5,000.00 USD)

Equipment Name/Description:	Justification:	Quantity:	Cost per unit	Total	Additional Notes:
				EQUIPMENT SUBTOTAL	$ -

SUPPLIES (Cost < 5,000.00 USD)

Supplies Name/Description	Justification:	Quantity:	Cost per unit:	Total	Additional Notes:
printring modules for data collection	data collection instruments	80000	$ 0.04	$ 3,200.00	*field work supplies for 6people (4 interviewers, 1 supervisors and 1 project coordinator, i resaerch assistant) *phone charges / internet WIFI rent @ office for 1000 Rs/month and Sim card with monthly top up for 6 people for 9 monthsin year 1 .
field work supplies*	bag/badge/stationeryincludin g	8	$ 7.80	$ 62.40	
Recurring stationery expenses	office use	12	$ 50.00	$ 600.00	
phone chargest/sim cards*	field work coordination	6	$ 28.00	$ 168.00	
Printing colour laminated flash cards and	For food group selection required for data collection	860	$ 0.50	$ 430.00	
Monthly Internet WIFI rental charges	Office internet use, skype calls etc..	12	$ 24.00	$ 288.00	
antivirus	protection of data in computer	$ 1.00	$ 48.00	$ 48.00	
				SUPPLIES SUBTOTAL	$ 4,796

TRAVEL

Destination:	Justification:	Quantity:	Cost per unit:	Total	Additional Notes:
Local Travel and Field Work	vehicle hiring for field work	0.75	$ 8,555.00	$ 6,416.25	
preperatory phase for meeting , permissi	iring for preperatory work rela	2	$ 80.00	$ 160.00	
			$ -	$ -	
			$ -	$ -	
			$ -	$ -	
				TRAVEL SUBTOTAL	$ 6,576

OTHER EXPENSES (Other Than Supplies)

Expense:	Justification:	Quantity:	Cost per unit:	Total	Additional Notes:
Incentives(Participant)	participation in data collection	800	$ 4.00	$ 3,200.00	800 plus survey instruments include Aim 1 , 2 & 3for translation and back translation charges (approx @ 60 Rs /module)
lation and Backtranslation of survey instru	for local language use	800	$ 1.00	$ 800.00	
during first quarter of study for IHMS clear	ance (paper work, phone charges , copying e		$ 300.00	$ 300.00	
digital cameras for field work	r food database and documen	2	$ 100.00	$ 200.00	
Training expenses	s stationary during training of interviewers		$ 100.00	$ 100.00	
computer	ta entry/storage/communicati	$ 1.00	$ 938.00	$ 938.00	
printer/copier/fax	comunication	$ 1.00	$ 313.00	$ 313.00	
cupboards with locks	storage of data in hard copy	$ 1.00	$ 300.00	$ 300.00	
				OTHER EXPENSES SUBTOTAL	$ 6,151
				TOTAL DIRECT EXPENSES	$ 51,145
				INDIRECT (10%)	$ 5,114
				GRAND TOTAL	$ 56,259

Budget justification, BLDE (Deemed to be University) (Sub Contract) Personnel:

- ***Shailaja S. Patil, MD, Co- Principle Investigator*** (4.20 calendar-months in year 1 & 4.20 in year 2), is Professor, Department of Community Medicine, Sri. B. M. Patil Medical College, BLDE (Deemed to be University). She will be responsible for scientific leadership, adherence to program vision, coordination of the study at the site, quality control, and financial accountability. She will work with her PI and Co-PIs in developing proposal lead the survey implementation and participate in presentation and writing manuscripts. Total salary is calculated considering she will work 35% of her time @ unit cost rate for each month based on the base salary of the investigator at her working institution.
- **(*TBH) Project Coordinator*** (24 .00 calendar-months), will be a MSc graduate / PhD trainee will assist Dr. Patil in coordinating all aspects of the project, including, hiring, training and coordination of field staff, execution and monitoring of field work, human subjects approval and adherence, and monitoring of data entry and coordinate financial transactions and maintain timeline of progress of the project .the salary is calculated on the basis of assumptions made referring the salaries of similar positions in other external funded projects in the local institute.***Project Coordinator*** will be full time (100% time) for this project.
- (TBN**) Research Assistant** (7.20 calendar-months), A junior faculty / a Ph.D trainee who will be helping in all aspects of the project to Dr.Patil , the consolidated salary is calculated on the basis of assumptions made referring the salaries of similar positions in the local institute.
- *(TBH**) Budget Coordinator*:** (24.00 calendar-months) It will be a person from finance section of the university who will be arranging the salary payments of all project staff at BLDE (Deemed to be University) including the tax deduction, maintaining receipts and financial transactions related papers. Getting the audit done for the project amount utilization at the end of first year and after completion of the project and maintaining and filing all the finance related documents. The salary is estimated based on the salaries of similar positions in other external funded projects carried out in the local institute depending on part time involvement.
- *(TBH)* ***Computer assistant/data entry personnel:*** (6.00 calendar months in 1st and 6.00 calendar months in 2nd year) the person will be a graduate or diploma in computer application, trained in data entry and data management. Will input data from interview forms, check data entered for accuracy, clean data, ensure that data is secure, and produce status reports as needed he will also maintain the error log book. The salary is estimated based on the payments made to similar position in the previous projects.
- *(TBH**) Field Supervisor 1*(FS)** (9.00 calendar months in 1st and 6.00 calendar months in 2nd year) she/he will be responsible for day to day monitoring of field

work, can also participate as field interviewer when required along with other field staff. She/he will monitor the interviewers to ensure that study protocol and human subjects' guidelines are being adhered to, check data for completeness and accuracy, and collect data sheets for delivery to the study coordination office. **FS** will arrange for day to day logistics needed for field work, plan and coordinate the travel for each day during data collection and ensure the availability of all the materials required for the data collection with the checklist, and has alternative plan for multiple visits if required and check all the survey instruments at the end of day and informs the project coordinator on daily basis. Salary is calculated based on the payments made to similar position in our previous projects.

- ***(TBH) Field staff / interviewers (4)*** (9.00 calendar months in 1st and 6.00 calendar months in 2nd year) (2 teams of 2 each).They will be a graduates or Medico-Social Workers. They will be responsible for conducting the interviews, taking prior consents and appointments of the study participants by phone and planning the day to day visits and re-visits in close coordination with field supervisor and project coordinator. They will adhere to human subject protocols during interview. Salary is estimated based on the previous payments made to similar positions made in our projects.

Supplies:

- *Printing modules for data collection*: 80000 printed sheets are required for collection of data from approximately 1600 study participants including the consent forms. Cost is generated by calculating @ 2 INR **(Indian Rupee)**for printing of single sheet.
- *Field works supplies*: It's a kit that contains Bag, Identity card/badge laminated for each interviewer and project staff and stationery required for field work. Cost is generated by calculating each field kit @ 500 INR approximately.
- *Recurring stationery expenditure*: Includes materials required for office use and field work like pen, pencil, paper etc. Totaling @ 2000 INR per month approximately.
- *Phone charge/ sim card:* All the 4 interviewers and 1 supervisor , 1Project coordinator will be provided with a Sim card in the beginning of the study and every month it will be recharged with top-up for the period of data collection, for communication with the project coordinator and for contacting the study participants etc., totaling @ 1800 INR per month approximately.
- *Flash cards and health education materials:* Approximately 250, they will be color printed and laminated. Cost is generated at @70 INR per card including lamination.
- *Monthly Internet WIFI rental charges:* Includes WIFI recharge at the project office for communication /Skype calls etc. with Emory University and elsewhere. It is calculated considering @ 1500 INR per month total for 24

months.

- *Computer:* it will be based at the project office to be used for data entry, data management, and analysis. BLDE **(Deemed to be University)** does not provide a restricted access computer for entering and storing data. **The computer** will be used for the sole purpose of this project, password protected, and stored in a secure cabinet. Cost is calculated based on the present rate of the standard company desktop sets available at the market.
- *Printer/copier/fax:*Used for printing and copying of questionnaires, information sheets, consent forms, training manuals, and other project related materials. Cost is calculated based on the present rate of the standard company printer/ copier/fax sets available at the market.
- *Antivirus:*Used for protection of compiled and analyzed data entered in the desktop.Cost is calculated based on the present rate of the standard company antivirus available at the market for two years.

Travel:

- *Local travel and field work:*It includes van rental including fuel charges accommodating minimum 6-7 people excluding the driver for travel of field teams, project staff for 9 months in 1st year and 6months in 2nd year. Calculated @ 1520INR per day (Hiring charges and Fuel) approximately.

Other expenses:

- *Translation/back translation of the survey instrument*: Translation of study forms and documents into Kannada (local language) and back-translation into English to ensure accuracy of translation. It is calculated @ 30 INR per module of approximately.
- *Incentives for the participants:* Incentives will be given to all the study participants @ 500 INR per participants/ approximately for 2-3 visits in 2 years.

APPENDIX C

SAMPLE INVOICE

APPENDIX C
SAMPLE INVOICE

YOUR INSTITUTION
ADDRESS
TELEPHONE/FAX

TO: EMORY UNIVERSITY
Via E-mail: invoices@emory.edu
ATLANTA, GA 30322

INVOICE DATE:
(YOUR ACCOUNT IDENTIFIER):
INVOICE#:

CONTACT/AWARD NO: _____38963NIH-Armenia/R01 TW010664

REIMBURSABLE EXPENSES FROM: _____ THRU _____

AMOUNT FOR THE CURRENT PERIOD $_____

EXPENSES	CURRENT EXPENSES	CUMULATIVE
SALARY/WAGES		
FRINGE BENEFITS (Rate: %)		
CONSULTANTS		
COMMUNICATIONS		
SUPPLIES		
TRAVEL		
EQUIPMENT		
PATIENT CARE		
OTHER	_____	_____
TOTAL DIRECT COSTS		
INDIRECT COST (Rate: %)	_____	_____
TOTAL EXPENSES	_____	_____

By signing this report, I certify to the best of my knowledge and belief that the report is true, complete, and accurate, and the expenditures, disbursements and cash receipts are for the purposes and objectives set forth in the terms and conditions of the Federal award. I further certify that payment made by EMORY under this Agreement shall not duplicate reimbursement of costs and services which are received from other sources. I am aware that any false, fictitious, or fraudulent information, or the omission of any material fact, may subject me to criminal, civil or administrative penalties for fraud, false statements, false claims or otherwise. (U.S. Code Title 18, Section 1001 and Title 31, Sections 3729–3730 and 3801–3812).

CERTIFIED CORRECT BY:

_____
NAME
TITLE

APPENDIX D

PRIME AWARD

Subaward Agreement – Non-Federal

Prime Awardee	Subawardee
Institution/Organization ("UNIVERSITY") Name: University of South Carolina Address: Sponsored Awards Management 1600 Hampton Street, Suite 414 Columbia, SC 29208 Principal Investigator: Dr. Christine Blake	Institution/Organization ("COLLABORATOR") Name: Emory University Address: 1599 Clifton Road Atlanta, Georgia 30322 Principal Investigator: Dr. Solveig Argeseanu Cunningham

Prime Award No.	Subaward No.	Purchase Order No.
OPP1110043	18-3594	2000038671

Sponsor

University of South Carolina

Subaward Period of Performance	Amount Funded this Action	Est. Total (if incrementally funded)
January 1, 2018 to December 31, 2018	140,292	129,708

Project Title: "Food Choice in Indian Households in the Context of the Nutrition Transition"

Reporting Requirements [Check here if applicable: X See Attachment 1]

Terms and Conditions

1) University hereby awards a cost reimbursable subaward, as described above, to Collaborator. The statement of work and budget for this subaward are shown in Attachment 4. In its performance of subaward work, Collaborator shall be an independent entity and not an employee or agent of University.
2) University shall reimburse Collaborator not more often than monthly for allowable costs. All invoices shall be submitted using Collaborator's standard invoice, but at a minimum shall include current and cumulative costs (including cost sharing), subaward number, purchase order number and certification as to truth and accuracy of invoice. *Invoices that do not reference University's subaward and purchase order numbers shall be returned to Collaborator.* Invoices and questions concerning invoice receipt or payments should be sent to the appropriate party's Principal Investigator, as shown in Attachment 2.
3) A final statement of cumulative costs incurred, including cost sharing, marked "FINAL," must be submitted to University's Principal Investigator NOT LATER THAN forty-five (45) days after subaward end date. The final statement of costs shall constitute Collaborator's final financial report.
4) All payments shall be considered provisional and subject to adjustment within the total estimated cost in the event such adjustment is necessary as a result of an adverse audit finding against the Collaborator.
5) Matters concerning the technical performance of this subaward should be directed to the appropriate party's Principal Investigator, as shown in Attachment 2. Technical reports are required as shown above, "Reporting Requirements."
6) Matters concerning the request or negotiation of any changes in the terms, conditions, or amounts cited in this subaward agreement should be directed to the appropriate party's Administrative Contact, as shown in Attachment 2. Any such changes made to this subaward agreement require the written approval of each party's Authorized Official, as shown in Attachment 2.
7) Each party shall be responsible for its negligent acts or omissions and the negligent acts or omissions of its employees, officers, or directors, to the extent allowed by law.
8) Either party may terminate this agreement with thirty days written notice to the appropriate party's Administrative Contact, as shown in Attachment 2. University shall pay Collaborator for all allowable, noncancellable obligations in the event of termination.
9) No-cost extensions require the approval of the University. Any requests for a no-cost extension should be addressed to and received by the Administrative Contact, as shown in Attachment 2, not less than thirty days prior to the desired effective date of the requested change.
10) The Subaward is subject to the terms and conditions of the Prime Award and other special terms and conditions, as identified in Attachment 1.

By an Authorized Official of UNIVERSITY:	By an Authorized Official of COLLABORATOR:
Brandi K. Boniface, Associate Director Sponsored Awards Management Date: 3/12/18	Viraj Parmar Digitally signed by Viraj Parmar DN: cn=Viraj Parmar, o, ou, email=viraj.k.parmar@emory.edu, c=US Date: 2018.03.19 14:44:03 -04'00' Date

Attachment 1
Research Subaward Agreement
Terms and Conditions

Special terms and conditions:

1. ***This project is incrementally funded contingent upon USC receiving payment from Funder and there is automatic carry forward.***
2. ***All term and conditions indicated in the RFA are applicable.***

3. ***Human Subjects***
   If human subjects are used in the conduct of research the protocol must be approved annually by the appropriate Institutional Review Boards. Subrecipient may not conduct research on humans unless there is evidence of an approved assurance of regulatory compliance and evidence of the annual review of the of the human subjects protocol.

4. ***Continuation of Terms and Condition is attached.***

Continuation of Attachment 1

Terms and Conditions to be applied as applicable.

Your organization has been selected to participate in this Project at our discretion. You may not make any statement or otherwise imply to donors, investors, media or the general public that you are a direct grantee of the Bill & Melinda Gates Foundation ("Foundation") or the Department for International Development of the United Kingdom of Great Britain and Northern Ireland ("DFID") (Funders). You may state that University of South Carolina is the Foundation and DFID's grantee and that you are a subgrantee, subcontractor or subawardee of University of South Carolina for the Project.

Charitable Purpose of the Grant. The charitable purpose of this grant is to gain a deep understanding of the drivers of food choice among the poor in developing countries in South Asia and Sub-Saharan Africa in order to guide on-going and future programs and research activities to improve food and nutrition security in poor countries and to foster a community of practice in food choice research in developing countries, as described in your attached proposal (the "Proposal") and budget.

Use of Grant Funds. Grant funds may only be used for the Project. Any grant funds unexpended or uncommitted at the end of the Grant Period must be promptly returned to the University of South Carolina. Any Budget cost category change of more than 10% must be approved in writing by the University of South Carolina in advance. You may not use the grant funds to reimburse any expenses you chose to incur prior to the Start Date.

Political Campaign/Lobbying Activity. Foundation Funds may not be used to influence the outcome of any election for public office or to carry on any voter registration drive. There is no agreement, oral or written, permitting the Foundation Funds to be directed to or earmarked for lobbying activity or other attempts to influence local, state, federal, or foreign legislation. Subgrantee confirms that the amount of funds received from the Foundation, via a Subgrant from the University of South Carolina, will not exceed the amount budgeted each year for nonlobbying activities. Subgrantee agrees to comply with lobbying, gift and ethics rules applicable to the Project under local, state, federal or foreign law.

Anti-Terrorism. Subgrantee confirms that it is familiar with the U.S. Executive Orders and laws prohibiting the provision of resources and support to individuals and organizations associated with terrorism and the terrorist related lists promulgated by the U.S. Government. Subgrantee will use reasonable efforts to ensure that it does not support or promote terrorist activity or related training, or money laundering. Further, Subgrantee will assure itself that the Grant Funds will not be made available, either directly or indirectly, to or for the benefit of, persons, groups or entities listed in European Council Regulation EC/2580/2001 (as amended) and/or the Terrorism (United Nations Measures) Orders 2009 of the United Kingdom, or contravene the provisions of those and that of any subsequent applicable anti-terrorism legislation.

Fraud and Anti-Corruption. The University of South Carolina, and Subgrantee have a zero tolerance approach towards fraud and fraudulent behavior that may lead to the misuse of Grant Funds. The University of South Carolina, and Subgrantee will promptly inform each other of any event which interferes or threatens to materially interfere with the successful implementation of the Project, whether financed in full or in part by DFID or the Foundation, including credible suspicion of or actual, fraud, corruption or any other financial irregularity or impropriety related to the Project (collectively, "Fraud"). In such event, Subgrantee will notify University of South Carolina. Subgrantee will take timely and appropriate action to investigate credible allegations of Fraud, and cooperate fully with investigations into such matters, whether led by University of South Carolina, DFID or the Foundation.

In the event of any credible indications that Grant Funds may have been subject to Fraud, the University of South Carolina may, at any time during the Grant Period and for a period of up to five (5) years thereafter, arrange for additional Fraud investigations, on-the-spot checks and/or inspections of Project records to be carried out. If Fraud is established by such investigations, Subgrantee agrees to work with the University of South Carolina and use its reasonable best efforts to recover the amount of funds subject to Fraud and restore them to the Project account or, at the direction of University of South Carolina,
directly to them. During such period(s) of investigation, Subgrantee acknowledges and accepts the right of University of South Carolina to suspend, withhold or terminate funding in accordance with the terms and conditions of this Grant Agreement.

Subgrants and Subcontracts. Subgrantee is responsible for flowing down the terms of this agreement to lower tier subgrantees and subcontractors. Any agreements with lower tier subgrantees and subcontractors Subgrantee engages to assist with the Project must include the following language: "Your organization has been selected to participate in this Project at the University of South Carolina's discretion. You may not make any statement or otherwise imply to donors, investors, media or the general public that you are a direct grantee of the Bill & Melinda Gates Foundation ("Foundation") or the Department for International Development of the United Kingdom of Great Britain and Northern Ireland ("DFID"). You may state that University of South Carolina is the Foundation and DFID's grantee and that you are a subgrantee or subcontractor of University of South Carolina for the Project."

Due Diligence. In utilizing the Grant Funds, Subgrantee will exercise the same care in the discharge of its functions under this Grant Agreement as it exercises with respect to the administration and management of its own resources and affairs. Subgrantee will cooperate fully to resolve any due diligence issues raised by University of South Carolina or a Funder (or a Funder's delegate(s)) regarding Subgrantees internal controls and systems, and agrees to notify the University of South Carolina of any material changes to Subgrantees procedures, controls or operating environment that are relevant to the Project during the Grant Period. In addition, Subgrantee will assess the internal controls and systems of any lower tier subgrantees or subcontractors of the Project prior to disbursing funds to such entities, and at regular intervals throughout the Grant Period, as appropriate given the amount of the Grant Funds and risks of the Project. Such assessments should address: (1) the reliability and integrity of the organization's financial controls, systems and processes; (2) the effectiveness and efficiency of its Project operations; (3) its procedures for safeguarding Project assets; and (4) its compliance with applicable law. Upon request, Subgrantee will share the results of such assessments with the Funders.

Reporting. Subgrantee is required to submit two reports regarding the expenditure of Grant Funds and its progress on the Project. The first report is due February 15, 2019, which is 45 days after the end of year one. Subgrantee also agrees to submit other reports that University of South Carolina may reasonably request.

Communications. Subgrantee agrees to be in regular communication with the University of South Carolina throughout the Grant Period regarding Subgrantee's progress and to notify the University of South Carolina in writing promptly of any major development that is likely to have a material impact on Subgrantee's ability to achieve the Project objectives.

Record Maintenance and Inspection. The University of South Carolina requires that Subgrantee maintain adequate records for the Project to enable the University of South Carolina to easily determine how the Grant Funds were expended. Subgrantees's books and records must be made available for inspection by University of South Carolina or its designee at reasonable times to permit such Funder to monitor and conduct an evaluation of operations under this grant.

Compliance. If (a) Funder or University of South Carolina is not reasonably satisfied with Subgrantee's progress on the Project; (b) significant leadership or other changes occur that University of South Carolina believes may threaten the Project; or (c) Subgrantee fails to comply with any term or condition of this Grant Agreement, the University of South Carolina will notify Subgrantee of the concerns and provide Subgrantee with a reasonable period of time to address them. If no resolution satisfactory to University of South Carolina is reached within that time period, University of South Carolina may, at its discretion, terminate its support of the Project and/or grant. If University of South Carolina determines that the cause of its concerns cannot be remedied, University of South Carolina may immediately terminate, suspend, or withhold payment of Grant Funds to the grant. On termination, if requested by the University of South Carolina, Subgrantee agrees to promptly return to University of South Carolina any unspent and uncommitted funds (as of the date of termination).

Indemnification. Subgrantee will indemnify, defend, and hold harmless the University of South Carolina and the Funders and their trustees, employees, and agents ("Indemnified Parties") from and against any and all demands, claims, actions, suits, losses, damages (including property damage, bodily injury, and wrongful death), arbitration and legal proceedings, judgments, settlements, or costs or expenses (including reasonable attorneys' fees and expenses) (collectively, "Claims") arising out of or relating to the acts or omissions, actual or alleged, of the Subgrantee or its employees, lower tier subgrantees, lower tier subcontractors, contingent workers, agents, and affiliates with respect to the Project or this Agreement. Subgrantee agrees that any activities by the University of South Carolina in connection with the Project, such as its review or proposal of suggested modifications to the Project, will not modify or waive the University of South Carolina or Funders' rights under this paragraph. An Indemnified Party may, at its own expense, employ separate counsel to monitor and participate in the defense of any Claim. The Subgrantee's indemnification obligations are limited to the extent permitted or precluded under applicable federal, state or local laws, including federal or state tort claims acts, the Federal Anti-Deficiency Act, state governmental immunity acts, or state constitutions. Nothing in this Agreement will constitute an express or implied waiver of your governmental and sovereign immunities.

Dissemination, Data Sharing, and Intellectual Property. Information about research funded through the DFC Competitive Grants Program will be made available on the public DFC website (http://www.driversoffoodchoice.org). Subgrantees will be asked to collaborate with the DFC team on research uptake and dissemination activities, which may include, among others, presentations at seminars and conferences, blogs, interviews and opinion pieces. Subgrantees will be expected to disseminate the results of their research as widely as possible, based on the premise that publicly-funded research data are a public good, produced in the public interest, and should be made openly available to other researchers in a timely manner to the maximum extent possible. As well as scientific communication, emphasis is placed by the funder on engagement with potential users and beneficiaries of research, and the route to application of its outcomes. Consideration of possible pathways to impact will form an important element of the assessment of proposals.

The DFC Competitive Grants Program will utilize the free Dataverse Network project to facilitate public access to datasets. The "Dataverse Network project develops software, protocols, and community connections for creating research data repositories that automate professional archival practices, guarantee long-term preservation, and enable researchers to share, retain control of, and receive web visibility and formal academic citations for their data contributions." Further information about this service can be found here: http://thedata.org/home. Datasets will be finalized for public access within six months after the end of each grant funding period. Datasets will not be made available for public access until 12 months after the end of each grant funding period.

During this 12 month period, the Subgrantee will have exclusive use of the data for publications and reports. After 12 months the data will be available for public access. Extensions up to 18 months may be requested by the Subgrantee and must be authorized by the DFC Competitive Grants Program. Users

have extensive previous experience in making data-use agreements and have a template to use to initiate agreements. In cases where grantees have pre-existing agreements or legal constraints that preclude providing full access to data, they will be required to identify these limitations in the Data Access Plan. Consultation with the DFC Competitive Grants Program staff and the Bill & Melinda Gates Foundation will be necessary to come to agreement on what data will and will not be made publicly available and how these limited data are to be shared prior to receipt of funding.

All intellectual property rights for all material (including but not limited to reports, data, designs, whether or not electronically stored, and technologies) produced by the investigator(s) or the investigators' personnel, and arising from research funded through the Grant, will be the property of the investigators' institution(s). The investigators' institution(s) will grant to the funders of the program, if requested, a world-wide, non- exclusive, irrevocable, royalty-free license to use all such material. If investigator(s) wish to apply for a patent for a particular application arising out of the information, however, they may request that publication of data is withheld until the patent application has been made. After that time, the data must be made freely available. The funders should be consulted about any request of this kind at an early stage, and any license(s) granted must be managed in a way that is consistent with the core principles of Global Access, i.e., that the findings of the research would be disseminated promptly and broadly, and that products and technologies arising from the knowledge gained would be made available and accessible at reasonable cost to people most in need in developing countries.

Privacy and Non-confidentiality Notice

The Bill & Melinda Gates Foundation is required by the U.S. Internal Revenue Service to publish a list of its grants. We also provide a general description of our grants on our web sites, in press releases, and in other marketing materials. Subject to the foundation's Privacy Policy, the foundation may also share your proposal, reports, and related materials with third parties, including external reviewers, key partners and co funders. This document is subject to the foundation's Terms of Use.

Attachment 2
Subaward Agreement

University Contacts	Collaborator Contacts
Administrative Contact Name: Natasha Dozier Sponsored Program Administrator Address: Office of Sponsored Awards Management 1600 Hampton Street, Suite 414 Columbia, SC 29208 Telephone: 803-777-5370 Email: ndozier@mailbox.sc.edu	Administrative Contact Name: Viraj Parmar Address: 1599 Clifton Road 4th Floor Atlanta, GA 30322 Telephone: 404-727-2503 Email: osp@emory.edu
Principal Investigator Name: Dr. Christine Blake Address: Arnold School of Public Health Dept. of Health Promotion, Education and Behavior Discovery One Bldg. RM 549 Columbia, SC 29208 Telephone: (803) 777-1484 Email: ceblake@mailbox.sc.edu	Principal Investigator Name: Dr. Solveig Argeseanu Cunningham Address: 1518 Clifton Road Department of Global Health Atlanta, GA 30322 Telephone: 404-727-6486 Email: sargese@emory.edu
Financial Contact Name: Gina Hambrick Address: Office of Contract and Grant Accounting 1600 Hampton Street, 6th Floor Columbia, SC 29208 Telephone: 803-777-4850 Email: hambricg@mailbox.sc.edu	Financial Contact Name: Bill Lambert Address: 1599 Clifton Road 4th Floor Atlanta, GA 30322 Telephone: 404-727-2503 Email: fgc@emory.edu
Authorized Official Name: Brandi Boniface Associate Director Address: Office of Sponsored Awards Management 1600 Hampton Street, Suite 414 Columbia, SC 29208 Telephone: 803-777-8749 Email: bonifacb@mailbox.sc.edu	Authorized Official Name: Holly Sommers Address: 1599 Clifton Road 4th Floor Atlanta, GA 30322 Telephone: 404-727-2503 Email: osp@emory.edu

This MEMORANDUM OF UNDERSTANDING DATED the 22 day of July, 2012.

BETWEEN:

BLDE UNIVERSITY, INDIA

- and -

THE UNIVERSITY OF MANITOBA, CANADA

WHEREAS:

A. The University of Manitoba and the BLDE University, for the purpose of furthering cooperation through educational and academic exchanges, hereby affirm their intent to promote such cooperation activities as will be of mutual benefit for their respective institutions. Cooperation activities are considered here to include but not be limited to:

1. Development of mutually beneficial academic programmes and courses;
2. Coordination of academic staff mobility for purposes of teaching, research and training;
3. Coordination of student mobility programs for study and research;
4. Coordination of academic activities such as joint research, publication and symposia;
5. Exchange of documentation and research materials in fields of mutual interest provided that, to the best knowledge of the respective institutions, there is no prohibition at law or otherwise against the exchange; and
6. Other activities considered by the parties to be of benefit to each party's education and research programs.

B. Details of the implementation of any particular cooperation activity resulting from this Memorandum of Understanding shall be negotiated between the two institutions as such specific case may arise, and will be outlined in a Supplementary Agreement between the institutions. Supplementary Agreements are subject always to availability of sufficient funds at the respective institutions.

C. The institutions recognize that this cooperative relationship may result in the development of various types of intellectual property and technology transfer. The institutions are committed to working in good faith to develop fair principles for dealing with intellectual property and technology transfer, including ownership, use, publication, and confidentiality. These principles will be developed in accordance with the parties' respective policies and collective agreements and will be incorporated into the Supplementary Agreements.

D. Both parties shall designate a liaison office for this Memorandum of Understanding and for any Supplementary Agreements. For the BLDE University, the office shall be the Principal, Shri. B. M Patil Medical College, Hospital and Research Centre, Bijapur, Karnataka State, India. For the University of Manitoba, the liaison office shall be the Office of International Relations.

E. This Memorandum of Understanding reflects the commitment of the institutions to academic educational and research cooperation as of the date first written above.

F. This Memorandum of Understanding may be amended by mutual written agreement

G. This Memorandum of Understanding may be terminated at any time by either party, provided that notice of termination is provided by the notifying party to the other party at least ninety (90) days in advance of the date on which the termination is intended to become effective. Any termination of this Memorandum of Understanding shall not have effect on any arrangement in place at the time that the notice is provided, where the arrangement arises from any Supplementary Agreements resulting from this Memorandum of Understanding. Supplementary Agreements may only be terminated in accordance with the terms contained therein.

IN WITNESS WHEREOF the parties hereto have executed the Memorandum of Understanding as of the date first written above

THE UNIVERSITY OF MANITOBA

Witness

Per: _____
Dr. David T. Barnard
President and Vice-Chancellor
The University of Manitoba

BLDE UNIVERSITY

Witness Dr. M.S. BIRADAR PRINCIPAL

Per: _____ 22/9/2012
Prof. B. G. Mulimani MSc. PhD. (McGill, Canada)
Vice-Chancellor
BLDE University

ಪ್ರೊ. ಎಚ್.ಬಿ. ವಾಲೀಕಾರ
ಕುಲಪತಿಗಳು
ಕರ್ನಾಟಕ ವಿಶ್ವವಿದ್ಯಾಲಯ
ಪಾವಟೆ ನಗರ, ಧಾರವಾಡ-೫೮೦ ೦೦೩

Prof. H. B. Walikar
Vice-Chancellor
Karnatak University
Pavate Nagar, Dharwad-580 003
✆ : 0836-2448600 Fax : 0836-2747884
E-mail : vckudharwad@gmail.com
Webmail : vc@kud.ac.in
Website : www.kud.ac.in

"University with Potential for Excellence"
"ಉತ್ಕೃಷ್ಟ ಸಾಮರ್ಥ್ಯ ಹೊಂದಿರುವ ವಿಶ್ವವಿದ್ಯಾಲಯ"

Ref. No. : KVCS/Prog./2013-14/251

Date : 25-6-2013

Dear Prof. Mulimani,

I am happy to inform you that your faculty members are permitted to utilize the facilities of scientific instruments available in the University Scientific Instrumentation Centre (USIC) and other Departments of our University for their research work.

With regards,

Yours sincerely,

Prof. H. B. Walikar

Prof. B. G. Mulimani
Vice-Chancellor
BLDE University
Sholapur Road
BIJAPUR- 586 103

Registrar
For record and needed action
BGM
26/6/13

MEMORANDUM OF UNDERSTANDING

Between

TULANE UNIVERSITY, USA

and

FACULTY OF MEDICINE, BLDE UNIVERSIY, INDIA

BLDE UNIVERSITY

The Administration of the Tulane Educational Fund through the Tulane University School of Medicine, a non-profit company incorporated in the State of Louisiana, USA ("Tulane University") and the **Faculty of Medicine, BLDE University**, Vijayapura, Karnataka State, India agree to enter into this Memorandum of Understanding (MOU) based on a foundation of trust for the mutual benefit and development of the two universities and the promotion of international understanding and goodwill.

A. Background:

I. The Parties seek to demonstrate by signing this Memorandum their commitment to co-operation in terms of common interest through the development of collaboration between Tulane University, USA and Faculty of Medicine, BLDE University, India.

II. The Parties recognize the mutual benefit each will gain from working together and the value this will add to the promotion of not only medical sciences research but also overall impact on health sectors globally.

B. Scope of Co-operation & Activities:

Tulane University and the Faculty of Medicine, BLDE University desire to explore and promote some or all of the following activities based on their respective academic and research needs, which may be formally developed through a separate legally binding agreement between the parties:

I. Exchange of research materials, publications and research information

II. Organization of joint research programs

III. Exchange of research students (Doctoral &Post doctoral) of basic sciences & clinical medicine.

IV. Exchange of academic staff of basic sciences and clinical medicine.

V. Exchange of administrative staff

C. Management of Co-operation:

I. The implementation of exchange based on the MOU shall be separately negotiated and determined by both universities.

II. Nothing shall diminish the full autonomy of either university, nor will any constraint or financial obligations be imposed by either upon the other in carrying out MOU.

III. The parties acknowledge that this MOU does not involve the transfer of monies between the parties. The parties further acknowledge that no sponsor funding exists regarding activity contemplated by this MOU.

IV. Any notice required to be given under this Agreement by either Party will be in writing and sent to the other Party by either hand delivery or certified mail return receipt requested as follows:

V. If to Tulane:

Dr. Lee Hamm, MD
Dean & Vice President
Tulane University Health Sciences Centre
1430 Tulane Avenue # 8001
New Orleans, LA 70112

With copy to:

Prof. L.G. Navar, PhD
Professor & Chairman,
Department of Physiology,
Tulane University School of Medicine
1430 Tulane Avenue # 8001
New Orleans, LA 70112

VI. If to BLDE University

Faculty of Medicine, BLDE University
BLDE University
Smt. Bangaramma Sajjan Campus
Vijayapura -586103, Karnataka; INDIA;
Tel: +91 8352 262770, Fax: + 91 8352 263303
Email: registrar@bldeuniversity.ac.in
Website: www.bldeuniversity.ac.in

D. Terms and termination:

I. The MOU will be valid for three (3) years from the Effective Date. Thereafter, renewal of the MOU will be subject to the written agreement of both Parties.
II. This MOU is subject to revision by mutual written agreement. It is also understood that either Party may terminate the MOU for any reason and at any time upon thirty (30) days prior written notice to the other party; although such action will only be taken after mutual consultation in order to avoid any possible inconvenience to all parties.
III. The MOU is effective when representatives of both institutions have signed and dated the document ("Effective Date").

AUTHORIZED TO SIGN FOR AND ON BEHALF OF TULANE UNIVERSITY, USA:

Signature---------- Date----------3/29/16

Name in Capitals: PROF. LEE HAMM, MD

Position in Organization: DEAN, TULANE UNIVERSITY SCHOOL OF MEDICINE

AUTHORIZED TO SIGN FOR AND ON BEHALF OF FACULTY OF MEDICINE, BLDE UNIVERSITY, INDIA:

Signature---------- Date----------March 8, 2016.

Name in Capitals: **PROF. DR.M.S.BIRADAR**, MD

Position in Organization: DEAN - FACULTY OF MEDICINE, BLDE UNIVERSITY

Signature---------- Date----------March 8, 2016

Name in Capitals: **PROF. B.G. MULIMANI**, PhD

Position in Organization: VICE-CHANCELLOR, BLDE UNIVERSITY

B. L. D. E UNIVERSITY VIJAYAPUR.

MEMORANDUM OF UNDERSTANDING

(MoU)

FOR

A FOUNDATION OF TRUST FOR THE MUTUAL BENEFIT AND DEVELOPMENT OF BOTH INSTITUTIONS AND THE PROMOTION OF INTERNATIONAL UNDERSTANDING

MoU

Between

BLDE UNIVERSITY, VIJAYAPURA, INDIA

AND

HIGH ALTITUDE PULMONARY AND PATHOLOGY INSTITUTE - IPPA / ZUBIETA UNIVERSITY, LA PAZ, BOLIVIA

May 11, 2017

MEMORANDUM OF UNDERSTANDING

Between

BLDE University, Vijayapura, INDIA

AND

High Altitude Pulmonary and Pathology Institute - IPPA / Zubieta University, La Paz, BOLIVIA

The Administration of the BLDE University, Vijayapura, INDIA (recognized u/s 3A UGC Act 1956, Government of India) and High Altitude Pulmonary and Pathology Institute - IPPA and its virtual scientific research branch Zubieta University La Paz, BOLIVIA (with Licencia de Funcionamiento ZCG121CA551B del Gobierno Municipal en La Paz, Bolivia y Matricula Fundemepresa #367671) agree to enter into this Memorandum of Understanding (MOU) based on a foundation of trust for the mutual benefit and development of the two Institutions and the promotion of International understanding and goodwill.

A. Background:

I. Both the University / Institute seek to demonstrate by signing this Memorandum their commitment to co-operation in terms of common interest through the development of collaboration between BLDE University, Vijayapura, INDIA and High Altitude Pulmonary and Pathology Institute - IPPA / Zubieta University, La Paz, BOLIVIA. The Universities / Institute recognize the mutual benefit each will gain from working together and the value this will add to the promotion of not only medical sciences research but also overall impact on health sectors globally.

B. Scope of Co-operation & Activities:

BLDE University and High Altitude Pulmonary and Pathology Institute - IPPA / Zubieta University desire to explore and promote some or all of the following activities based on their respective academic and research needs-

I. Exchange of research materials, publications and research information
II. Organization of joint research programs with collaborations.
III. Exchange of research scholars
IV. Adjunct/Visiting Professorship for both the Parties
V. Exchange of faculty members/consultants including training in Pulmonology and high altitude.
VI. Exchange of administrative staff

C. Management of Co-operation:

I. Nothing shall diminish the full autonomy of either university/Institute, nor will any constraint or financial obligations be imposed by either upon the other in carrying out MOU.

II. The BLDE University and IPPA/ Zubieta University acknowledge that this MOU does not involve the transfer of monies between the parties. The parties further acknowledge that no sponsor funding exists regarding activity contemplated by this MOU.

III. Any notice required to be given under this Agreement by either Party will be in writing and sent to the other Party by either hand delivery or certified mail return receipt requested as follows:

IV. If to IPPA/Zubieta University, La Paz, Bolivia:

Name: Prof. Dr. Gustavo Zubieta-Calleja
Designation: Director / President
Tel: 591 2224 5394
Cel: 591 73258026
Email: gzubietajr@altitudeclinic.com

Copy to:
Lucrecia De Urioste
International relations
High Altitude Pulmonary and Pathology Institute
email:ldeuz@yahoo.com
Tel: 591 72597119

V. If to BLDE University

Faculty of Medicine
BLDE University
Smt.Bangaramma Sajjan Campus
Vijayapur-586103, Karnataka; INDA;
Tel: +91 8352 262770,Fax: + 91 8352 263303
Email: registrar@bldeuniversity.ac.in
Website: www.bldeuniversity.ac.in

Copy to:
Dr.J.G.Ambekar,PhD
Registrar
BLDE University
Vijayapura-586103,Karnataka, India
Email: registrar@bldeuniversity.ac.in
Tel: 91 8352 262770 (Ext.2327)

D. Terms and termination:

I. This memorandum is subject to revision or renewal by mutual agreement. It is also understood that either university/Institute may terminate the MOU at any time upon prior written notice to the other party; although such action will only be taken after mutual consultation in order to avoid any possible inconvenience to all parties.

II. The MOU will be valid for five (5) years in the instance. Thereafter, renewal of the MOU will be subject to the written agreement of both parties.

III. The MOU is effective when representatives of both institutions have signed and dated the document.

AUTHORIZED TO SIGN FOR AND ON BEHALF OF IPPA/ZUBIETA UNIVERSITY, LA PAZ, BOLIVIA:

Signature----------
Date---May 04, 2017
Name in Capitals: PROF. DR.GUSTAVO ZUBIETA-CALLEJA, MD
Position in Organization: DIRECTOR / PRESIDENT

Signature----------
Date---MAY 9TH, 2017
Name in Capitals: Lucrecia De Urioste
Position in Organization: International Relations

AUTHORIZED TO SIGN FOR AND ON BEHALF OF BLDE UNIVERSITY, INDIA:

Signature----------
Date---11.05.2017.
Name in Capitals: PROF.DR.M.S.BIRADAR,MD
Position in Organization: VICE CHANCELLOR

B. L. D. E. UNIVERSITY VIJAYAPUR

Signature----------
Date---11.05.2017.
Name in Capitals: PROF.DR.S.P.GUGGARIGOUDAR,MS
Position in Organization: DEAN – FACULTY OF MEDICINE

BLDE UNIVERSITY, VIJAYAPURA

ZUBIETA UNIVERSITY, LA PAZ, BOLIVIA

MEMORANDUM
OF
UNDERSTANDING

BETWEEN

KARNATAKA STATE WOMEN'S UNIVERSITY, BIJAPUR
AND
BIJAPUR LIBERAL DISTRICT EDUCATION UNIVERSITY, BIJAPUR

FOR
UTILIZING FACILITIES FOR RESEARCH WORK

Memorandum of Understanding for Utilizing Facilities for Research Work

This Agreement is made on this twenty-eight day of January 2012 between Karnataka State Women's University, Bijapur and BLDE University, Bijapur are hereafter individually referred to as 'party' and collectively as the 'parties'.

WHEREAS

1. Karnataka State Women's University is a State University. (Hereinafter referred as KSWUB)
2. BLDE University, Bijapur is a deemed University. (Hereinafter referred as BLDEUB)
3. BLDE University, Bijapur desires to utilize the facilities available at Women's University for research collaboration/activities.
4. The parties in order to give effect to the afore said mentioned understanding are desirous by the way of this agreement (hereafter referred to as agreement) to enter into a (legal) and binding contractual relationship between them on the terms and conditions set forth herein.

NOW THE AGREEMENT WITNESSETH AND IT IS HEREBY AGREED BY AND BETWEEN THE PARTIES HERE TO AS FOLLOWS:

ARTICLE-1: DEFINATIONS

1. Party shall mean Karnataka State Women's University, Bijapur or BLDE University, Bijapur, separately and parties shall mean KSWUB and BLDEU collectively.
2. Term shall mean the duration of the Agreement which shall be FIVE YEARS from the date of signing the Agreement and subsequent Extension mutually agreed.
3. Research facilities mean laboratories (Biochemistry, Microbiology and Immunology, Biotechnology) and Equipments- HPLC, PCR etc.

ARTICLE-2: SCOPE OF ENGAGMENT AND OBLIGATIONS OF THE PARTIES

2.1. The parties agree that for the terms and conditions set forth herein, KSWUB hereby permits BLDEU to utilize the facilities.

2.2. KSUWB shall supervise the research work, methodology and objectives handling of Equipments, use of reagents etc) in the safe, efficient and proper manner consistent with prudent management and research practices. BLDE University's Shri. B.M.Patil, Medical College, Bijapur, shall avail facilities provided by KSWUB.

2.3. BLDE University shall pay for all costs such as cost of reagents, consumables, materials, software etc that are required for research projects of BLDE University.

2.4. KSWUB shall provide assistance technique and guidance to research worker of BLDEU, free of cost.

2.5. BLDEU shall also provide assistance related to research work of KSWUB, free of cost.

2.6. Both the parties should include the names of research assistances involved, while publishing the research work.

2.7. The following departments of BLDEU would be involved in research work, Gen. Medicine, Paediatrics, Dermatology, Gen. Surgery, Obst. & Gyanc., Community Medicine, Pathology, Pharmacology, Biochemistry & Anatomy and animal house facility. These departments would utilize the research facilities of Biochemistry, Immunology & Biotechnology, Food Processing and Pharmaceutical Chemistry departments of KSWUB.

2.8. Additional equipments procured by BLDEU shall be repaired and continue to remain as property of BLDEU, KSWUB, will not have any right, what so ever on those equipments.

2.9. BLDEU would be responsible for repair and maintenance of equipments owned by BLDEU.

ARTICLE-3: INITIAL TERM AND RENEWAL TERM

The term of agreement shall comprise of the initial period of FIVE years from the date of signing this agreement.

Parties may, at their option (hereinafter referred to as the Renewal Term option) continue the agreement on the same terms and conditions as a set for herein mutually agreed for further period of 5 years (herein after referred to as Renewal Term) immediately following the lapse of initial term.

ARTICLE-4: TERMINATION

The agreement cannot be terminated by either party prior to the expiry of the initial period other than the reasons listed below in the clause 4.1 & 4.2.

4.1. TERMINATION BY KSWUB:

KSWUB may forthwith terminate this Agreement on any of the following occasion:

If BLDEU shall apply for or consent to the appointment of a receiver or liquidator of BLDEU or of all, or a substantial part of its assets, make a general assignment for the benefit of creditors, file a petition seeking reorganization or make any arrangements with its creditors or take advantage of any insolvency law, or if an order, judgement or decree shall be entered by any court of competent jurisdiction, on the application of a creditor, adjudicating BLDEU insolvent or approving a petition seeking reorganization of BLDEU or appointing a receiver or liquidator of BLDEU or all or a substantial part of its assets, and such order judgement or decree shall continue unstayed and in effect for any period of ninety (90) consecutive days then in case of any such even KSWUB may at this sole option, terminate this Agreement effective forthwith upon written notice to BLDEU.

4.2. TERMINATION BY BLDEU:

BLDEU may forthwith terminate this Agreement in the event that any of the following occur:

If KSWUB shall apply for consent to the appointment of a receiver or liquidator of KSWUB or of all or a substantial part of its assets, make a general assignment for the benefit of creditors, file a petition seeking reorganization or make any arrangements with its creditors to take advantage of any insolvency law, or if an order, judgment or decree shall be entered by any court of competent jurisdiction, on the application of creditor, adjudicating KSWUB insolvent or approving a petition seeking reorganization of KSWUB or appointing a receiver or liquidator of KSWUB or all or a substantial part of its assets, and such order, judgment or decree shall continue unstayed and in effect for any period of ninety (90) consecutive days then in case of any such event BLDEU may at its sole option, terminate this Agreement effective forthwith upon written notice to KSWUB.

ARTICLE-5: FORCE MEASURE AND SUSPENSION OF OPERATIONS

The parties agree that all events beyond their respective control being force measure including fire, flood, war, acts of God, lightening, earthquake, collapse of structure, government policies, macro economic factors, etc; which have the effect of preventing the performance of the Agreement entered in to between the parties. So affected shall be constructed to imply-automatic suspension of the obligations to perform temporarily or permanently, as case may be depending upon facts and the circumstances of the event.

ARTICLE-6: INDEMNIFICATION

Both the parties agree to indemnify and hold each other harmless against any loss or damages which either party may incur due to acts or omission arising out of the activities of the other party. The parties indemnify and hold each other harmless from any loss and damages by reason of or arising out of

6.1. Their proven or willful misconduct.

6.2. Their proven breach of the duties and obligations that they are required to perforator under the terms of the agreement.

6.3. In no event shall either party be liable for indirect, special or consequential damages which may arise under agreement.

6.4. The indemnity contained in this article shall not prejudice either party from exercising additional or alternative remedy or applicable rights under the law and or the party shall take indemnity insurance cover to protect each other and from any third party against the risk of compensation claim by the third party/court of law.

ARTICLE-7: RIGHTS AND REMEDIES

All rights and remedies confirmed under the agreement or by law shall be cumulative and may be exercised singularly or concurrently.

IN WITNESS WHEREOF THE PARTIES HAVE CAUSED THE AGREEMENT TO BE EXECUTED BY THEIR DULY AUTHORISED REPRESENTATIVES AS OF THE DATE, MONTH AND YEAR FIRST HERE-IN-ABOVE WRITTEN.

B Mulimani

Dr. B. G. Mulimani
Vice Chancellor
BLDE University,
Bijapur.

ಬಿಎಲ್‌ಡಿಇ ವಿಶ್ವವಿದ್ಯಾಲಯ
ವಿಜಾಪುರ-586101.

Prof. Geetha Bali
Vice Chancellor
Karnataka State Women's University,
Bijapur

REGISTRAR.
BLDE University, Bijapur.
28/1/2012
Dr J G Ambekar, Registrar

28/1/2012
Dr Akram Naikwadi, Dean R&D

28/1/2012
Prof G R Naik
Registrar

28/1/2012
Prof S A Kuyazi
Dean, Social Sciences

INTERNATIONAL COLLABORATIVE RESEARCH PROJECT

(2017 -2019)

Laboratory of Vascular Physiology and Medicine, Department of Physiology, BLDE University's Shri B.M.Patil Medical College, Hospital & Research Centre, Vijayapura-586103, Karnataka, India

AND

Department of Physiology, Tulane University School of Medicine, Tulane University, New Orleans LA70118, USA

February 2017

BLDE University, India & Tulane University, USA

PROJECT TITLE:

Hypoxia, metal exposure and cell signaling pathways: Evaluation of vascular integrity with renal functions in male albino rats supplemented with ascorbate and calcium channel blocker.

DURATION: 2 YEARS

1. **Background:**

Hypoxia signaling is one pathway that contributes to metal ion-induced carcinogenesis by disrupting cellular iron homeostasis though competition with iron transporters or iron-regulated enzymes In-vitro studies of human and rodent cells by Salnikow et al. showed that the HIF-1 signaling pathway is activated by exposure to carcinogenic nickel compounds [Salnikow K, 2000]. Several other hypoxia-inducible genes were up-regulated by heavy metal in a HIF-dependent manner. Additionally, other genes were induced by heavy metal in an HIF-1-independent manner, suggesting that heavy metal exposure activates several signaling pathways. Assessing the induction of these pathways after exposure is essential to the understanding of cancer development related to metal exposure [ATSDR 2003]. Recent studies indicate the ability of ascorbic acid to regulate factors that may influence gene expression, apoptosis and other cellular functions In many studies Vitamin C protects against cell death triggered by various stimuli and a major proportion of this protection has been linked with its antioxidant ability. Studies of the anti-apoptotic activity of Vitamin C have revealed a role of Vitamin C in modulation of the immune system. Several studies reported the mechanisms by which Vitamin C regulates the AP-1 complex, including the Fos and Jun superfamilies. Ascorbate treated cells exposed to UV-B irradiation led to a 50% decrease in JNK phosphorylation (which activated AP-1), therefore inhibiting the JNK/AP-1 signaling pathways [Das & Saha 2014; Wu et al 2002]. As one of the common pathway to induce HIF-1 signaling mechanism by hypoxia, heavy metal exposure is also via ROS generation hence the role of antioxidant like vitamin c or cilnidipine as calcium channel blocker to counteract this phenomenon are very much in research interest [Chang 2006].

Hypoxia may also modulate the effects of NO on endothelial function. The mechanism by which nitric-oxide (NO) production increases during hypoxia is unknown. The generated NO can induce various effects, or react with reactive oxygen species like superoxide and hydrogen peroxide to generate peroxynitrite. NO can also react with other potential signaling molecules, which are likely to be produced temporally and spatially alongside NO. Heavy metals like nickel, Cr-VI or lead either directly or through inducing cellular hypoxia make profound changes in renal function including glomerular hemodynamics [Prashad et al 2001].

There are major gaps in our knowledge regarding the short- and long-term effects of hypoxia, especially when it comes to linking genomic and cellular responses with the physiological adaptation. It is also not clear whether chronic sustained hypoxia have any special impact when it is exposed simultaneous with heavy metal and possibly alters cardiovascular functions and renal hemodynamics with or without supplementation of ascorbic acid and calcium channel blocker.

2. Aims & Objective:

Defining the mechanisms by which mammalian cells and organisms adapt to acute and chronic perturbations in ambient oxygen tension is critical to the understanding of maintenance of homeostasis and consequently the development of therapeutic strategies to counteract hypoxia-induced cell damage. It is also important to understand how heavy metal interacts with hypoxia in physiological system like cardiovascular system and renal hemodynamics.

Following are the objectives:-

I. To evaluate whether the supplementation of l-ascorbic acid as an antioxidant and cilnidipine as L/N type calcium channel blocker in the studies of hematological, biochemical and histopathological alterations of arterial system (skeletal, elastic and coronary artery) in metal exposed (normoxic) male albino rats.

II. To evaluate effect of supplementation of l-ascorbic acid and cilnidipine as L/N type calcium channel blocker on electrophysiological, hematological, biochemical and histopathological parameters in arterial system (skeletal, elastic and coronary artery) of male rats simultaneously exposed to normobaric chronic hypoxia (10% oxygen) and heavy metal. We shall also evaluate wall thickness in elastic artery and coronary artery including normalized wall thickness (NWI) and arterial lumen diameter as the part of vascular integrity.

III. We shall also evaluate autonomic nerve functions, electrocardiographic and baroreflex sensitivities (BRS) of animals exposed chronic hypoxia or metal exposure and supplemented with l-ascorbic acid or L/N type calcium channel blocker in both anaesthetized and conscious animals by telemetry system.

IV. **The project will also evaluate how partial cerebral ischemia by middle cerebral arterial occlusion (MCAO) differentially influences electrophysiology of rats normal as well as hypoxia pretreated rats.** Also to observe whether calcium channel blocker or diavalent cation line nickel or lead treatment have any role on it ? Further to evaluate possible alterations of any renal functions in rodent stroke models with low oxygen adaption sub chronically with or without divalent cationic exposures.

V. The project will explore the effect of chronic hypoxia in rats exposed to heavy metal on cellular transcriptional and gene expression pathways (HIF 1α, NOS2, NOS3 and VEGF) with or without supplementation of l-ascorbic acid or treated with calcium channel blocker (cilnidipine) in cardiovascular integrity.

VI. To study acute and chronic heavy metal exposed release of nitric oxide (NO) by the vascular endothelial cells and also from the renal tissues and its action in regulating renal function. Study on micro analysis of plasma and urine , the role of superoxide anion (O^{2-}) and NO in the control of renal blood flow and tubular reabsorption of various electrolytes after heavy metal exposure in rats.

VI The study will also continue to extend on the patients of Stroke, AMI, COPD and obstructive sleep apnea (OSA) and their vascular functions and renal hemodynamics.

3. Significance and impact/value of the project:

The proposed study will enlighten the significance of l-ascorbic acid and calcium channel blocker on heavy metal toxicities on the subjects who are exposed to high altitude or the patients who are suffering from stroke, acute myocardial infarctions (AMI), chronic obstructive pulmonary disorders (COPD) or patients with obstructive sleep apnea(OSA).. The possible expected outcome of this project will definitely indicate the link between hypoxia gene transcription factors and heavy metal in relation to vascular health including kidney functions. The role l-ascorbic acid on cell signaling pathways or cilnidipine as calcium channel blocker to regulate hypoxia transcription factors with or without exposure to metal will definitely be important for understanding cardiovascular medicine and renal physiology better. A link between cerebral ischemia and renal hemodynamics may also establish.

4. Justification of the Collaboration between BLDE University & Tulane University:

There are various methods for quantitatively determining the concentration of both NO^{2-} and NO^{3-} ions. The most common methods involved the use of the Griess reagent which reacts with NO^{2-} ion to produce a stable azo end product which is purple in color and can be quantified using colorimeteric or spectrophotometric analytical techniques. Recently a potentially more accurate, less time consuming, and less tedious method has been developed for assaying both NO^{2-} and NO^{3-} which relies on the use of ion selective electrodes for both NO^{2-} and NO^{3-} ions. Hypertension and Renal Center of Excellence Laboratory of Prof. D.S.AMajid at Tulane University is one of the outstanding research lab for study on the level of intrarenal NO activity by the use of a NO sensitive micro-electrode. Renal regional blood flow responses to alteration in intrarenal NO activity may also be assessed with the aid of Laser Doppler needle Flowmetry (LDF). Both Nitric Oxide sensitive microelectrode and LDF techniques are not available in India. Beside these BLDE University will be benefitted by learning the various techniques on renal hemodynamics like including 24-hour hemodynamic and activity monitoring by radio telemetry system, renal functional experiments (clearance experiments), renal nerve activity recording and echocardiography. This technical knowhow will provide the understanding of functional cardiovascular physiology and also provides a focused and systematic approach to the study of the basal physiology and pathophysiology of the animal cardiovascular system using 2D echocardiography. 2-D guided M-Mode & Doppler with 15 MHz Siemens Acuson Sequoia provides high resolution image analysis of chamber dimensions, wall thicknesses and ventricular function in lightly sedated mice or rats. Some unique and advance experimental procedures to evaluate changes in blood pressure and heart rate in alert mice also need to be done at 'Hypertension & Renal Centre of Excellence Laboratory' of Tulane University, USA. For this purpose Osmotic mini- infusion pump technique will be helpful for BLDE University researchers to understand a convenient and reliable method for controlled agent delivery in vivo, while avoiding the need to handle the animal during the dosing period. After learning these sophisticated technique the Indian collaborator will be benefitted to establish these techniques for his ongoing research projects in Laboratory of Vascular Physiology and Medicine

of The Department of Physiology. Similarly BLDE University laboratory will discriminate its experience to USA Collaborator on various hypoxia models (chronic sustained & intermittent) in rats and mice. Laboratory will also help USA Collaborators to understand the pharmacokinetics of in vivo heavy metal exposure and alteration of histological architecture in mice or rats models. Beside these electrophysiological evaluation of rats or mice in metal and Medicine will also enlighten the USA collaborator on metal oxygen interactions in vivo. BLDE University 1500 bedded teaching hospital will also cater the adequate patients of AMI, Stroke, COPD and OSA which will help to understand better clinical application on human being from the proposed collaboration between BLDE University, India and Tulane University, USA.

5. Methodology:

Rats will be exposed to chronic sustained hypoxia by using a 300-liter acrylic chamber and given inspired oxygen (10% O_2 & 90% N_2). The hypoxic environment will be established with the inflow of a mixture of room air and nitrogen that will be regulated by an oxygen analyzer (model 175518A, Gold Edition, Vacuum Med). CO_2 will be absorbed by soda lime 27 granules, and excess humidity will be removed by a desicator. Rats will be exposed to hypoxia for 20 days. Lead acetate (2.5 mg/100 g b.wt,i.p) will be injected for 10 doses every alternate days for similar duration and l-ascorbic acid to be fed orally at a dose of 50mg/100g body weight (b.wt.) daily and cilnidipine at a dose of 1 mg/kg/day; ip for 20 days respectively. Autonomic functions, baroreflex sensitivities (BRS), other electrophysiological parameters and pneumography of live rats or mice to be taken by PC based MP-45 Biopac before sacrifice of the animals. Serum and tissues (liver, kidney, lungs, heart and whole brain) oxidative stress parameters (MDA, Glutathione, GSH-Px, Catalase, SOD) and nitric oxide along with serum antioxidant vitamins like C & E to be evaluated by biochemical assay methods. Serum HIF-1α, i-NOS, e-NOS and VEGF concentration will be evaluated by ELISA techniques. Apart from these complete hematological profiles and tissue histopathology (liver, kidney, lungs, heart and whole brain) also to be done on experimental animals. The evaluation of arterial thickness at elastic, skeletal and coronary artery along with normalized wall index to be done by trinocular microscope fitted with PC based Digitizer software.

The arterial wall thickness, chamber dimension, ventricular function and coronary artery normalized wall index (NWI) will be evaluated by 2D echocardiography. 2-D guided M-Mode & Doppler with 15 MHz Siemens Acuson Sequoia which provides high resolution images (May required support from Tulane University) besides routine histology.

Experimental protocol to evaluate heart rate, BP etc. in conscious rat/mice with or without cerebral ischaemia to be done beside renal hemodynamics studies, evaluation of drug delivery system by Osmotic mini- infusion pump technique also to be done. Beside these in vitro procedure of O2 production in renal tissues need to be measured (Tulane University supports are needed).

The Advance Procedure of Tulane University for some experiments mentioned below:--

a) Procedures for in-vivo experiments in mice: For chronic experiments, mice will be housed in a temperature and light controlled room and will be allowed free access to standard diet (Ralston-Purina, St. Louis, MO) and tap water. The implantation of osmotic minipumps and telemetry devices (description given below) will be carried out in mice as described in the protocols. Urine will be collected from these mice using metabolic cages. Urine collection will be made in containers with 10 μL of 0.005% butylated hydroxytolune (Sigma Chemical) to prevent ex-vivo production of 8-isoprostane and also with antibiotics (penicillin/streptomycin-100U/ml each) to prevent bacterial growth during collection. Urine will be centrifuged at 1000 rpm for 10 minutes at 40C and stored in aliquots at -800C until assayed. For acute experiments, mice will be anesthetized with Inactin (thiobutabarbital sodium, 150 mg.kg-1, bw) intra-peritoneally (i.p.) and then placed on a servo-controlled surgical table that maintains body temperature at 370C, and a tracheostomy will be performed to allow the animals to breathe air enriched with oxygen. The right carotid artery will be cannulated with PE-10 tubing connected to PE-50 tubing for continuous measurement of arterial pressure and blood sampling. Arterial pressure will be measured with a pressure transducer connected to the carotid cannula and will monitored with the Acknowledge data acquisition system (Biopac Inc.). The right jugular vein will be catheterized with a PE-10 tube for iv fluid infusion. The bladder will be catheterized with PE-50 tube via a supra-pubic incision for urine collections. During surgery, an isotonic saline solution containing 6% BSA will be infused. After surgery, the infusion fluid will be changed to isotonic saline containing 1% albumin, 7.5% Inulin (Inutest, Laevosan, Linz / Donau, Austria), and 1.5 % PAH (Merck Sharpe & Dohme, West Point, PA).

b) Procedure for osmotic mini-pump implantation: Surgical anesthesia will be induced by 5% isoflurane in oxygen flushed at 1 L/min for 90s and then Isoflurane will be adjusted (0.75 -1.5%) to maintain anesthesia. The skin will be shaved at the interscapular region, where an incision of the skin (about 1 cm) will be performed to make a subcutaneous space for the osmotic mini-pump. Sterile mini-pumps filled with ANGII solution or vehicle will be inserted into the prepared subcutaneous space and the incision will be closed with a suture and a topical antiseptic will be applied. The animals will be placed back in the cages and their recovery will be monitored during the decay time of the anesthesia. These procedures are routinely performed in Prof.Majid's laboratory

c) Procedures for radiotelemetry device implantation: The catheter of the transmitter body will be placed in the carotid artery in mice. After 10 days of acclimatization, radio-transmitters (TA-11PA-C10, DSI) will be implanted in mice assigned for the telemetry experiment to monitor the arterial blood pressure continuously. Mice will be anesthetized using 2% iso-flurane. A midline skin incision 2 cm long from chin to manubrium will be performed to isolate the common carotid artery. A blunt trocar will be passed from the neck incision to the abdominal region through the lateral aspect under the skin. The implant catheter will be placed into the common carotid artery. The transmitter body will be placed under the skin in the abdominal region. The skin will be sutured and topical antiseptic will be applied. Mice will be placed on a 12:12-h light-dark cycle and will receive food and water ad libitum throughout the study. After 10-14 days of recovery, we will

begin monitoring systemic blood pressure and heart rate continuously using the telemetry data acquisition system (DSI, St. Paul, MN). The pulses from the receiver will be relayed to a calibrated pressure output adapter (R11CPA; Data Sciences) where they will be converted to analog voltages representing blood pressure waveforms. Custom-written online software will process the blood pressure waveform and detect the systolic blood pressure (SBP), diastolic blood pressure (DBP), and the inter-beat interval (IBI) for each cardiac cycle and calculate MAP and HR. The average SBP, DBP, MAP, HR, and the standard deviation of the IBI (SD of IBI) will be calculated for each 30-s period of the day.

d) Analytical procedures for plasma and urine samples: The macro and microanalytical procedures routinely used in Prof.Majid's laboratory includes analysis of inulin and PAH in plasma and urine samples. GFR is determined by the inulin clearance technique. Sodium and potassium concentrations and osmolarity will be measured by flame photometry and vapor pressure osmometry respectively. Concentrations of nitrate/nitrite (NOx), 8-isoprostane, and protein concentration will be determined in plasma and urine. **All the routine serum electrolytes and tests for renal functions including renal histopathology to be done in BLDE University**

e) In–vitro measurement of O2- production: The direct measurement of O2- production will be assessed in vitro in the renal tissue (cortex and medulla). The kidney will be quickly removed, gently cleaned of surrounding tissue and cut into segments that will be incubated at 37 °C for 30 min in modified Krebs-HEPES buffer (KHB; pH 7.4). The tissue segments will then be transferred into test tubes containing 2 ml of either 25 μmol/L lucigenin or 25 μmol/L lucigenin plus 125 μmol/L NADPH (in KHB) and equilibrated in the dark for 10 min. The chemiluminescence will then be averaged for 3 min using a TD 20/20 luminometer (Turner Designs). Results will be expressed as counts/g of dry tissue.

Heavy metal & hypoxic gene expression (to be done at BLDE University, India):

HIF-1$^{\alpha}$, i-NOS, e-NOS and VEGF gene expression and characterization of its DNA binding activity. and molecular composition to be studied in respiratory and cardiac tissues by using Real time PCR in all the experimental groups. The project will also quantify and analyze alteration of various stress induced proteins and steroids heme oxygenase or ferritin in blood by HPLC/ELISA to understand hypoxia or metal induced stress. Heavy metal concentration in blood and various tissues in different experimental conditions will also to be evaluated by atomic absorption spectrophotometery.

Tissue sampling: The hypoxic and control rats will be sacrificed by cervical dislocation without anesthesia; the chest will be opened and the lungs and cardiovascular system including elastic artery, skeletal artery, coronary artery and myocardial tissues (atrium and ventricle) will be immediately removed. Tissue samples will be washed in ice-cold physiological buffer, frozen in liquid nitrogen and to be stored at -80 °C in order to avoid RNA degradation. The entire procedure must be completed in 5 minutes from the removal of the animals from the cage.

Total RNA extraction: 1ml of Trizol Reagent (Invitrogen) will be added to 50-60mg of frozen lung samples and the suspension will be homogenized on ice, in order to not damage and to preserve the samples from degradation. Once the tissue is completely homogenized, 0. 2 ml of chloroform/1ml of TRIZOL to be added, shaken by hand for ten seconds and maintained on ice for 2 minutes. The samples will now be centrifuged at 1200xg for 15 minutes at 4 °C: the aqueous phase that contained RNA will be removed and transferred to a new tube with 0.5 ml of isopropanol. After 10 minutes at 4 °C, samples will be centrifuged at 12000xg for 10 minutes at 4 °C. The RNA formed a gel-like pellet on the side and bottom of the tube. The supernatant to be removed and the RNA pellet washed with 0.5 ml of 70% ethanol. After re-suspension of the pellet, the tube will be centrifuged at 7500xg for 10 minutes at 4 °C, the supernatant removed and the RNA pellet dried in air for 5 minutes. The RNA re-suspended in RNAase-free-water (20-50µl, depending on the amount of the RNA pellet) and to be incubated at 55 °C for 5 minutes will be then stored at -80 °C. The concentration of RNA in each sample will be determined by reading the absorbance of 1µl of each sample with a NANODROP Spectrophotometer (Thermo Fisher). The RNA integrity will be assessed by electrophoresis, running of nucleic acid on agarose gel.

Protein extraction: 40 mg of each sample of lung and cardiac tissue will be homogenized with a glass/glass homogenizer, and nuclear and cytosolic proteins will be separately extracted using a commercially available kit (NE-PER Nuclear and Cytoplasmic extraction reagent, Pierce) according to manufacturer's protocol. The protein concentration will be assessed using a BCA Protein Assay Kit (Pierce), and Bovine Serum Albumin (BSA) will be used for a standard curve. 2 µl of each sample will be tested to quantify the protein content. Proteins were preserved at -80 °C for Western Blot assays.

Western Blots: Cytosolic or nuclear proteins (30µg) of each lung sample fraction will be separated by home-made 8% polyacrylamide gel under reducing conditions and electro-transferred to nitrocellulose paper. To check the success of the transfer, the membranes will be incubated on an agitator for 5 minutes with Ponceau Red and then to be washed three times with deionized water. Blots will be blocked for 1 hour in blocking buffer (5% skimmed milk powder in TBST) and then incubated overnight at 4 °C with primary antibody (for HIF-1a,VEGF, i-NOS and eNOS Cell Signaling, Sigma Aldrich). After three washings with TBST, membranes will be incubated with secondary antibody (Pierce) for 1 hour at room temperature. The excess of antibody will be removed by washing with TBST. α-Tubulin (Cell Signaling) and Lamin A (Abcam) will be used to normalize the cytosolic and nuclear proteins, respectively. Proteins will be visualized using ECL detection reagents (Pierce).

The protocol has already been approved by Institutional Ethical Committee / Institutional Animal Ethical Committee (IEC/ IAEC) of BLDE University's Shri B.M.Patil Medical College, Hospital & Research Centre, Bijapur, Karnataka as per the guidelines of ICMR (2006).

6. References

Agency for Toxic Substances and Disease Registry (ATSDR). Toxicological Profile for Nickel. U.S. Department of Health and Human Services, Public Health Service, ATSDR. Atlanta, Georgia, USA: U.S. Government Printing Office; 2003. p-16.

Chaing AA.Obstructive sleep apnea and chronic intermittent hypoxia: a review. Chin J Physiol. 2006 Oct 31;49(5):234-43

Das KK, Saha S. Hypoxia, Lead Toxicities and Oxidative stress: Molecular interactions and antioxidant (Vitamin C) defense Current Signaling Transduction & Therapy 2015 DOI: 10.2174/1574362410666150225232258

Prasad M, Fearon IM., Zhang M, Vollmer A., Nurse, C.A.. Expression of P2X2 and P2X3 receptor subunits in rat carotid body afferent neurones: role in chemosensory signalling. J. Physiol. 2001; 537, 667–677

Salnikow K., Blagosklonny M., Ryan H., Johnson R., Costa M. Carcinogenic nickel induces genes involved with hypoxic stress. Cancer Res 2000; 60: 38-41

Wu F, Tyml K., Wilson JX. Ascorbate inhibits iNOS expression in endotoxin- and IFN gamma-stimulated rat skeletal muscle endothelial cells. FEBS Letters 2002; 520: 122-6.

7. Financial responsibility: None to each other. Both the University will take care of needs separately as per their research requirements.

8. Principal Collaborators:

BLDE UNIVERSITY, VIJAYAPURA, INDIA:-

Prof.Kusal K.Das,PhD,
Professor
Laboratory of Vscular Physiology and Medicine
Department of Physiology
BLDE University, Karnataka, India

TULANE UNIEVRSITY, NEW ORLEANS, USA
Prof.Dewan S.A.Majid, MBBS, MD, PhD
Professor of Physiology &
Director- Mouse Phenotype Core
Hypertension Centre of Excellence,
Tulane University School of Medicine, New Orleans, LA70118,USA

Signature & Date:- 9/2/2017

Prof.Kusal K.Das,PhD
(Principal Collaborator)
Professor of Physiology
Laboratory of Vsacular Physiology & Medicine
Shri B.M.Patil Medical College, Hospital &
Research Centre BLDE University
VIJAYAPUR-586103, Karnataka, INDIA

Signature & Date: D.S.A.Majid 2/9/17.

Prof.Dewan S.A.Majid,MD;PhD
(Principal Collaborator)
Professor of Physiology
Renal & Hypertension Centre of Excellence
Tulane University School of Medicine,
Tulane University, New Orleans LA70118, USA

Signature & Date:- 9/2/17.

Dr.M.S.Biradar
Vice Chancellor
BLDE University
Vijayapur-586103, Karnataka, INDIA

BLDE UNIVERSITY, VIJAYAPURA

Signature & Date:- L Gabriel Navar 2/9/17

Dr.L.Gabriel Navar
Professor and Chair
Department of Physiology
Co-Director, Renal & Hypertension Centre
of Excellence
Tulane University School of Medicine,
Tulane University, New Orleans LA70118,USA

PROJECT- II (Clinical)

INTERNATIONAL COLLABORATIVE RESEARCH PROJECT

(2017 -2019)

BLDE UNIVERSITY

Tulane University
SCHOOL OF MEDICINE

Department of Medicine & Laboratory of Vascular Physiology and Medicine, BLDE University's Shri B.M.Patil Medical College, Hospital & Research Centre, Vijayapura-586103, India

AND

THRCE, Tulane University School of Medicine, Tulane University, New Orleans LA70118,USA

PROJECT TITLE:

Relationship of urinary AGT to Central Hemodynamics and the Response to Antihypertensive Therapy

DURATION: 2 YEARS

1. Background:

Hypertension is the leading causes of the global burden of disease. Hypertension doubles the risk of cardiovascular diseases, stroke, renal failure and peripheral vascular disease. Although antihypertensive therapy clearly reduces the risk of cardiovascular and renal disease, large segments of hypertensive population are either untreated or inadequately treated. Uncontrolled hypertension induces structural and functional alterations in the kidney, which can eventually lead to end-stage renal disease . Effective control of blood pressure (BP) retards the progression of renal failure and reduces the morbidity and mortality rates associated with hypertensive vascular disease. (1) Renin–angiotensin system (RAS), one of the most important mechanisms of BP regulation and water– electrolyte homeostasis, have provided an improved understanding of the pathophysiology of hypertension.(2,3) In recent years, the focus of interest on the RAS has shifted to the role of the local/tissue RAS in specific tissues . Many studies have reported the importance of the tissue RAS in the brain , heart , adrenal glands , vasculature , and kidneys . Further, there is substantial evidence that the major fraction of angiotensin II present in renal tissues is locally generated from angiotensinogen (AGT) delivered to the kidney as well as from AGT locally produced by the proximal tubule cells . Renin secreted by the juxtaglomerular apparatus cells into the renal interstitium and vascular compartment also results in the local generation of angiotensin I . Angiotensin-converting enzyme is abundant in the kidney and is present in the proximal tubules, distal tubules, and collecting ducts .(4) Angiotensin I delivered to the kidney can also be converted to angiotensin II .

Therefore, all of the components necessary to generate intrarenal angiotensin II are present along the nephron.

Urinary excretion rates of AGT provide a specific index of the intrarenal RAS status in angiotensin II- dependent hypertensive rats.

2. Aims & Objective:.

a) To determine uAGT in hypertensive subjects, and to correlate uAGT with brachial arterial blood pressure (SBP), augmentation index (AI75), and pulse wave velocity (PWV) as measured with applanation tonometry.

b) To correlate the degree of blood pressure reduction by RAS inhibition or diuretic with reductions in uAGT.

c) To correlate uAGT and uAGT on therapy with central blood pressure parameters as measured by applanation tonometry.

d) To correlate treatment type with changes in uAGT

3. Need for the study

uAGT will correlate with brachial blood pressures but more closely with ABPM. Central blood pressure assessment will provide an even more detailed description of the relationship between uAGT as representing RAS activation in the kidney and arterial vascular stiffness.(5) uAGT will serve as an index of efficacy of treatment with RAS blockers as opposed to diuretic therapy. The quantitative aspects of our ELISA approach allow the comparison of data among subjects over time with ease. If the aims of the proposed study are achieved, the activated intrarenal RAS can be monitored by measuring uAGT levels in these patients. Therefore, this translational research project holds the potential to 16 achieve the greatest impact for individualized patient management and monitoring the efficacy of treatment with AT1 receptor blockers. This clinical translational study will define and characterize the uAGT levels in hypertensive subjects and correlate these uAGT levels with response to angiotensin II type 1 (AT1) receptor blockers as opposed to diuretic therapy.

4. Significance and impact/value of the project:

a) uAGT will define a subgroup of subjects with RAS driven nephrogenic hypertension

b) uAGT will better correlate with ambulatory blood pressure measurement rather than routine clinic blood pressure

c) uAGT will correlate with central systolic blood pressure (SBP), augmentation index, and PWV

d) uAGT will predict response to antihypertensive therapy with AT1 receptor blockers.

5. Review of literature

It has previously been reported that intrarenal AGT is predominantly localized in proximal tubules, and that Ang II infused rats had increases in renal AGT mRNA and protein as well as an increase in the rate of urinary AGT excretion. Chronic Ang II infusion compared to normal rats showed a significantly increased urinary excretion rate of AGT in a time- and dose-dependent manner. The urinary excretion rate of AGT was closely correlated with systolic blood pressure and kidney Ang II content, but not with plasma Ang II concentration. uAGT excretion was significantly lower in volume dependent hypertensive rats than in Ang II-dependent hypertensive rats. Rat AGT was detected in plasma and urine before and after an acute injection of exogenous human AGT. However, human AGT was detected only in the plasma collected after acute administration of human AGT but was not detected in the urine in Ang II-dependent hypertensive or sham-operated normotensive rats. The failure to detect human AGT in the urine demonstrated limited glomerular permeability and/or tubular degradation. This suggests that uAGT originates from the kidneys and not from plasma in rats. It has been reported that AT1 receptor blocker (ARB) treatment prevented the enhancement of intrarenal AGT immunoreactivity in Ang IIinfused hypertensive rats. Moreover, uAGT paralleled intra-renal AGT immunoreactivity in Ang II-infused hypertensive rats with/without ARB treatment. These data indicate uAGT provides a specific index of intrarenal RAS status in Ang II infused rats. Development of AGT ELISA: uAGT in humans can be quantitated by using AGT ELISA (6). AGT is the only known substrate for renin, the rate-limiting enzyme of the RAS. Because the level of AGT is close to the Michaelis–Menten constant for renin, changes in AGT levels as well as renin levels can control the activity of the RAS,

and upregulation of AGT levels may lead to increases in the angiotensin peptide levels and in BP . Recent studies on experimental animal models and transgenic mice have documented the involvement of AGT in the activation of the RAS and development of hypertension.(7) Genetic manipulations that lead to overexpression of AGT have consistently been shown to cause hypertension (8). In human genetic studies, a linkage has been established between the *AGT* gene and hypertension (8). Thus, AGT plays an important role in BP regulation.

It is now apparent that the documentation of blood pressure by routine clinical sphygmomanometric methods is not adequate for research or even clinical purposes due to the frequent presence of white- coat and masked hypertension effects. ABPM is established as the most reliable determinant of BP, and of the relationship of BP to the development of cardiovascular disease . However, current sphygmomanometric and oscillometric devices, including ABPM, only record the peak and trough of the peripheral arterial pulse waveform, resulting in several limitations. BP is a biomarker for possible hypertensive cardiovascular disease, but is not a disease of itself. Arterial stiffness, as measured by applanation tonometry, reflects loss of large vessel compliance and better reflects the extent of cardiovascular disease. It is established that central systolic aortic pressure is a better predictor of cardiovascular outcome than peripheral BP, but peripherally obtained BP does not accurately reflect central pressure because of pressure amplification. In all groups peripheral pulse pressure (pPP) and central SBP were strongly correlated, suggesting increased aortic stiffening is associated with predictable widening of pPP . Data from the Bogalusa Heart Study using applanation tonometry suggest a stronger correlation between in blacks than whites; furthermore, analysis of race determinants of the difference between central SBP and peripheral SBP showed that whites had a phenotype characterized by an increase in double product and systemic vascular resistance whereas black subjects had a phenotype characterized by age and subendocardial viability ratio . Lastly, antihypertensive medications have differing effects on central pressures despite similar reductions in brachial blood pressure. Applanation tonometry can determine the shape of the aortic waveform from the radial artery; waveform analysis not only indicates central

systolic and diastolic pressure but also determines the influence of pulse wave reflection on the central pressure waveform. It can serve as an important adjunct to brachial blood pressure measurements in initiating and monitoring hypertensive treatment . What is needed is a prospective trial starting with untreated hypertensive subjects that will allow correlation of uAGT with BP as determined by ABPM and central hemodynamic monitoring and correlate changes in both BP and uAGT in response to either RAS blockers or diuretics. The present study will generate pilot data to allow assessment of the feasibility of conducting a large scale clinical trial.

6. Material and Methods.

Subjects will be recruited from BLDE University's Shri B.M.Patil Medical College Hospital ,Vijayapur, Karnataka, India and Tulane UMC, and community health clinics, New Orleans, LA,USA as well as advertisements and community health screenings. Inclusion Criteria: Male or female subjects over age 21 and less than age 75 who have Stage 1 hypertension (brachial BP $\geq$ 140/90 and < 160/100), who have not received antihypertensive medications for 2 weeks, and who are not receiving NSAID drugs. Subjects with diabetes or chronic kidney disease (Cr Cl < 60) will be excluded as these conditions have also been shown to stimulate uAGT levels . At the screening visit, subjects who meet inclusion criteria by office BP will sign informed consent and have 10 cc blood drawn for complete metabolic profile and HgbA1c for safety and confirmation of inclusion criteria. These subjects will return within one week for repeat brachial BP measurement. Those subjects still meeting inclusion criteria will undergo ABPM. Vascular status will further be characterized by applanation tonometry. A blood specimen will be obtained for evaluating renin, aldosterone concentrations and collection of urine samples can be made from 8AM to 8PM and 8PM to 8AM at every **12-hour interval** to evaluate uAGT, renin, creatinine, total protein, and albumin. This 12h interval urine collection is keeping in mind with influence of circadian rhythm. Eligible subjects will be randomized by lot to treatment with either the Ang II receptor blocker irbesartan 75 mg once daily or the diuretic HCTZ 25 mg once daily. Subjects will return in 2 weeks for repeat brachial BP measurement; if BP > 140/90 mmHg irbesartan will be increased to 150 mg once daily or HCTZ to 50 mg

once daily. Subjects will then return for a 6-week visit that will complete the study. At this visit brachial BP, ABPM, and applanation tonometry will be repeated together with 24-hour urine and blood samples as at the baseline visit. This will complete the clinical study and subjects will be returned to primary care providers with a report of their response to therapy. Since this study will have no placebo group and all patients will receive approved drugs that have displayed many years of efficacy and safety, there are no unusual risks for participating subjects.

6.1. Measurements:

Urine collection will be obtained, quickly stored at -70°C, and analyzed for concentrations of AGT, renin, total protein, albumin, and creatinine as previously described The uAGT concentrations, Urinary 8-isoprostane (oxidative stress marker) and urinary albumin concentrations will be normalized by urinary creatinine concentrations of AGT and renin. Serum will be quickly separated, stored at -70°C, and analyzed for concentrations of AGT, HbA1C and renin. Assay Techniques: Urinary concentrations of albumin and creatinine will be measured with a DCA 2000 Analyzer (Bayer AG, Leverkusen, Germany). Urinary concentrations of AGT will be measured with human AGT ELISA kits as previously described. The coefficients of variation of the intra assay and of the inter assay of this AGT ELISA are 4.4 and 4.3%, respectively. Renin measurements will be performed by standardized radioimmunoassay procedures.

6.2 Methodology:

Brachial BP will be measured in a sitting position from the non-dominant arm as a mean of 16 3 consecutive measurements at 5-minute intervals. The mean of the 2 closest BP values will be used in further analysis. ABPM. Validated oscillometric SpaceLabs 90217 monitors will be programmed to obtain BP at 20 min intervals between 6:00 AM and 10:00 PM, and at 30-minute intervals from 10:00 PM until 6:00 AM. Recordings which are completed for at least 20 hrs and contain 10 readings during the awake period and 5 readings during sleep will be used for analysis. Ambulatory hypertension will be defined as a 24-hr BP > 130/80 mm Hg. Central Pressure and Augmentation Index: Standard cuffs will be placed over the brachial and femoral arteries of subjects, and

artery waveforms will be recorded with a high-fidelity micromanometer (applanation tonometry SphygmoCor, AtCor Medical) from the right carotid artery, and pulse wave analysis performed of the systolic portion of the pulse curve in accordance with established guidelines. The corresponding ascending aortic waveforms will then be generated, using a validated transfer function, from which central systolic and diastolic BPs, central pulse pressure, and AI75 will be calculated. PWV will be measured directly as carotid femoral interval.

6.3 Statistical Analysis

A sample size of 64 in each group would be required to detect a 20% difference in uAGT levels with a power of 90%, using either multiple regression analysis or paired t tests and assuming a (two tailed) significance level of 0.05. Because of limited resources, a pilot study is first necessary to justify a larger and more definitive clinical trial. Thus we will plan this as a pilot study with 10 subjects in each group. If data trends suggest differences between groups, such an observation will justify further expansion of this project. Baseline characteristics of patients will be compared with McNemar, paired t, and Wilcoxon rank sum tests, as appropriate. Pearson's correlation will be used to correlate parameters with uAGT levels. Cox proportional hazards models will be used to estimate hazard ratios (HRs) and 95% confidence intervals (CIs), comparing primary and secondary outcomes in the valsartan group with those in the diuretic group. All tests will be 2 tailed, and a p value $\leq$ 0.05 considered statistically significant. All statistical analyses will be carried out with PASW version (SPSS, Inc., Chicago, Illinois).

7. Financial Disclosures: None

8. References:

1. Harrisons principles of Internal medicine. 19th edition.
2. Kobori H, Nangaku M, Navar LG, Nishiyama A. The intrarenal renin–angiotensin system: from physiology to the pathobiology of hypertension and kidney disease. Pharmacol Rev. 2007;59:251–287.[PubMed]
3. Dzau VJ, Re R. Tissue angiotensin system in cardiovascular medicine. A paradigm shift? Circulation. 1994;89:493–498. [PubMed]

4. Gould AB, Green D. Kinetics of the human renin and human substrate reaction. Cardiovasc Res. 1971;5:86–89. [PubMed]
5. Hiroyuki Kobori, Maki Urushihara, Ji H. Xu . urinary angiotensinogen is correlated with blood pressure in men. J Hypertens. 2010 Jul; 28(7): 1422–1428.
6. Katsurada A, Hagiwara Y, Miyashita K, Satou R, Miyata K, Ohashi N, et al. Novel sandwich ELISA for human angiotensinogen. Am J Physiol Renal Physiol. 2007;293:F956– F960.[PubMed]
7. Ding Y, Davisson RL, Hardy DO, Zhu LJ, Merrill DC, Catterall JF, Sigmund CD. The kidney androgen-regulated protein promoter confers renal proximal tubule cell-specific and highly androgen-responsive expression on the human angiotensinogen gene in transgenic mice. J Biol Chem. 1997;272:28142–28148. [PubMed]
8. Inoue I, Nakajima T, Williams CS, Quackenbush J, Puryear R, Powers M, et al. A nucleotide substitution in the promoter of human angiotensinogen is associated with essential hypertension and affects basal transcription in vitro. J Clin Invest. 1997;99:1786–1797. [PubMed]
9. Nelson MR[1], Stepanek J, Cevette M Noninvasive measurement of central vascular pressures with arterial tonometry: clinical revival of the pulse pressure waveform? Mayo Clin Proc. 2010 May;85(5):460-72. doi: 10.4065/mcp.2009.0336.
10. Nichols WW[1], Singh BM. Augmentation index as a measure of peripheral vascular disease state. Curr Opin Cardiol. 2002 Sep;17(5):543-51.
11. Nichols WW Clinical measurement of arterial stiffness obtained from noninvasive pressure waveforms. Am J Hypertens. 2005 Jan;18(1 Pt 2):3S-10S
12. O' Rourke M. Arterial stiffness, systolic blood pressure, and logical treatment of arterial hypertension. Hypertension. 1990;15:339-34

Investigators

BLDE University (INDIA):

1. Dr.Rajesh M.Honutagi, MD (PI)
   Professor of Medicine
2. Dr.S.S.Patil,MD
   Associate Professor of Medicine
3. Dr.M.S.Biradar,MD
   Professor of Medicine

Coordinator: Kusal K.Das,PhD
Professor, Laboratory of Vascular Physiology & Medicine

Kusal K. Das
Prof. & Head
Physiology
BLDEU'S Shri B.M.Patil Medical College, Hospital & R.C.
Vijayapur-586103.

THRCE, TULANE University (USA)

1. Ryosuke Sato, PhD
   Assistant Professor, THRCE
2. Akemi Sato, MS
   Medical Research Specialist, THRCE

Coordinator:
Dewan S.A.Majid,MD;PhD
Professor, THRCE, Tulane University, USA

D.S.A. Majid

Principal Collaborator (BLDE University, India):
Dr.M.S.Biradar
Vice Chancellor
BLDE University
Vijayapur-586103,
Karnataka, India

VICE-CHANCELLOR
BLDE University
VIJAYAPUR-586103.
Karnataka, India.

Principal Collaborator (THRCE, Tulane University,USA):
Dr. L. Gabriel Navar
Professor and Chair
Department of Physiology, Co-Director,
THRCE, Tulane University School of Medicine,
Tulane University, New Orleans
LA70118,USA

L Gabriel Navar

B.L.D.E. UNIVERSITY VIJAYAPUR

11 AUG 2017

MEMORANDUM OF UNDERSTANDING
(MoU)

FOR COLLABORATIVE RESEARCH ON

COMPOSITIONAL ANALYSIS OF URINARY CALCULI IN PATIENTS WITH UROLITHIASIS BY RAMAN AND IR SPECTROMETRIC ANALYSIS

BETWEEN
KARNATAK UNIVERSITY, DHARWAD
AND
BLDE UNIVERSITY, VIJAYAPURA

22nd December, 2015

PREAMBLE

Memorandum of Understanding (MoU) on Research Work between the Department of Physics, Karnatak University, Dharwad and the BLDE University, Vijayapur.

The purpose of this MOU is to formalize the on-going research collaboration between **Karnatak University, Dharwad, represented by Prof. J.R.Tonannavar$_{M.Sc.PhD.}$, as Principal Investigator I and Prof. (Smt) Jayashree V.Yenagi $_{M.Sc.PhD.}$, as Co-investigator, and BLDE University, Vijayapur, represented by Dr. S.B. Patil $_{M.D.M.Ch.}$, as Principal Investigator II, Head of the Department of Urology, Shri B.M. Patil Medical College, Hospital and Research Centre.**

BACKGROUND:

The research programs and missions of the Karnatak University, Dharwad and BLDE University, Vijayapur, are complementary. The on-going collaboration by both the Research Groups is about the identification of mineral compositions in *renal calculi* (kidney/ureter/bladder stones) removed from patients suffering from Urolithiasis at B.M.Patil Medical College, Hospital and Research Center, Vijayapur**.** The collaboration by both the Research Groups has produced valuable Raman and IR spectral data, analysis and publication of mineral compositions in renal calculi of some patients.

AIMS AND OBJECTIVES:

The on-going collaboration by both the Research Groups is about the identification of mineral compositions in *renal calculi* (kidney/ureter/bladder stones) removed from patients suffering from Urolithiasis at B.M.Patil Medical College, Hospital and Research Center, Vijaypur. The method of analysis is based on using highly accurate and reliable Raman and IR spectroscopy techniques Both Dr.J.R.Tonannavar and Dr.Jayashree Yenagi provide expertise in Raman and IR spectroscopic analysis, while Dr.S.B.Patil provides expertise in the analysis of aetiological and clinical aspects of the disease.

It is proposed that the outcome of the research would lead to a creation of unique spectral profile data of the patients thereby contributing to the health care of the patients in and around Vijayapur.

ROLES AND RESPONSIBILITIES:

Each party (party means Karnatak University, Dharwad/BLDE University, Vijayapur) intends to implement the following provisions of this MOU, under the responsibility of the Vice- Chancellor of Karnatak University, Dharwad and Vice-Chancellor of BLDE University. Both the parties agree to confer permission on any release or publication of data generated through jointly conducted research. Karnatak University, Dharwad or BLDE University, Vijayapur, agree to strive toward co-authorship of publicatiolis. All data and models resulting from the research efforts conducted under this MOU may be placed in the public domain.

LIMITATIONS:

A) All commitments made in this MOU are subject to the availability of appropriated funds and each party's budget priorities. Nothing in this MOU, in and of itself, obligates the either University to expend appropriations or to enter into any contract, assistance agreement, interagency agreement, or other financial obligation.

B) This MOU is neither a fiscal nor a funds obligation document. Any endeavour involving reimbursement or contribution of funds between the parties to this MOU will be handled in accordance with applicable regulations and procedures of the parties, and will be subject to separate subsidiary agreements that will be effected in writing by representatives of both parties.

PROPRIETARY INFORMATION:

To carry out the joint work resulting from this MOU, the BLDE University may need to disclose proprietary information to Karnatak University, Dharwad. For the purpose of this MOU, proprietary information is defined as information that an affected business claims to be confidential and is not otherwise available to the public. Karnatak University, Dharwad agrees not to disclose, copy, reproduce or otherwise make available in any form whatsoever to any other person, firm, corporation, partnership, association or other entity information designated as proprietary or confidential information without consent of the *BLDE University.*

INTELLECTUAL PROPERTY:

The parties agree that any copyrightable subject matter, including educational or informational material or software, except privately published journal articles, created either jointly or separately by the parties from the activities conducted under this MOU, will be placed in the public domain. The parties agree that all journal articles, presentations and other communications created jointly by the parties (parties here mean research groups, Vibrational Spectroscopy Group, Department of Physics and Department of Urology, Shri B.M. Patil Medical College, Hospital and Research Centre, BLDE University) may be published as journal articles, reviews, monographs , books or in any digital from and the same may be intimated to the Karnatak University and BLDE University. The parties, if necessary, may review research activities conducted under the MOU. The parties agree that any patented invention created by the Karnatak University or BLDE University pursuant to the terms of this MOU will be jointly owned by the parties regardless of inventor ship, unless an alternative agreement indicates otherwise.

REDRESSAL OF DISPUTES: Any disputes between Karnatak University, Dharwad and BLDE University, Vijayapur, will be resolved by the Vice-Chancellor of Karnatak University and Vice-Chancellor of BLDE University.

Signed on **22nd** day of **December 2015.**

22/12/15

Vice-Chancellor
Karnataka University, Dharwad

Vice-Chancellor
Karnatak University
Pavate Nagar, Dharwad-580 003

Vice-Chancellor
BLDE University, Vijayapur

VICE-CHANCELLOR
BLDE University,
Vijaypur-586103.

B. L. D. E UNIVERSITY VIJAYAPUR

MODIFICATION/DURATION/TERMINATION:

This MOU will be effective when signed by both the parties. This MOU may be amended at any time by the mutual written consent of the parties. This MOU may be terminated by either party at anytime by one party notifying the other party in writing 90 days in advance of the termination date.

COMPLEMENTARY INFORMATION
ANNEXURE I

1.	NAME OF THE RESEARCHERS AND ADDRESS	(1)DR. S. B. PATIL PROFESSOR AND HEAD OF DEPARTMENT OF UROLOGY (2)DR. JAGDISH R. TONANNAVAR PROEFESSOR, DEPT OF PHYSICS
2.	NAME OF THE INSTITUTION	(1)SHRI B.M. PATIL MEDICAL COLLEGE, HOSPITAL AND RESEARCH CENTER BLDE UNIVERSITY BIJAPUR – 586103 KARNATAKA. (2) KARNATAK UNIVERSITY PAVATE NAGAR DHARWAD – 580 003 KARNATAKA
3.	TITLE OF THE TOPIC	ANALYSIS OF URINARY CALCULI IN PATIENTS WITH UROLITHIASIS BY RAMAN AND IR SPECTROMETRIC ANALYSIS
4.	BRIEF RESUME OF THE INTENDED WORK 4.1 NEED FOR THE STUDY 4.2 AIMS & OBJECTIVES OF THE STUDY	 REFER ANNEXURE I REFER ANNEXURE II

5.	MATERIAL AND METHODS 5.1 SOURCE OF DATA 5.2 METHOD OF COLLECTION OF DATA 5.3 ETHICAL CLEARANCE	 REFER ANNEXURE III REFER ANNEXURE ENCLOSED
6.	LIST OF REFERENCES	REFER ANNEXURE IV
7.	INFORMED CONSENT FORM	REFER ANNEXURE V
8.	SCHEME OF CASE TAKING	REFER ANNEXURE VI
9.	NAME AND DESIGNATION OF 9.1 PRINCIPAL INVESTIGATOR-I 9.2 SIGNATURE 9.3 PRINCIPAL INVESTIGATOR-II 9.4 SIGNATURE	 DR. S. B. PATIL M.S.M.Ch. (UROLOGY) PROFESSOR AND HEAD OF DEPARTMENT OF UROLOGY PROF. & HOD DEPT. OF UROLOGY B.L.D.E. University's Shri B.M. Patil Medical College Hospital & R.C. BIJAPUR-586103. DR. JAGDISH R. TONANNAVAR PROEFESSOR, DEPT OF PHYSICS KARNATAK UNIVERSITY DHARWAD – 580 003
10.	10.1 NAME OF THE PRINCIPAL. 10.2 SIGNATURE	22/4/15 PRINCIPAL & DEAN FACULTY OF MEDICINE B.L.D.E. University's Shri B. M. PATIL MEDICAL COLLEGE, HOSPITAL & RESEARCH CENTRE, VIJAYAPUR-586103

NEED FOR THE STUDY AND REVIEW OF LITERATURE

The lifetime prevalence of kidney stone disease is estimated at 1% to 15%, with the probability of having a stone, varying according to age, gender, race, and geographic location. In the United States, the prevalence of stone disease has been estimated at 10% to 15% [1,3,4,5]. Kidney stone disease is a common disease with multifactorial etiopathogenesis [1,2]. The majority of stone formers have disturbances either in the metabolism and excretion of stone constituents or in promoters 6 and inhibitors of crystallization 7. Clinical and epidemiological studies have documented that several types of risk factors are involved in disease etiology, such as dietary habits, warm climate, and familial occurrence[1,8]. The identification of the components of kidney stones is essential as it provides information that could be useful for doctors to find out the underlying cause of kidney stones and to decide whether to treat kidney stone patients medically or surgically.

A study of the chemical composition of renal stones is important for understanding their etiology as well. And the therapy for the stone disease is usually based on the analysis of calculi, permitting a proper management of the disease and the prevention of its recurrence.

Specially, highly accurate and reliable Fourier Transform IR and Raman spectrometry method are helpful here[10-13]. While IR technique is very popular, the Raman method strongly complements IR and together the two methods provide a highly reliable spectral data for identification of mineral species in kidney stones. This analysis is essential to guide therapy.

OBJECTIVE OF THE STUDY

This study is to investigate the mineral composition and type of kidney stones in patients suffering from urolithiasis by using Raman and FTIR Spectrometric methods.

ANNEXURE – II

OBJECTIVE OF THE STUDY:

Compositional Analysis of Urinary Calculi in Patients with Urolithiasis by Raman and IR Spectrometric Techniques

By

Dr.J.Tonannavar,M.Sc,PhD, Professor and Dr.Jayashree Yenagi, M.Sc,PhD, Professor

Vibrational Spectroscopy Group, Department of Physics, Karnatak University, Dharwad

And

Dr.Siddangouda B.Patil,MD, MCh, Professor

Head, Department of Urology, Shri B.M.Patil Medical College and Hospital Bijapur

BLDE University, Bijapur

I. Introduction:

Patients suffering from Urolithiasis are treated at the Department of Urology, BLDE University's Shri B.M.Patil Medical College and Hospital Bijapur. Conventional techniques such as chemical wet method and X-ray of urinary calculi of the patients located in kidney, ureter and bladder (KUB) are employed before diagnosis is undertaken. However, these methods are not accurate for guiding diagnosis. Therefore, it is proposed to employ other well-proven modern physical techniques that are very accurate, reliable and sensitive for determining mineralogical chemical components in the samples of kidney stones both at the qualitative and quantitative levels. The physical techniques include IR spectroscopic and X-ray diffraction analysis. Another complementary technique to IR, called Raman spectroscopy, can also employed.

A condition of the formation of mineral containing stones in the human urinary tract is a common health disorder affecting men and women all over the world. People belonging

to all age groups – even less than 1 year to 70 years olds -, with male to female ratio of 2:1, are affected by the disease. Incidence of Urolithiasis is only rising with substantial suffering and financial cost to patients. Coming under the Stone Belt nations, it is estimated that over two million Indians are suffering from Urolithiasis with incidences and compositions of calculi being geographic-, diet- lifestyle- and genetic predisposition-specific. All this calls for an accurate analysis of chemical (mineralogical) constituents at molecular and structural levels in the stones as precursor investigation to complement diagnosis and management of the disease.

II. Techniques of Analysis: Among the physical methods employed including the X-ray diffraction analysis, IR spectroscopic technique provides accurate mineral compositional analysis of stones with more than 90 per cent success rate. The technique works on the principle of absorption and detection of IR radiation by vibrationg chemical functional groups which make up molecules and whose network in turn constitutes into mineral solids (stones). The functional groups have characteristic vibrational frequencies and can be used as 'finger print' for the identification of the groups. The instrument technology incorporating Fourier Transform principle for IR analysis has matured, providing highest sensitivity, reproducibility and resolution for very accurate compositional analysis. Strongly complementary to IR spectroscopy is Raman spectroscopy which fundamentally works on the phenomenon of scattering of light radiation by the samples. While the Raman technique gives the same information as IR, more often it is complementary and a strong substitute for structural analysis. It also has the advantage of simple sample handling comapred to IR. Imaging techniques are also available which enable us to see surface morphology at nanometer scale thereby providing greater details than the conventional microscopy. The imaging techniques include Scanning Electron Microscope (SEM) and Atomic Force Microscope (AFM). Besides, X-ray diffraction analysis provides structural details such as

type of mineral – whewellitw or whedellite – with arrangement of molecular functional groups and bond lengths and bond angles and other details.

III. Materials:

The typical mineral compounds present in stone samples are:

Common chemical compounds present as mineral constituents in stone samples:

1. calcium oxalate monohydrate,
2. calcium oxalate dihydrate,
3. pentacalcium hydroxytriphosphate,
4. tricalcium phosphate,
5. calcium hydrogen phosphate dihydrate,
6. magnesium ammonium phosphatehexahydrate,
7. magnesium hydrogen phosphate trihydrate,
8. calcium sulphate dihydrate,
9. calcium carbonate,
10. uric acid,
11. uric acid dihydrate,
12. ammonium acid urate,
13. sodium acid uratemonohydrate,
14. cystine
15. xanthine

These chemicals will be procured for IR and Raman spectral measurements and other studies.

IV. Experimental Methodology:

In determining percenatge compositions of components of mineral inclusions in stone samples, IR and Raman spectral measurements may be used as for approximate estimations. However, for more reliable estimation, it is required to create reference spectral library of pure materials and their mixtures with known concentrations in order to make comparison with sample spectra and deduce the quantitative percentage of components. These methods will be employed in the

proposed study. Apart from making spectral measurements of the pure mineral compounds for

comparative and deductive study, theoretical *ab initio* modeling calculations will be carried out which give rise to IR and Raman spectra and a host of other properties to aid

experimental analysis. The FT-IR and Raman spectrometer facilities and AFM available at USIC, Karnatak University, Dharwad, will be used for measurements. Other measurements on X-ray diffractometer and SEM will be carried out outside of Karnatak University as and when necessary. Collection of samples will be done by the Department of Urology, BLDE University's Shri B.M.Patil Medical College and Hospital. The sample handling, preparation and IR/Raman spectral measurements will be carried out at Karnatak University.

V. Research Personnel:

The proposed study includes analysis of a large number of stone samples using the above techniques, spread over months (say, 24 months), a dedicated research personnel is required for performing the measurements. The Vibrational Spectroscopy Group has assigned one full-time student, Kumari Gauri Deshpande, to the investigation leading to a PhD thesis. The thesis will be submitted by her to Karnatak University for the award of PhD degree.

VI. Deliverables:

A series of IR and Raman spectral measurements have been carried out. Analysis of the spectra show that the major chemical constituent are calcium oxalate monohydrate, calcium oxalate dihydrate, calcium hydrogen phosphate dihydrate, pentacalcium hydroxytriphosphate, etc, in most of the samples and uric acid in one sample. Spectra of the pure mineral compounds for comparative analysis will be undertaken with a view to create a Reference Library for patients treated for future routine analysis of stone samples. Further, AFM images of some samples also have been recorded.

In the second round of study, twenty bladder stones have been sublect to Raman and IR spectral mesurements. The study of bladder stones is rare and the present study is expected to lead to revealing results. The spectral data is in a state of analysis.

VII. Publication of Results

Results and analysis of the proposed studies will be presented at conference/symposia and published as full papers in peer-reviewed journals. The anonmity of the patients will be maintained throughout the investigations. Authorship will be shared between the two Groups. All the results and analysis will be, as proposed, the material for a Ph D thesis to be submitted by the research student assigned to the study. Exchange of results for

diagnostic purposes will be on mutually agreed basis and will jointly form property of Karnatak University and BLDE University's Shri B.M.Patil Medical College and Hospital.

The proposed study has been completed on the ten stone samples collected from different male and female patients and a research paper has been accepted for publication in an international journal (please see **Enclosure-IIA**).

Prof. Jagdish R. Tonannavar
Principal Investigator-I

Dr. S. B. Patil
Principal Investigator-II

ANNEXURE – III

MATERIALS AND METHODS

SOURCE AND METHOD OF COLLECTION OF DATA:

- Stones removed from patients who are admitted with clinical diagnosis of urinary calculi under urology in BLDEU's SHRI B. M. PATIL MEDICAL COLLEGE HOSPITAL AND RESEARCH CENTRE, BIJAPUR are taken as subjects for this study.
- After taking the informed consent, data would be collected using a proforma.
- The specimens are first washed carefully with distilled deionized water and dried with dry air for several hours.

INCLUSION CRITERIA:

- All patients suffering from urolithiasis undergoing intervention.

EXCLUSION CRITERIA: Not able to procure calculi/fragments for analysis.

INVESTIGATIONS / INTERVENTIONS

Investigations or interventions required in this study are routine standardized procedures.

These investigations are required as routine before taking any patient for stone removal:

1. Complete blood count.
2. Urine Routine
3. Serum creatinine.
4. Ultrasonography of abdomen and pelvis.
5. CT Scan or IVU as required

ANNEXURE – IV

REFERENCES:

1] Jaeger P. Genetic versus environmental factors in renal stone disease. *Curr Opin Nephrol Hypertens* 1996; 5: 342 – 346.

2] Baggio B. Genetic and dietary factors in idiopathic calcium nephrolithiasis: what do we have, what do we need? J Nephrol. 1999; 12: 371 – 374.

3] Serio A, Fraioli A. Epidemiology of nephrolithiasis.*Nephron Suppl*. 1999; 81: 26 – 30.

4] Rivers K, Shetty S, Menon M. When and how to evaluate a patient with nephrolithiasis? *Urol Clin North Am*. 2000; 27: 203 – 213.

5] Soucie JM, Coates RJ, Mc Clellan W, Austin H, Thun M. Relation between geographic variability in kidney stones, prevalence and risk factors for stones. *Am J Epidemiol.* 1996; 143: 487 – 495.

6] Siddiqui AA, Sultana T, Bucholz NP, Waqar MA, Talati J. Proteins in renal stones and urine of stone formers. *Urol Res*. 1998; 26: 383 – 388.

7]Dussol B, Berland Y. Urinary kidney stone inhibitors: what is the news? *Urol Int*. 1998; 60: 69-73.

8.]Curhan GC, Willett WC, Rimm EB, Stampfer MJ. Family history and risk of kidney stones. J Am Soc Nephrol. 1997; 8: 1568 – 1573.

10] Vimal Kumar et al. *International Journal of Engineering Science and Technology* Vol. 2(3), 2010, 278-286

11] A. Trinchieri, R. Lizzano, P. Bernardini, M. Nicola, F. Pozzoni, A.L. Romano, M.P. Serrago, S. Confalanieri : Effect of acute load of grapefruit juice on urinary excretion of citrate and urinary risk factors for renal stone formation. *Dig Liver Dis*, 2002, 34[Suppl 2]: S160–
S163.

12]Kesner F., Dominak I.: Kidney Stone Analysis by Nicolet FT IR spectrometer, *NICODOM*, 1996.

13]Kevin Sudlow, Alfred Woolf: Identification of renal calculi by their Raman spectra, *Clinica Chimica Acta*, 203(1991), 387-394.

ANNEXURE V

SAMPLE INFORMED CONSENT FORM

B.L.D.E.U.'s SHRI B.M. PATIL MEDICAL COLLEGE HOSPITAL AND RESEARCH CENTRE, BIJAPUR – 586103, KARNATAKA

TITLE OF THE PROJECT: **ANALYSIS OF URINARY CALCULI IN PATIENTS WITH UROLITHIASIS BY USING FTIR AND RAMAN METHODS**

PRINCIPAL INVESTIGATOR-I: Dr. S. B. PATIL
PROFESSOR AND HEAD OF THE
DEPARTMENT OF UROLOGY

PRINCIPAL INVESTIGATOR-II: Dr.JAGDISH R.TONANNAVAR
PROFESSOR, DEPT OF PHYSICS
KARNATAK UNIVERSITY, DHARWAD

PURPOSE OF RESEARCH:

I have been informed that this study will analyse the effectiveness of FTIR and Raman FTIR method for stone analysis which helps in preventing the recurrence of stones as well as morbidity associated with stone diseases.

I have been explained about the reason for doing this study and selecting me/my ward as a subject for this study. I have also been given free choice for either being included or not in the study.

BENEFITS: I understand that my participation in this study will help to analyse the effectiveness of these different methods of stone analysis and helps in guiding the management of stone disease.

CONFIDENTIALITY:

I understand that medical information produced by this study will become a part of this Hospital records and will be subjected to the confidentiality and privacy regulation of this hospital. Information of a sensitive, personal nature will not be a part of the medical records, but will be stored in the investigator's research file and identified only by a code number. The code key connecting name to numbers will be kept in a separate secure location.

If the data are used for publication in the medical literature or for teaching purpose, no names will be used and other identifiers such as photographs and audio or video tapes will be used only with my special written permission.

REQUEST FOR MORE INFORMATION:

I understand that I may ask more questions about the study at any time. Dr. S. B. Patil will be available to answer my questions or concerns. I understand that I will be informed of any significant new findings discovered during the course of this study, which might influence my continued participation.

If during this study, or later, I wish to discuss my participation in or concerns regarding this study with a person not directly involved, I am aware that the social worker of the hospital is available to talk with me.

And that a copy of this consent form will be given to me for keep for careful reading.

REFUSAL OR WITHDRAWAL OF PARTICIPATION:

I understand that my participation is voluntary and I may refuse to participate or may withdraw consent and discontinue participation in the study at any time without prejudice to my present or future care at this hospital.

I also understand that Dr. S. B. Patil will terminate my participation in this study at any time after he has explained the reasons for doing so and has helped arrange for my continued care by my own physician or therapist, if this is appropriate.

I understand that by my agreement to participate in this study, I am not waiving any of my legal rights.

I have explained to _____ the purpose of this research, the procedures required and the possible risks and benefits, to the best of my ability in patient's own language.

(Investigator-I)

STUDY SUBJECT CONSENT STATEMENT:

I confirm that Dr. S. B. Patil has explained to me the purpose of this research, the study procedure that I will undergo and the possible discomforts and benefits that I may experience, in my own language.

I have been explained all the above in detail in my own language and I understand the same. Therefore I agree to give my consent to participate as a subject in this research project.

_____ _____

(Participant) Date

_____ _____

(Witness to above signature) Date

ಸಮ್ಮತಿ ಪತ್ರ

ಬಿ.ಎಲ್.ಡಿ ಇ ವಿಶ್ವವಿದ್ಯಾಲಯ, ಶ್ರೀ ಬಿ.ಎಂ ಪಾಟೀಲ ವೈದ್ಯಕೀಯ ಮಹಾವಿದ್ಯಾಲಯ ಆಸ್ಪತ್ರೆ ಹಾಗೂ ಸಂಶೋಧನಾ ಕೇಂದ್ರ ವಿಜಯಪುರ 586103

ಸಂಶೋಧನೆಯ ಹೆಸರ : ಏನಾಲಿಸಿಸ್ ಆಫ್ ಯುರಿನರಿ ಕ್ಯಾಲ್ಕ್ಯಲೈ ಇನ್ ಪೇಶಂಟ್ಸ ವಿಥ್ ಯುರೋ ಲಿಥಿಯಾಸಿಸ್ ಬೈ ಯೂನಿಂಗ್ ಎಫ್.ಟಿ.ಐ.ಆರ್ ಏಂಡ್ ರಾಮನ್ ಮೆಥೆಡ್ಸ

ಪ್ರಧಾನ ಸಂಶೋಧಕ I : ಡಾ.ಎಸ್.ಬಿ ಪಾಟೀಲ ಪ್ರಾಧ್ಯಾಪಕರು ಹಾಗೂ ಮುಖ್ಯಸ್ಥರು ಯೂರಾಲಾಜಿ ವಿಭಾಗ

ಪ್ರಧಾನ ಸಂಶೋಧಕರುII: ಡಾ.ಜಗದೀಶ ತೋನವ್ನವರ, ಪ್ರಾಧ್ಯಾಪಕರು ಭೌತಶಾಸ್ತ್ರ ವಿಭಾಗ, ಕರ್ನಾಟಕ ವಿಶ್ವವಿದ್ಯಾಲಯ ಧಾರವಾಡ

ಸಂಶೋಧನೆಯ ಉದ್ದೇಶ: ಮೂತ್ರ ಜನಕಾಂಗ ಹಾಗೂ ಮೂತ್ರಕೋಶಗಳಿಗೆ ಸಂಬಂಧಪಟ್ಟ ವಿವಿಧ ಹರಳುಗಳ ಸಂರಚನೆ ಕುರಿತಾಗಿ ಅಧ್ಯಯನ ಮಾಡುವುದು.

ಮೂತ್ರ ವಿಸರ್ಜನಕಾಂಗ ವ್ಯೂಹ ಸಂಬಂಧ ಹರಳುಗಳ ವಿಶ್ಲೇಷಣೆಯಲ್ಲಿ ಬಳಸುವ ಏಫ್.ಟಿ.ಐ.ಆರ್ ಹಾಗೂ ರಾಮನ್ ವಿಧಾನಗಳ ಕಾರ್ಯಕ್ಷಮತೆಯನ್ನು ಈ ಅಧ್ಯಯನ ನಿರೂಧಿಸುತ್ತದೆ ಎಂಬುವುದರ ಕುರಿತಾಗಿ ಸಂಶೋಧಕರು ನನಗೆ ವಿವರಿಸುತ್ತಾರೆ. ಮಾತ್ರವಲ್ಲ ಈ ವಿಧಾನಗಳಿಂದ ಹೆಚ್ಚು ಮರಕಳಿಸದಂತೆ ಹಾಗೂ ಜೊತೆ ಜೊತೆಗೆ ಎದುರಾಗಬಹುದಾದ ರೋಗಗಳನ್ನು ನಿವಾರಿಸಬಹುದು ಎಂಬುದರ ಕುರಿತಾಗಿ ವಿವರಿಸುತ್ತಾರೆ.

ನನ್ನನ್ನು /ನನ್ನ ಮಗುವನ್ನು ಅಧ್ಯಯನಕ್ಕೆ ಆಯ್ಕೆ ಮಾಡಿಕೊಂಡ ಕಾರಣವನ್ನು ಅವರು ತಿಳಿಸಿರುತ್ತಾರೆ. ಅಧ್ಯಯನದಲ್ಲಿ ನನಗೆ ಮುಕ್ತ ಆಯ್ಕೆಯನ್ನು ಅವರು ನೀಡಿರುತ್ತಾರೆ

ಪ್ರಯೋಜನೆಗಳು

ಈ ಅಧ್ಯಯನದಲ್ಲಿ ನಾನು ಭಾಗವಹಿಸುವುದರಿಂದ ಸಂಶೋಧಕರಿಗೆ ಹರಳು ವಿಶ್ಲೇಷಣೆಯಲ್ಲಿ ಮೇಲ್ಕಾಣಿಸಿದ ವಿಧಾನಗಳ ಕಾರ್ಯಕ್ಷಮತೆಯನ್ನು ಪತ್ತೆ ಹೆಚ್ಚಲು ಸಾಧ್ಯವಾಗಬಹುದು ಮಾತ್ರವಲ್ಲ ಹರಳು ಚಿಕಿತ್ಸೆಗೆ ಅಧ್ಯಯನದ ಫಲಶ್ರುತಿ ಸಹಾಯ ಮಾಡಬಹುದು.

ಗೌಪ್ಯತೆ:

ಈ ಅಧ್ಯಯನದಿಂದ ಲಭ್ಯವಾಗುವ ವೈದ್ಯಕೀಯ ಮಾಹಿತಿ ಆಸ್ಪತ್ರೆ ದಾಖಲಾತಿಯ ಒಂದು ಅಂಶವಾಗಿದ್ದು ಗೌಪ್ಯತೆಯಿಂದ ಕಾಪಾಡಿಕೊಂಡುಬರುವುದರ ಕುರಿತು ನನಗೆ_____

ವ್ಯಕ್ತಿಯ ಸೂಕ್ಷ್ಮ ಹಾಗೂ ವಯಕ್ತಿಕ ಮಾಹಿತಿಯು ಆಸ್ಪತ್ರೆಯ ದಾಖಲಾತಿಗೆ ಸಂಬಂಧ ಪಡುವುದಿಲ್ಲಾ ಬದಲಾಗಿ ಅಂತಹ ಸಂಗತಿಗಳನ್ನು ಅಧ್ಯಯನಕಾರರು ತಮ್ಮ ಸಂಶೋಧನಾ ಕಡತದಲ್ಲಿ ಜೋಪಾನವಾಗಿ ಇರಿಸುತ್ತಾರೆ ಮಾತ್ರವಲ್ಲ ವಿಶೇಷ ಗುರುತಿನ ಸಂಖ್ಯೆಯನ್ನು ಅದಕ್ಕೆ ನೀಡುತ್ತಾರೆ ಹೆಸರನ್ನು ಪತ್ತೆಹಚ್ಚುವ ಗುರುತಿನ ಸಂಖ್ಯೆಯನ್ನು ಪ್ರತ್ಯೆಕವಾಗಿ ಭದ್ರ ಜಾಗದಲ್ಲಿ ಇರಿಸಲಾಗುತ್ತದೆ.

ಮಾಹಿತಿಯನ್ನು ಪ್ರಕಟಿಸುವಾಗ ಅಥವಾ ವಿಧ್ಯಾರ್ಥಿಗಳಿಗೆ ಕಲಸಿಕೊಡುವಾಗ– ವ್ಯಕ್ತಿಯ ಹೆಸರನ್ನು ಬಳಸಬಾರದು ಒಂದೊಮ್ಮೆ ವ್ಯಕ್ತಿಯ ಪತ್ತೆ ಹಚ್ಚಬಲ್ಲ ಭಾವಚಿತ್ರ, ಧ್ವನಿ/ದೃಶ್ಯ ಸುರಳಿಗಳನ್ನು ಬಳಸಿಕೊಳ್ಳವಂತಹ ಸಂದರ್ಭ ಬಂದಲ್ಲಿ ವಿಶೇಷ ಲಿಖಿತ ಪರವಾನಿಗೆಯನ್ನು ವ್ಯಕ್ತಿಯಿಂದ ಪಡೆದು ಕೊಳ್ಳಬೇಕಾಗುತ್ತದೆ.

ಹೆಚ್ಚಿನ ಮಾಹಿತಿಗಾಗಿ ಕೋರಿಕೆ

ಅಧ್ಯಯನದ ಯಾವುದೇ ಪೀಳಿ, ನಾನು ಅಧ್ಯಯನಕಾರರಿಗೆ ಅನುಮಾನ ಬಂದಾಗ ಪ್ರಶ್ನೆಗಳನ್ನು ಕೇಳಬಹುದು. ಡಾ. ಎಸ್ ಬಿ ಪಾಟೀಲರು ನನ್ನ ಪ್ರಶ್ನೆಗಳನ್ನು ಉತ್ತರಿಸಲು ಸದಾ ಲಭ್ಯರಿರುತ್ತಾರೆ. ಅದ್ಯಯನದ ವೇಳಯಲ್ಲಿ ಪತ್ತೆಹಚ್ಚಲಾದ ಹೊಸ ಸಂಗತಿಗಳನ್ನು ಅವರ ನನಗೆ ವಿವರಿಸಬೇಕಾಗುತ್ತದೆ. ಅಧ್ಯಯನದಲ್ಲಿ ನಾನು ಭಾಗವಹಿಸುವದನ್ನು ಮುಂದುವರೆಸಬೇಕೇ ಅಥವಾ ಬೇಡವೇಂಬುದನ್ನು ಈ ಸಂಗತಿ ನಿರ್ಧರಿಸಬಹುದು.

ಅಧ್ಯಯನ ವೇಳೆಯಲ್ಲಿ ಅಥವಾ ಆನಂತರ ನನ್ನ ಮಾಹಿತಿಗಾಗಿ ಈ ಒಪ್ಪಿಗೆ ಪತ್ರದ ದ್ವಿಪ್ರತಿಯೊಂದನ್ನು ನಾನು ಪಡೆದು ಕೊಳ್ಳಬಹುದು. ಭಾಗವಹಿಸುವಿಕೆಯಿಂದ ಹಿಂಪಡೆಯುವುದು/ನಿರಾಕರಣೆ

ನಾನು ಸ್ವ–ಇಚ್ಚೆಯಿಂದ ಈ ಅಧ್ಯಯನದಲ್ಲಿ ಭಾಗವಹಿಸುತ್ತಿದ್ದು ಯಾವುದೇ ಸಮಯದಲ್ಲಿ ನಾನು ನನ್ನ ಸಮ್ಮತ್ತಿಯನ್ನು ಹಿಂಪಡೆದು ಭಾಗವಹಿಸುವದನ್ನು ನಿಲ್ಲಿಸಬಹುದು.

ವಿಶೇಷ ಸಂದರ್ಭದಲ್ಲಿ ಸಕಾರಣವಾಗಿ ಡಾ. ಎಸ್ ಬಿ ಪಾಟೀಲರು ನನ್ನನ್ನು ತಮ್ಮ ಅಧ್ಯಯನದಿಂದ ನಮ್ಮನ್ನು ಹೊರಗಿಟ್ಟು, ಸೂಕ್ತ ಪೂರಕ ಚಿಕಿತ್ಸೆಗಾಗಿ ನನ್ನ ಆಯ್ಕೆ ವ್ಯದ್ಯರಲ್ಲಿ ಚಿಕಿತ್ಸೆ ಪಡೆಯಲು ಸಹಕರಿಸಬಹುದು.

ಈ ಅಧ್ಯಯನದಲ್ಲಿ ಭಾಗವಹಿಸುವ ವಿಷಯದಲ್ಲಿ ನಾನು ಯಾವುದೇ ನ್ಯಾಯಾಂಗ ರೀತ್ಯಾ ಹಕ್ಕುಗಳನ್ನು ಬಳಸಿಕೊಳ್ಳವುದಿಲ್ಲ.

ನಾನು_____ ಇವರಿಗೆ ಈ ಸಂಶೋಧನೆಯ ಉದ್ದೇಶ ವಿಧಿ ವಿಧಾನಗಳು, ಅಸಖ್ಯ ಹಾಗೂ ಪ್ರಯೋಜನಗಳು ಕುರಿತಾಗಿ ರೋಗಿಯ ಮಾತೃ ಭಾಷೆಯಲ್ಲಿ ನನ್ನ ಸಾಮರ್ಥ್ಯಕ್ಕೆನುಗುಣವಾಗಿ ವಿವರಿಸಿದ್ದೇನೆ.

ಸಂಶೋಧಕ I

ಭಾಗಯಾಗುವ ಅಭ್ಯರ್ಥಿಯ , ಸಮ್ಮತಿ ಹೇಳಿಕೆ

ನಾನು ಈ ಮೂಲಕ ಧೃಡಪಡಿಸುವದೇನೆಂದರೆ ಡಾ.ಎಸ್ ಬಿ ಪಾಟೀಲ ಅವರು ಸಂಶೋಧನೆಯ ಉದ್ದೇಶ ಒಳಗಾಗಬೇಕಾಗಿರುವ ವಿಧಿ ವಿಧಾನಗಳು, ಎದುರಾಗಬಹುದಾದ ಕ್ಲೇಶ ಹಾಗೂ _____ ಕುರಿತಾಗಿ ನನ್ನ ಮಾತೃ ಭಾಷೆಯಲ್ಲಿ ತಿಳಿಸಿದ್ದಾರೆ.

ಮೇಲ್ಕಾಣಿಸಿದ ಎಲ್ಲ ಮಾಹಿತಿಗಳನ್ನು ಅಧ್ಯಯನಕಾರರು ನನ್ನ ಮಾತೃ ಭಾಷೆಯಲ್ಲಿ ನನಗೆ ಅರ್ಥವಾಗುವ ರೀತಿಯಲ್ಲಿ ತಿಳಿಸಿರುತ್ತಾರೆ.

ಆದುದರಿಂದ ಈ ಅಧ್ಯಯನದಲ್ಲಿ ಅಭ್ಯರ್ಥಿಯಾಗಿ ಭಾಗವಹಿಸುವ ನಿಟ್ಟಿನಲ್ಲಿ ಸಮ್ಮತಿಯನ್ನು ಕೊಡಲು ಈ ಮೂಲಕ ನಾನು ಒಪ್ಪಿರುತ್ತೇನೆ.

ಅಭ್ಯರ್ಥಿ ದಿನಾಂಕ

ಸಾಕ್ಷಿ ಸಹಿ ದಿನಾಂಕ

ANNEXURE – VI

SCHEME OF CASE TAKING:

1) Name:
2) Age: IP NO:
3) Sex: DOA:
4) Religion: DOS:
5) Occupation:
6) Residence:
7) CHIEF COMPLAINTS:

8) HISTORY:

9) EXAMINATION:

10) INVESTIGATION:

BLOOD: Hb URINE: Albumin:
TC : Sugar:
DC: Microscopy:
ESR:
BT, CT:
SERUM CREATININE:
RBS:
USG ABDOMEN:
CT-Scan KUB:

METABOLIC WORK-UO:

14) FINAL DIAGNOSIS:

SITE:
SIZE:
HF UNITS:

Spectrochimica Acta Part A: Molecular and Biomolecular Spectroscopy 154 (2016) 20–26

Contents lists available at ScienceDirect

Spectrochimica Acta Part A: Molecular and Biomolecular Spectroscopy

journal homepage: www.elsevier.com/locate/saa

Identification of mineral compositions in some *renal calculi* by FT Raman and IR spectral analysis

J. Tonannavar [a,*], Gouri Deshpande [a], Jayashree Yenagi [a], Siddanagouda B. Patil [b], Nikhil A. Patil [b], B.G. Mulimani [c]

[a] Vibrational Spectroscopy Group, Department of Physics, Karnatak University, Pavate Nagar, Dharwad 580 003, India
[b] Department of Urology, Shri B.M.Patil Medical College, Hospital and Research Centre, Vijaypur 586 103, India
[c] BLDE University, Vijaypur 586 103, India

ARTICLE INFO

Article history:
Received 4 July 2015
Received in revised form 26 September 2015
Accepted 4 October 2015
Available online 8 October 2015

Keywords:
Renal calculi
IR
Raman
DFT

ABSTRACT

We present in this paper accurate and reliable Raman and IR spectral identification of mineral constituents in nine samples of *renal calculi* (kidney stones) removed from patients suffering from nephrolithiasis. The identified mineral components include Calcium Oxalate Monohydrate (COM, whewellite), Calcium Oxalate Dihydrate (COD, weddellite), Magnesium Ammonium Phosphate Hexahydrate (MAPH, struvite), Calcium Hydrogen Phosphate Dihydrate (CHPD, brushite), Pentacalcium Hydroxy Triphosphate (PCHT, hydroxyapatite) and Uric Acid (UA). The identification is based on a satisfactory assignment of all the observed IR and Raman bands (3500–400 cm^{-1}) to chemical functional groups of mineral components in the samples, aided by spectral analysis of pure materials of COM, MAPH, CHPD and UA. It is found that the eight samples are composed of COM as the common component, the other mineral species as common components are: MAPH in five samples, PCHT in three samples, COD in three samples, UA in three samples and CHPD in two samples. One sample is wholly composed of UA as a single component; this inference is supported by the good agreement between ab initio density functional theoretical spectra and experimental spectral measurements of both sample and pure material. A combined application of Raman and IR techniques has shown that, where the IR is ambiguous, the Raman analysis can differentiate COD from COM and PCHT from MAPH.

1. Introduction

Stone disease (Nephrolithiasis) in men and women is common health problem and the incidence is growing worldwide [1]. This disease most commonly affects 20–40 years age group resulting in significant morbidity and loss of work. There has been significant progress in the treatment of *calculi* over the last two to three decades and the estimated cost of treatment, for instance, is two billion dollars per year in the US [2,3]. With probably 5–7 million patients suffering in India too, the incidence is more prevalent over the upper western geographical region referred to as 'stone belt' though it is not uncommon in other regions [4]. Recurrence of stone is the biggest challenge in the management of patients suffering from Nephrolithiasis. It is estimated that 50% of the patients will experience recurrent stone disease within 10 years [5]. Knowing the type of stone helps in preventing the recurrence by modifying the diet and other risk factors. Hence it is an important determinant in management of stone disease. Various techniques of stone analysis are available ranging from the traditional wet chemical analysis to sophisticated techniques like FTIR, X-Ray diffraction, SEM, thermal analysis [6,7]. We discuss in the present paper Raman and FTIR spectroscopic analysis of nine kidney stones, identifying six different molecular mineral species distributed over the samples.

While the chemical wet method, TA and SEM provide information on chemical composition, all the other methods give mineralogical composition, and SEM and PM provide surface morphology as well. It must be pointed out that XRD and IR spectroscopy give complete information of mineralogical content compared to other methods. With its advantage of no sample preparation, the Raman technique is strongly complementary to IR and in some cases it can even be a substitute [8–11]. Fundamentally, both IR and Raman give the same information on the characteristic vibrational frequencies and structural aspects of chemical functional groups. IR radiation is absorbed by the vibrating chemical functional groups that make up a sample, producing characteristic absorption bands which facilitate identification of the functional groups. While Raman technique is based on the scattering of light radiation by the chemical functional groups and produces characteristic Raman bands which facilitate identification of the functional groups as in IR, it is more structure sensitive with the ability to differentiate spectral aspects [12].

In the present work, a batch of nine *renal calculi* (kidney stone samples) surgically removed from patients suffering from Nephrolithiasis

* Corresponding author.
E-mail address: jrtonannavar@kud.ac.in (J. Tonannavar).

http://dx.doi.org/10.1016/j.saa.2015.10.003
1386-1425/

have been analyzed for the determination of their mineralogical content. This work forms a part of major program of studying mineralogical content of hundreds of renal calculi of different patients being treated at Shri B.M.Patil Medical College, Hospital and Research Centre in Vijaypur town (16.82°N, 75.72°E) in the northern part of Karnataka State, India. The proposed study envisages, apart from potential benefit of the knowledge of mineral content in stone samples for diagnosis and treatment, correlations between minerals and etiology aspects covering recurrence, food habits, life style, genetic pre-disposition and geography. Stones are generally composite minerals formed as solid concretions from dissolved minerals in supersaturated urine [13]. Urolithiasis is the result of pathological deposition of these stones as biominerals in kidney, ureter or bladder (KUB). Common minerals found in stone samples include Calcium Oxalate Monohydrate (COM, whewellite), Calcium Oxalate Dihydrate (COD, weddellite), Magnesium Ammonium Phosphate Hexahydrate (MAPH, struvite), Calcium Hydrogen Phosphate Dihydrate (CHPD, brushite), Penta CalciumHydroxyTriphosphate (PCHT, hydroxyapatite) and other rare materials [14]. Another rare organic matter responsible for stone formation is Uric Acid (UA). Except in rare cases, stone samples are usually composed of more than one type of mineral with COM and/or COD, both being dominant in occurrence and relative abundance. Other minerals include MAPH, CHPD, PCHT and organic matter, UA. In the present study we have found that while all the eight stone samples have each COM as the common component, one sample is composed of UA as a single component: among the eight samples, five have three mineral components each, one sample has four components, and two samples have only two components each.

Analysis of mineral content in stone samples using IR technique has been going on for years [15,16]. The technique is proved to be highly reliable for qualitative identification of mineral composition though commercially quantitative methods are available and some studies also have been reported [17,18]. In the determination of mineral components, it has become a common practice to identify the most reliable but a few characteristic bands due to a mineral species while other bands that have occurred with these characteristic bands remain unassigned. This may in part be attributed to reliance only on the IR technique. The Raman spectroscopic technique, on the other hand, can not only strongly complement IR but in some cases it can differentiate COD from COM and PCHT from MAPH as has been demonstrated in the present study. A single characteristic COD band at 1474 cm^{-1} is Raman active which differentiates COD from COM which produces two Raman modes at 1489 and 1462 cm^{-1}. While two PCHT's characteristic IR bands occur at 604 and 568 cm^{-1}, one MAPH's band at 559 cm^{-1} and CHPD's band at 584 cm^{-1} thereby making PCHT identification difficult but a Raman band at 961 cm^{-1} with an IR band at 1030 cm^{-1} in PCHT makes it identifiable from the other two minerals, MAPH and CHPD. It is the objective of the present study to combine both Raman and IR spectral analysis for a complete and satisfactory assignment of bands due to mineral species in all the nine stone samples. For accurate identification of the typical mineral constituents, namely, COM, COD, MAPH, CHPD, PCHT and UA, we measured IR and Raman spectra of the pure compounds of COM, MAPH, CHPD and UA and assigned 'marker bands' in them by determining most of the bands of molecular groups to ensure a satisfactory spectral analysis and identification of the mineral constituents.

2. Materials and Methods

2.1. Sample Collection

The samples, labeled S1 to S9 as shown in Fig. 1, were collected of the patients being treated at Shri B.M. Patil Medical College, Hospital and Research Centre. They were distilled water-washed, dried and used. The samples have irregular shapes, with sizes varying from 5 mm to 20 mm. The colors and hues the samples possess are indicative of their mineral compositions and degree of relative abundance. Pure mineral compounds, calcium oxalate monohydrate (COM), magnesium ammonium phosphate hexahydrate (MAPH), uric acid (UA) and calcium hydrogen phosphate dihydrate (CHPD) from Sigma-Aldrich were used as received for spectral measurements.

2.2. Experimental

The spectra (4000–400 cm^{-1}) were measured on *ThermoFisher* NICOLET-6700 FT-IR spectrometer which consisted of Alum standard ETC. Ever-Glo IR source and DTGS detector equipped with KBr windows. The surfaces of stone samples were cut with a sterile scalpel and then ground with agate mortar and pestle. A pellet was prepared for each sample with a dry KBr in the ratio 1:100. The pellet obtained was transferred to the instrument to obtain spectra with a resolution of 4 cm^{-1} at 100 scans.

The Raman spectra were measured on a *ThermoFisher* NXR FT-Raman Module, with a resolution of 4 cm^{-1}. This module consisted of Nd:YVO_4 laser (1064 nm) as an excitation source. The interferometer bench comprised a CaF_2 beam splitter and LN_2 cooled Ge detector. Two sampling configurations were used. A 180° scattering configuration was used as a non-destructive method for the samples in their natural form. Spectra were recorded for different orientations. Powdered samples were excited in a glass bottle and spectra were recorded. The first method produced orientation-dependent spectra showing changes both in appearance of bands and intensities. The uniform spectra produced by the second method with little orientation dependence have been used in the analysis. A total of 256 numbers of scans were taken for each spectral measurement.

2.3. Ab initio Calculations

The uric acid (UA) as an organic molecule is amenable to ab initio quantum chemical calculations and therefore we have computed molecular geometry and IR and Raman spectra at density functional theory's B3LYP/6-31++G level. These calculations were performed using *Gaussian 09 W* and *GaussView 5.0.9* suite of programs [19,20].

3. Results and Discussion

For accurate identification of the typical mineral constituents, namely, COM ($CaC_2O_4 \cdot H_2O$), COD ($CaC_2O_4 \cdot 2H_2O$), MAPH ($MgNH_4PO_4 \cdot 6H_2O$), CHPD ($CaHPO_4 \cdot 2H_2O$), PCHT ($Ca_5(PO_4)_3OH$) and UA ($C_5H_4N_4O_3$),we measured IR and Raman spectra (Figs. 2 and 3) of the pure samples of COM, MAPH, CHPD and UA and assigned their 'marker bands' due to chemical functional groups. These spectra have been employed as a reference for assigning the spectra of the nine stone samples. The assignments for these pure materials are in agreement with reported data [15]. As for the identification of COD and PCHT bands, we have relied upon reported assignments [12,14,15,21–24]. The IR and Raman spectra of the samples S1–S9 are presented in Figs. 4 and 5 and the characteristic bands of constituents of the samples along with assignments are presented in Tables 1 & 2. All the stone samples, S1 to S8, have been found to be mixtures of two or three mineral components except the sample S9 which is apparently composed of UA as a single component. While mineral components in a given stone sample show their characteristic bands, whether IR or Raman or both, the accurate description of vibrational modes of all the bands is not straightforward because molecular functional groups in the minerals exist mostly as anion and cation assembly in a complex environment with some of their bands defying easy assignments. Technically speaking, the occurrence and intensities of characteristic IR absorption bands depend upon the square of change in electric dipole moment of molecular species during vibrations, symmetry properties of the vibrations and molecular population. As for the Raman bands, the occurrence and intensities of characteristic bands depend upon the square of change in electric polarizability of molecular species during vibrations, symmetry properties, fourth power of the

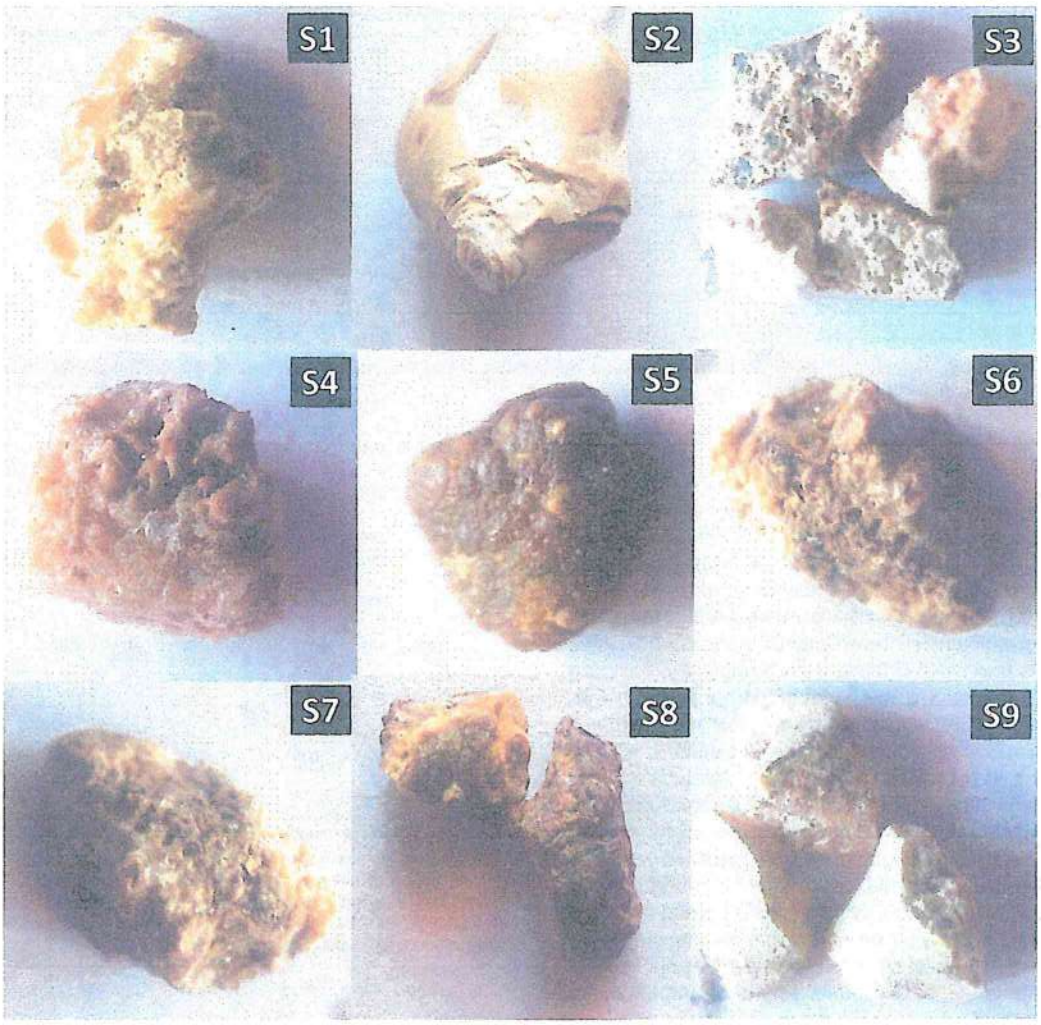


Fig. 1. Pictures of kidney stone samples taken with a 10 MP digital camera.

frequency of excitation light radiation and molecular population [25]. In a multi-component-borne stone sample, these factors operate in varying degrees for producing IR and Raman marker bands which form the ultimate base for the identification of unknown minerals in the sample. A typical IR spectrum of a stone sample (Figs. 2 and 4) consists mainly of very broad absorption band(s) spread over 3500 to 2000 cm^{-1}; the

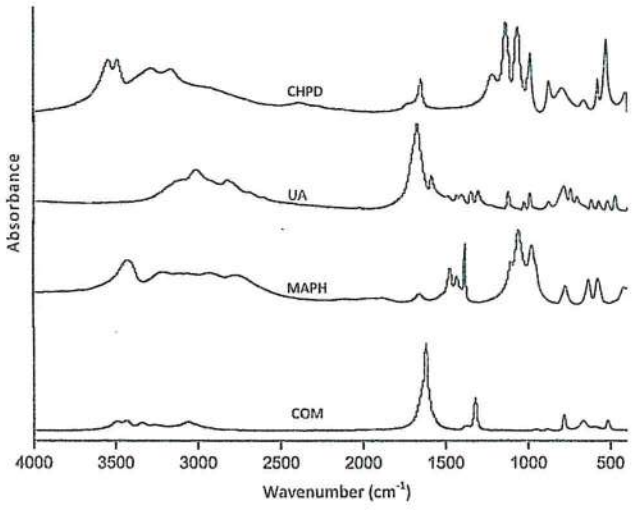


Fig. 2. FT-IR spectra of pure COM, MAPH, CHPD and UA taken as reference.

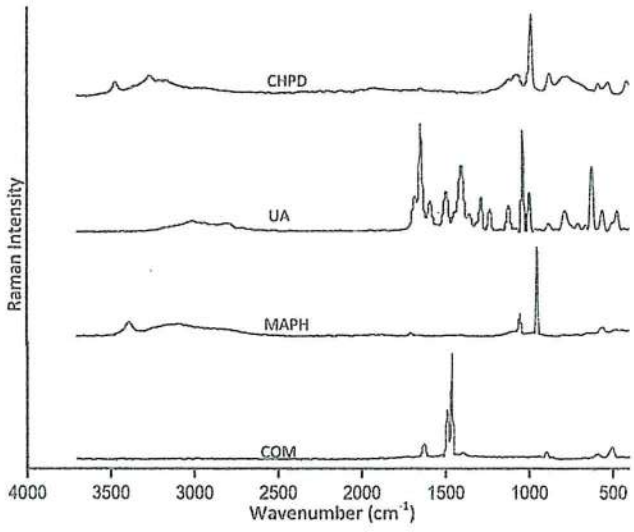


Fig. 3. FT Raman spectra of pure COM, MAPH, CHPD and UA taken as reference.

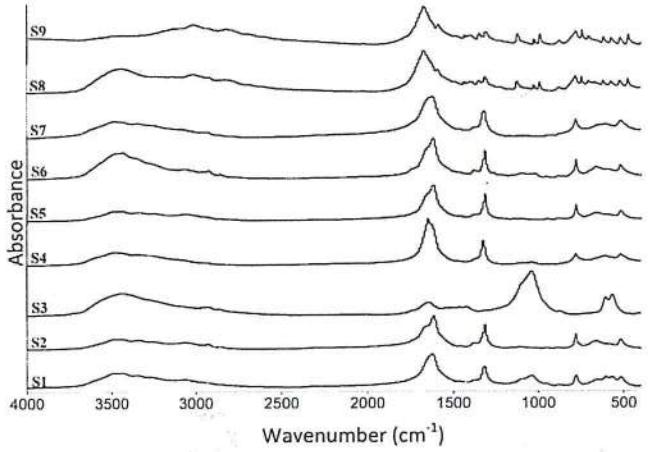


Fig. 4. FT-IR spectra of nine kidney stone samples S1–S9.

extent of breadth varying in proportion to the presence of water in the sample, as for example, in COM and COD (while we have not measured COD spectrum but it would be similar to COD's) or strong inter-/intramolecular associations [26]. Sometimes a couple of narrower bands show in this region (Fig. 2 for pure CHPD). For stone samples, the region is mostly marked by a structure less broad band(s) invariably attributed to water (O–H) bands associated with hydrogen bonding [8]. The region 1800 to 500 cm^{-1} shows characteristic bands of functional groups with varying breadth and intensities controlled by the aforementioned factors. The Raman spectra, on the other hand, show less number of bands (except for the UA, Fig. 5) but nonetheless are either the same bands as IR or strongly complementary. In some cases, the Raman bands act as determinant in differentiating minerals where IR is unclear and this is demonstrated in the present study. The advantage of Raman in revealing structural aspects especially below 400 cm^{-1} where IR is useful makes it an indispensible technique though such analysis is beyond the scope of the present study [11]. For the convenience of spectral analysis, we follow the general scheme of classification of the mineral components of *renal calculi* by grouping the stone samples (S1 to S9) into Oxalates, Phosphates and Purines [8].

3.1. Oxalates Bands

There are five marker bands near 1620, 1487, 1394, 890 and 592 cm^{-1} arising from the oxalate ion (COO^- or CO_2^-) [15,27,28]. While in a given IR or Raman spectrum of a sample not all these five

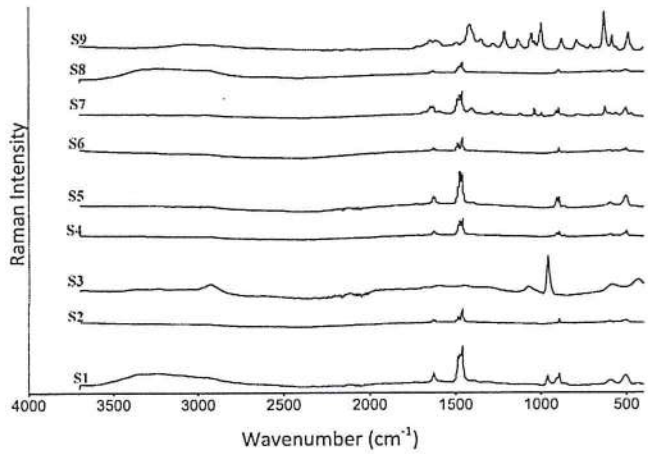


Fig. 5. FT Raman spectra of nine kidney stone samples S1–S9.

Table 1
Wave numbers of IR and Raman marker bands (in cm^{-1}) and assignments of functional groups in mineral components of the samples S1 to S4.

S1		S2		S3		S4		Assignment*
IR	R	IR	R	IR	R	IR	R	
1654[a]	–	**1668**	–	1654[b]	–	**1656**	–	$\delta(NH_4^+)$:MAPH
1619	1628	**1615**	1628	–	1636[c]	**1619**	**1627**	$\nu_{as}(COO^-)$:COM
–	1488	–	**1487**	–	–	–	**1489**	$\nu_s(COO^-)$:COM
–	1477	–	–	–	–	–	–	$\nu_s(COO^-)$:COD
–	–	–	–	1474	–	–	–	$\nu_4(NH_4^+)$:MAPH
1459	–	1461	–	–	–	1468	–	$\nu_4(NH_4^+)$:MAPH
–	**1462**	–	**1462**	–	1460	–	**1461**	$\nu_s(COO^-)$:COM
–	1400	–	1398	–	–	1391	1398	ν_s(C–O) + ν_s(C–C):COM
1388	–	1388	–	–	–	–	–	$\nu_4(NH_4^+)$:MAPH
1315	–	**1314**	–	1316	–	1315	–	$\nu_s(COO^-)$ + δ(O–C = O):COM
1111	–	1112	–	–	–	1110	–	$\delta(PO_4^{3-})$:MAPH
–	–	1082	–	–	–	–	–	$\nu_3(PO_4^{3-})$:MAPH
1037	–	–	–	**1036**	–	–	–	$\delta(PO_4^{3-})$:PCHT
–	–	1017	–	–	–	–	–	$\nu_3(PO_4^{3-})$:MAPH
–	**963**	–	–	–	**961**	–	–	$\delta(PO_4^{3-})$:PCHT
952	–	958	963	–	–	948	–	δ(O–H):COM
–	896	–	895	–	894	–	894	ν_s(C–C):COM
884	–	884	–	872	–	883	870	ν(C–C):COM
780	–	780	–	780	–	780	–	δ(O–C=O) + ν(M–O):COM
659	–	663	–	–	–	659	–	ν(O–C–O):COM
608	–	–	–	604	–	–	–	$\nu_4(PO_4^{3-})$:PCHT
–	593	593	602	–	590	603	596	$\nu(COO^-)$ + Water libration:COM
569	–	–	567	–	–	–	–	$\nu_4(PO_4^{3-})$:PCHT
–	–	–	–	565	–	–	–	δ(OPO):MAPH
517	–	517	–	–	–	518	522	ν(Ca–O):COM
–	505	–	503	–	–	–	503	β(O–C–O) + ν(C–C):COM
426	434	428	–	–	435	426	–	δ(O–P–O):MAPH

Note: The frequencies in [a] bold have very very strong to very strong intensities; [b] those underlined have medium strong to medium intensities and [c] others have medium to very weak intensities the range. *Functional group(s) with mineral identified are shown. The Greek symbols ν, β and δ refer to stretching, in plane and out of plane bending respectively and subscripts to them are as = antisymmetric; s = symmetric. For ν_1, ν_2, ν_3, and ν_4 descriptions refer section of phosphate bands.

IR and five Raman bands are observed but a total of five of IR and Raman bands occur in the spectra. The IR spectra of the five samples (S1, S2, S4, S6, S7) show a very strong absorption at 1620 cm^{-1} with a corresponding sharp but very weak Raman band at 1628 cm^{-1}. This is assigned to asymmetric COO^- stretching vibration. The same Raman band is observed in two more samples S5 and S8 but not in their IR spectra. The Raman spectra show a distinct doublet at 1493 and 1468 cm^{-1} with peak intensity ratio of 1.7:1; the two bands are identified as symmetrical C–O stretching mode. A band around 952 cm^{-1} in IR spectrum of COM arises due to O–H bending vibration. The spectra of the samples S1, S2 and S4 show this band. One more Raman band near 1474 cm^{-1}, not observed in the pure sample spectrum of COM measured by us but has been invariably assigned to the pure sample of COD, lies between 1493 and 1468 cm^{-1}; it is a Raman marker for the identification of COD and is assigned to symmetrical C–O stretching mode [12,29,30]. The bands at 886(IR)/895 cm^{-1}(R) and 516(IR)/504 cm^{-1}(R) respectively are assigned to C–C stretch and O–C–O in-plane bending vibrations [31]. Dihydrate only shows a sharp single band near 1474–1480 cm^{-1} close to the mean of monohydrate doublet [12,14,32]. Another important spectral feature of pure COM is that it shows closely lying bands between 3477–3047 cm^{-1} which are due to symmetric and asymmetric O–H stretch vibrations appearing as a smooth broad band in COD [31]. The COM shows an IR band at 516 cm^{-1} and one Raman band at 504 cm^{-1} are respectively assigned to Ca–O and C–C stretchings. All the stone samples containing COM with the exception of samples S3 and S9 show these bands.

Table 2
Wave numbers of IR and Raman marker bands (in cm^{-1}) and assignments of functional groups in mineral components of the samples S5 to S9.

S5		S6		S7		S8		S9		Assignment*
IR	R	IR	R	IR	R	IR	R	IR	R	
–	–	–	–	–	–	**1670**[a]	–	**1674**	–	ν(C=O):UA
–	–	–	–	**1654**	–	–	–	–	–	δ(NH_4^+):MAPH
–	–	–	–	–	**1647**	–	–	–	**1647**	ν(C=O):UA
1644	–	**1649**	–	–	–	–	–	–	–	β(O–H):CHPD
–	1632[b]	**1619**	1628[c]	**1620**	–	–	1627	–	–	$\nu_{as}(COO^-)$:COM
–	–	–	–	–	1590	1591	–	1590	1590	ν(C=N) + ν (C=C):UA
–	1536	–	–	–	–	–	–	–	–	$\nu_s(COO^-)$:COM
–	–	–	–	–	–	1492	–	1489	1495	ν(C=N):UA
–	**1485**	–	**1487**	–	1489	–	**1487**	–	–	$\nu_s(COO^-)$:COM
1474	**1477**	–	1479	–	–	–	–	–	–	$\nu_s(COO^-)$:COD
–	–	1462	–	1464	–	–	–	–	–	δ(NH_3^+):MAPH
–	**1465**	–	**1462**	–	**1462**	–	**1461**	–	–	$\nu_s(COO^-)$:COM
–	–	–	–	–	–	1436	–	1436	–	δ(C=N–H) + ν(C–C) :UA
–	1401	–	–	–	**1403**	1399	1397	1401	**1404**	δ(C=N–H):UA
1389	–	1383	1394	1388	–	–	–	–	–	ν_s(C–O) + ν_s(C–C):COM
–	–	–	–	–	1357	1349	–	1349	1351	δ(C=N–H):UA
1324	–	**1315**	–	**1317**	–	–	–	–	–	$\nu_s(COO^-)$ + δ(O–C=O):COM
–	–	–	–	–	–	1312	–	1310	–	δ(C=N–H):UA
–	1299	–	–	–	1282	–	–	–	1282	δ(C=N–H):UA
–	–	–	–	–	1229	1233	1235	1218	1212	ν(C–O) + δ(O–H):UA
1130	–	–	–	–	–	–	–	–	–	δ(PO_4^{-3}):CHPD
–	1086	–	–	–	–	–	–	–	–	ν_3(PO_4^{-3}):CHPD
–	–	–	–	1117	1117	–	1123	1123	1118	Ring Vibration:UA
1026	–	–	–	1014	1036	–	–	1026	**1034**	ν(C–O) + δ(O–H):UA
–	–	–	–	–	995	992	1006	992	997	Ring Vibration:UA
–	–	–	–	–	941	–	–	–	–	ν_1(PO_4^{-3}):MAPH
–	898	–	895	884	894	–	894	–	–	ν(C–C):COM
–	–	–	–	–	873	–	867	878	878	δ(NCN):UA
779	–	780	–	780	–	781	–	783	787	δ(O–C=O) + ν(Ca–O):COM
–	–	–	–	–	–	744	–	745	–	ν(C–N):UA
–	–	–	–	–	703	705	705	706	704	δ(O=CN) + δ (NCN):UA
–	–	663	–	–	–	673	–	–	–	ν(O–C–O):COM
–	–	–	–	–	624	618	–	619	**625**	Ring breathing:UA
607	597	594	596	606	–	–	605	600	–	ν(COO^-) + Water libration:UA
–	–	–	–	–	–	574	–	574	584	Ring Vibration:UA
–	–	–	–	–	561	–	563	–	560	δ(NCN):UA
–	–	–	524	–	–	–	–	–	–	ν_4(PO_4^{-3}):CHPD
–	–	–	–	–	–	–	–	522	–	Skeletal ring deformation:UA
516	–	518	–	517	–	521	–	–	–	ν(Ca–O):COM
–	504	–	503	–	501	–	501	–	–	β(O–C–O) + ν(C–C):COM
–	–	–	–	–	470	474	–	474	470	Skeletal ring deformation:UA
–	–	421	–	–	–	–	–	–	–	δ(OPO):MAPH

Note: The frequencies in [a] bold have very very strong to very strong intensities; [b] those underlined have medium strong to medium intensities and [c] others have medium to very weak intensities the range. *Functional group(s) with mineral identified are shown. The Greek symbols ν, β and δ refer to stretching, in plane and out of plane bending respectively and subscripts to them are as = antisymmetric; s = symmetric. For ν_1, ν_2, ν_3, and ν_4 descriptions refer section of phosphate bands.

3.2. Phosphates Bands

The next most common minerals of the investigated stone samples contain phosphates, calcium and magnesium phosphates in MAPH and CHPD.

3.2.1. NH_4^+ Group Vibrations in MAPH

A free NH_4^+ ion forms a regular tetrahedron with T_d symmetry. As a result there are nine normal modes of vibration with their symmetry species distribution $A_1 + E + 2F_2$ corresponding to four fundamental vibrational frequencies ν_1, ν_2, ν_3 and ν_4. The ν_1 belongs to A_1 as symmetric stretching mode; ν_2 belongs to E as deformation mode and ν_3, as asymmetric stretching and ν_4 as triply degenerate deformation modes (i.e., two pairs of three modes each) that belong to F_2. The fundamental frequencies of NH_4^+ molecule appear at 3033 (ν_1), 1685 (ν_2), 3134 (ν_3) and 1397 (ν_4) cm^{-1}. The bands at 3134 and 1397 cm^{-1} belong to species F_2 and are triply degenerate and band at 1685 cm^{-1} is doubly degenerate [25]. When NH_4^+ is a functional unit as in MAPH, its symmetry is lowered from T_d on account of strong inter-molecular interactions which cause band splitting and shifting: ν_2 splits into two frequencies and ν_3 and ν_4 each splits into three frequencies [31]. Measured Raman spectra of pure MAPH sample show band around 3060 cm^{-1} which may be assigned to ν_1. Two bands at 1660 cm^{-1} (IR) and 1704 cm^{-1} (R) are identified to have originated from the splitting of the degenerate band at 1685 cm^{-1}. The triply degenerate band at 1397 cm^{-1} splits to produce IR bands at 1473, 1445 and 1384 cm^{-1}. The 3134 cm^{-1} band is weak in NH_4^+ and as such probably occurs near the region 3500–3000 cm^{-1} in the sample to escape observation. The stone samples S1, S2, S3, S4 and S7 have a very strong to fairly strong band in the narrow range near 1650–1670 cm^{-1} which may readily be assigned to MAPH's ν_2 component. A medium intense IR band at 773 cm^{-1} is identified as Mg–O stretching in MAPH. It must be noted that samples containing both COM and MAPH constituents, as for example, S2, show a band near 780 cm^{-1}.

3.2.2. PO_4^{-3} Group Vibrations in MAPH, CHPD and PCHT

The free PO_4^{-3} ion has the same symmetry as NH_4^+ and therefore it has exactly the same number of vibrational modes and symmetry species [33]. The fundamental frequencies of the PO_4^{-3} ion are measured at 980 (ν_1), 363 (ν_2), 1082 (ν_3) and 512 (ν_4) cm^{-1} [22]. Two strong Raman bands in the measured spectrum of MAPH at 950 and 1052 cm^{-1} are assigned to ν_1 and ν_3 respectively. A Raman band at 572 and IR band at 559 cm^{-1} arise as a result of splitting of ν_4. A

weak Raman band at 437 cm^{-1} is assigned to ν_2. However, the spectra of the stone samples S1, S2 and S3 show band around 565 cm^{-1} and 430 cm^{-1} and the second band alone is seen in the S4's IR spectrum. The sample S7 shows a Raman band at 941 cm^{-1} which is assigned to ν_1 [34].

In CHPD, while the ν_1 appears at 985 cm^{-1} the two bands at 1062 and 1075 cm^{-1} are identified as split components of triply degenerate ν_3 mode. A medium strong band at 411 cm^{-1} in the Raman spectrum may be assigned to ν_2 and bands at 584 and 525 cm^{-1} are assigned to triply degenerate ν_4 mode. While the Raman spectrum of the sample S5 shows a band at 1086 cm^{-1} assigned to ν_3, a Raman band in the sample S6 at 524 $cm^{-1}$is due to ν_4 mode. The IR spectrum of the pure material of CHPD shows a strong band at 1649 cm^{-1} arising from the in-plane bending of water molecules, and the corresponding band in the samples S5 and S6 has occurred at 1644 and 1649 cm^{-1} respectively.

As for PCHT containing PO_4^{-3} group, a strong Raman band at 961 cm^{-1} is identified with symmetric P–O stretching of ν_1 mode. The same band at 961 cm^{-1} is observed in the samples S1 and S3 along with IR bands at 1030, 604 and 568 cm^{-1} which complete the characterization of hydroxyapatite [13,29]. The IR band at 568 cm^{-1} in S1 and S3 has been assigned to MAPH.

3.3. Purine Bands

The remarkable closeness of the IR and Raman spectra of the pure UA (Figs. 6, 7) with that of experimentally measured spectra clearly suggests that the sample S9 is apparently composed of single component of UA material. The abundance of UA as a single mineral component is rare and more rare is the presence of UA with COM, as has been found in the sample S8 and as a minor component with other mineral constituents as in the samples S5 and S7. In order to ascertain its rich IR and Raman bands in the measured spectra and assign them satisfactorily, we performed ab initio density functional theory calculations on UA [19]. We computed both IR and Raman spectra at B3LYP/6-31++G level of theory for a free uric acid molecule that served as if it were vapor spectra. The simulated spectra are in very good agreement with the experiment (Figs. 6 and 7). Assignments were aided by the forms of normal modes visualized in *GaussView5.0.9* [20]. The UA shows bands at 1489(IR)/1495(R) and 1404 cm^{-1} (IR and R) due to C = N stretch. The corresponding predicted bands are 1537 and 1365 cm^{-1}. A band at 1590 (IR/R) cm^{-1} arises due to C=C and C=N in-plane ring stretching with a predicted band at 1609 cm^{-1}. The N–H in hetero-aromatic ring has stretching vibrations with bands between 3143 and 2034 cm^{-1}. There are three carbonyl groups (C=O) in the UA. A very strong Raman band at 1648 cm^{-1} corresponds to carbonyl group stretching vibration in the aromatic ring; it is predicted very accurately at 1654 cm^{-1}. Another strong band of the same mode at 1674 (IR)/1680 (R) cm^{-1} comes from the five-member ring fused to the aromatic ring; this mode is also accurately predicted at 1686 cm^{-1}. The vibrational frequencies predicted are in agreement with the reported data [35]. The two observed distinct frequencies discriminate the two carbonyl groups in different chemical environments. A band predicted at 1644 cm^{-1} is not observed but is a strongly coupled vibrations. On account of excellent agreement between all the spectra, we conclude that S9 is constituted entirely of UA probably with no identifiable mineral(s). All the bands mentioned above have been observed in the IR and Raman spectra of S7, S8 and S9.

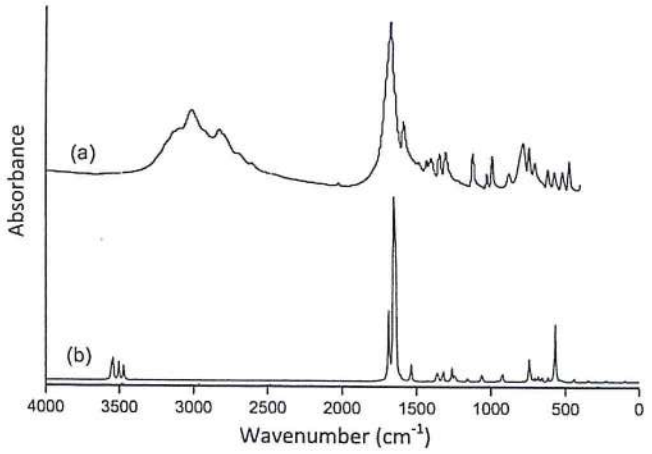


Fig. 6. IR spectra of Uric Acid (a) Experimental and (b) Computed (computed frequencies scaled by 0.9608).

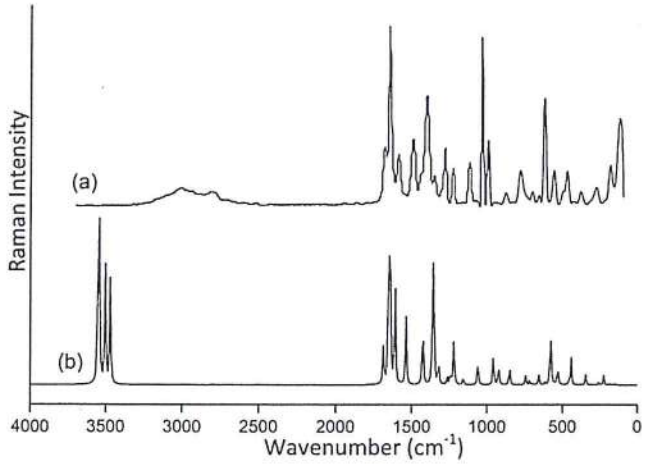


Fig. 7. Raman spectra of Uric Acid (a) Experimental and (b) Computed (computed frequencies scaled by 0.9608).

3.4. Identified Minerals

Based on the Raman and IR spectral analysis, six different mineral components have been identified that are distributed among nine stone samples as presented in Table 3. Four components have been identified in the samples S1, S5 and S6. The samples S3 and S7 have three components each whereas S2, S4 and S8 have only two components each. The sample S9 is exceptionally single component being wholly uric acid. Since the total number of IR marker bands due to different mineral components in a given sample varies as the species concentration, we show this compositional pattern in Fig. 8. It should be noted, for example, that the relative number of bands due to COM and UA in the sample S8 strongly suggests that their relative species concentration, qualitatively speaking, is in favor of dominant UA and this is borne out in the S9 which is only UA component. This holds good for the other samples. It may therefore reasonably be inferred that Fig. 8, at least qualitatively, gives the relative species concentration of the mineral components. Number of IR marker bands for each mineral species in each of the samples S1–S9 is presented in Table 4.

Table 3
Identified mineral components as constituents in stone samples S1 to S9.

Sample	Identified mineral(s)
S1	COM, PCHT, MAPH, COD
S2	COM, MAPH
S3	COM, PCHT, MAPH
S4	COM, MAPH
S5	COM, CHPD, COD, UA
S6	COM, CHPD, MAPH, COD
S7	COM, MAPH, UA
S8	COM, UA
S9	UA

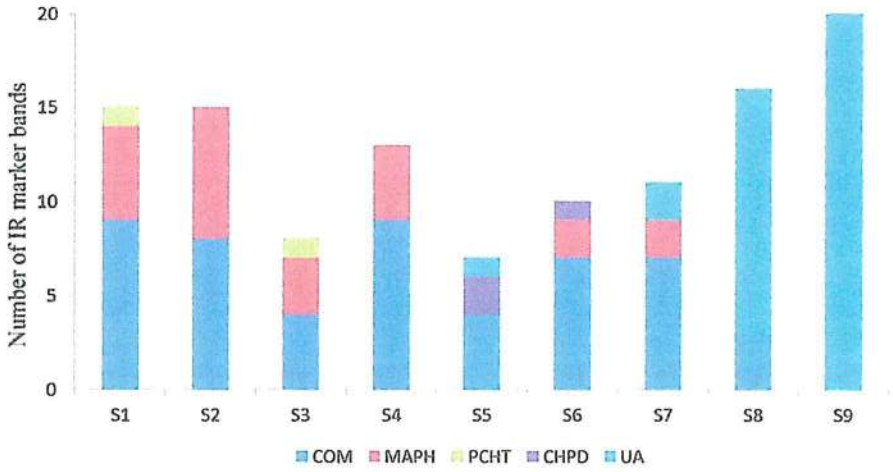


Fig. 8. Total share of IR marker bands among different mineral species in each of the samples S1–S9.

Table 4
Number of IR marker bands for each mineral species in each of the samples S1–S9.

Stone samples	Identified minerals				
	Oxalates	MAPH	PCHT	CHPD	UA
S1	9	5	1	0	0
S2	8	7	0	0	0
S3	4	3	1	0	0
S4	9	4	0	0	0
S5	4	0	0	2	1
S6	7	2	0	1	0
S7	7	2	0	0	2
S8	3	0	0	0	13
S9	0	0	0	0	20

4. Conclusions

The Raman and IR spectroscopy are highly reliable techniques for the identification of mineral constituents in *renal calculi*. The Raman technique is identical with and in some cases strongly complementary to IR, as has been demonstrated in differentiating COD from COM and PCHT from MAPH in some samples where IR is ambiguous. While the knowledge of mineral constituents as deduced for the nine samples would aid diagnosis, the sample size of nine stones does not qualify for any general inference to be drawn with respect to etiological aspects. The study would be extended for a larger sample size to correlate the etiological issues and produce a uniquely geography-centric mineral pattern of patients distributed around Vijaypur.

Acknowledgments

The financial support by the BLDE University under the grant number ECR/383/Inst/KA is gratefully acknowledged. We thank the Director, USIC at Karnatak University for FT-IR and Raman spectrometer facilities sponsored under DST-funded PURSE Program. One of us (GD) is thankful to Karnatak University for awarding a Research Fellowship under the UGC-UPE scheme.

References

[1] C.D. Scales Jr., A.C. Smith, J.M. Hanley, C.S. Saigal, Eur. Urol. 62 (2012) 160–165.
[2] Y. Lotan, Adv. Chronic Kidney Dis. 16 (2009) 5–10.
[3] M.S. Pearle, E.A. Calhoun, G.C. Curhan, J. Urol. 173 (2005) 848–857.
[4] http://www.karunya.edu/.
[5] N.F. Michael, K.P. Paul, M.P. Glen, in: A.J. Wein (Ed.), Campbell-Walsh Urology, 10th ed., 2012.
[6] S.G. Garcia, F.M. Rodrigueg, F.R. Baron, R.M. Bermudez, O.A. Feu, F.S. Martin, H.V. Mavrich, A.O. Samper, Actas Urol. Esp. 35 (6) (2011) 354–362.
[7] I. Singh, Int. Urol. Nephrol. 40 (3) (2008) 595–602.
[8] B.H. Stuart, Infrared Spectroscopy: Fundamentals and Applications, John Wiley & Sons, Inc., Hoboken, New Jersy, 2004.
[9] F. Kesner, I. Dominak, Kidney Stone Analysis by Nicolet FTIR spectrometer, NICODOM, Czech Republic, Europe, 1996.
[10] J.R. Ferraro, Introductory Raman Spectroscopy, Academic Press, CA, USA, 2002.
[11] E. Smith, Modern Raman Spectroscopy, John Wiley & Sons, Inc., Hoboken, New Jersy, 2005.
[12] K. Sudlow, A. Woolf, Clin. Chim. Acta 203 (1991) 387–394.
[13] D. Bazin, M. Daudon, C. Combes, C. Rey, Chem. Rev. 112 (2012) 5092–5120.
[14] P. Carmona, J. Bellanato, E. Escolar, Biospectroscopy 3 (1997) 331–346.
[15] M. Modlin, P.J. Davies, S. Afr. Med. J. 59 (1981) 337–341.
[16] F. Grases, L.G. Ferragut, A.C. Bauza, Recent Research Developments In Pure & Applied Analytical Chemistry, vol. 1, 1998.
[17] A.K. Mukherjee, J. Indian Inst. Sci. 94 (2014) 35–44.
[18] J.L.G. Álvarez, M.J.T. Martinez, M.A. Fernandez, Clin. Biochim. 45 (2012) 582–587.
[19] M.J. Frisch, G.W. Trucks, H.B. Schlegel, G.E. Scuseria, M.A. Robb, J.R. Cheeseman, G. Scalmani, V. Barone, B. Mennucci, G.A. Petersson, H. Nakatsuji, M. Caricato, X. Li, H.P. Hratchian, A.F. Izmaylov, J. Bloino, G. Zheng, J.L. Sonnenberg, M. Hada, M. Ehara, K. Toyota, R. Fukuda, J. Hasegawa, M. Ishida, T. Nakajima, Y. Honda, O. Kitao, H. Nakai, T. Vreven, J.A. Montgomery Jr., J.E. Peralta, F. Ogliaro, M. Bearpark, J.J. Heyd, E. Brothers, K.N. Kudin, V.N. Staroverov, R. Kobayashi, J. Normand, K. Raghavachari, A. Rendell, J.C. Burant, S.S. Iyengar, J. Tomasi, M. Cossi, N. Rega, J.M. Millam, M. Klene, J.E. Knox, J.B. Cross, V. Bakken, C. Adamo, J. Jaramillo, R. Gomperts, R.E. Stratmann, O. Yazyev, A.J. Austin, R. Cammi, C. Pomelli, J.W. Ochterski, R.L. Martin, K. Morokuma, V.G. Zakrzewski, G.A. Voth, P. Salvador, J.J. Dannenberg, S. Dapprich, A.D. Daniels, Ö. Farkas, J.B. Foresman, J.V. Ortiz, J. Cioslowski, D.J. Fox, Gaussian 09, Revision B.01, Gaussian, Inc., Wallingford CT, 2010.
[20] R. Dennington, T. Keith, J. Millam, GaussView 5.0, Semichem Inc., Shawnee Mission, KS, 2009.
[21] E.K. Girija, S. Narayana Kalkura, P.B. Sivaraman, Y. Yokogawa, J. Sci. Ind. Res. 66 (2007) 632–639.
[22] P.A. Bhatt, P. Paul, J. Chem. Sci. 120 (2008) 267–273.
[23] R. Selvaraju, A. Raja, G. Thiruppathi, Spectrochim. Acta 114 (2013) 650–657.
[24] N.Q. Dao, M. Daudon, Infrared and Raman Spectra of Calculi, Elsevier, Amsterdam, 1997.
[25] G. Herzberg, Molecular spectra and Molecular structure, vol. II, Van Nostrand, Reinhold, New York, 1945.
[26] G. Gilli, P. Gilli, The Nature of the Hydrogen Bond, Oxford Scientific Publications, 2009.
[27] M.L. Giannossi, V. Summa, in: Cumhur Aydinalp (Ed.), An Introduction to the Study of Mineralogy, InTech, Croatia 2012, pp. 123–146.
[28] R. Selvaraju, G. Thiruppathi, A. Raja, Spectrochim. Acta A 93 (2012) 260–265.
[29] Q. Ma, H. He, C. Liu, Atmos. Environ. 69 (2013) 281–288.
[30] M. Daudon, M.F. Protat, R.J. Reveillaud, H. Jaeschke-Boyer, Kidney Int. 23 (1983) 842–850.
[31] R.L. Frost, J. Yang, Z. Ding, Chin. Sci. Bull. 48 (17) (2003) 1844–1852.
[32] K. Nakamoto, Infrared and Raman Spectra of Inorganic and Coordination Compounds (Part A and B), John Wiley & Sons, Inc., Hoboken, New Jersy, 2009.
[33] V. Stefov, B. Soptrajanov, F. Spirovski, I. Kuzmanovski, H.D. Lutz, B. Engelen, J. Mol. Struct. 689 (2004) 1–10.
[34] S.K.H. Khalil, M.A. Azooz, J. Appl. Sci. Res. 3 (5) (2007) 387–391.
[35] D.P. Chong, J. Theor. Comput. Sci. 1 (1) (2013) 104.

Dr. Sathya Subramani, M.D., Ph.D.,
Professor and Head
Dept of Physiology
Email: sathya@cmcvellore.ac.in

Christian Medical College
Thorapadi post, Vellore 632002,
Tamil nadu, India.
Phone: (91) 416 2284268 (off), 2263208 (res)
Mobile: 94434 87868

21.08.2017

Dr. Kusal K.Das, PhD
Professor of Physiology
BLDE University's Shri B.M.Patil Medical College
Vijayapura-586103, Karnataka.

B. L. D. E. UNIVERSITY VIJAYAPUR

Dear Sir,

Greetings from Vellore!

The intention of this letter is to explore the possibilities of collaborative research with your lab. I understand that your lab works on the mechanisms of hypertension in a hypertensive rat model. Our lab strives to understand vascular physiology by working with different model systems. One preparation is the spiral strip of a small artery from goat legs procured from a slaughter house. Tension is recorded from the strip using a force transducer. Tension changes in response to vaso-modulators helps us understand signalling pathways involved in vasorelaxation (Ref.:Renu R. Raj and Sathya Subramani. Phenylephrine decreases vascular tension in goat arteries in specific circumstances. PLOS One. June 30, 2016).

We also record intra-arterial blood pressure in anesthetized rats (carotid and femoral artery) and rabbits (central ear artery); the animals can be kept under anaesthesia comfortably for 8 to 10 hours and recordings of intra-arterial blood pressure, ECG and respiratory movements can be made.

On another front, we have also developed a cuff based blood pressure apparatus which gives the whole range of systolic (and diastolic) pressure variations over a respiratory cycle in humans (instead of point measurements as is done currently). Once validated, we propose to establish country-wide normative data to help define hypertension in the Indian context.

Given similar interests, we would like to explore possible areas of collaborative research with your laboratory.

Thanks and regards,

Sincerely,

Sathya Subramani

Professor & Head
Department of Physiology
Christian Medical College,
Vellore - 632 002, Tamilnadu, India.

Forwarded to Registrar BLDE University for needful.

23/8/17

Prof. Kusal K. Das PhD
Laboratory of Vascular Physiology & Medicine
Department of Physiology
BLDE University's Shri B.M.Patil Medical College,
Vijayapur-586103, Karnataka, India.

By the Directions of Hon'ble Vice-chancellor the said collaboration is approved

29/8/17

REGISTRAR
BLDE University, Vijayapura.

MEMORANDUM OF UNDERSTANDING

BLDE UNIVERSITY's
Shri. B. M. PATIL MEDICAL COLLEGE, HOSPITAL AND RESEARCH CENTRE, VIJAYAPURA

and

KARNATAKA INSTITUTE FOR DNA RESEARCH, DHARWAD

FOR COLLABORATIVE RESEARCH ON

HUMAN GENETICS AND MOLECULAR MEDICINE

MoU

BETWEEN

BLDE UNIVERSITY, VIJAYAPURA

and

KARNATAKA INSTITUTE FOR DNA RESEARCH, DHARWAD

11th June 2016

MEMORANDUM OF UNDERSTANDING
(MoU)

FOR COLLABORATIVE RESEARCH ON

HUMAN GENETICS AND MOLECULAR MEDICINE

MoU

BETWEEN
BLDE UNIVERSITY, VIJAYAPURA
and
KARNATAKA INSTITUTE FOR DNA RESEARCH, DHARWAD

11th June 2016

BLDE UNIVERSITY

KIDNAR

MEMORANDUM OF UNDERSTANDING
Between
BLDE UNIVERSITY, VIJAYAPURA
and
KARNATAKA INSTITUTE FOR DNA RESEARCH, DHARWAD

This Memorandum of Understanding is entered into and executed on this the 11th day of June 2016 by and among:

BLDE UNIVERSITY, VIJAYAPURA
[Hereinafter to be referred to as "BLDEU of First Party"]

AND

KARNATAKA INSTITUTE FOR DNA RESEARCH, DHARWAD.
[Hereinafter to be referred to as "KIDNAR of Second Party"]

The First Party has requested the Second Party for utilizing the facilities for undertaking research activities, offered by the Second Party.

The Hon'ble Vice-Chancellor of First party, and the Hon'ble Director of Second party, will mutually coordinate to oversee the implementation of this agreement.

NOW THIS MEMORANDUM OF UNDERSTANDING WITNESSETH AS UNDER

1. Both the parties shall form a Joint Committee comprising of designated members equal in number from both parties to explore newer opportunities for research in the field of molecular genetics and asscociated medical subjects.
2. The Joint Committee also decide streaming of the funds for the research projects with the mutual consent of both the parties.
3. The First Party will recognize eligible Faculty Members at KIDNAR as PhD guide and allow the research students of KIDNAR to enroll for PhD, as per rules.
4. The Second Party agrees to provide access to First Party to use required facilities available in KIDNAR, and also help the First Party to setup state of the art genetic laboratory.
5. The Second Party will receive all the samples and relevant information provided by the First Party for conducting joint research and provides services for genetic analysis like FISH and Karyotyping. The modus operandi and financial implications will be negotiated, in good faith, by both the parties on a project-to-project basis.
6. The information, data and results related to the research are the common property of both the parties and are not allowed to be transferred to any third party without the prior consent of the other party.

7. All credentials arising out of the joint research work undertaken under this MoU, will be shared appropriately by both the parties as decided by the Joint Committee.
8. The period of agreement is 10 years from the date of final execution of the contract and can be extended for further periods on mutually agreed terms and conditions.
9. Both the parties can take up any other projects individually without the consent of the other party.
10. The First Party is permitted to access all the details on the progress of the study, data and results on the joint studies or projects undertaken under this venture.
11. Both the parties will put all efforts inviting grants for various research projects from funding sources. Grants can be invited by both the parties respectively unconnected to each other. The expenses incurred for all the research projects initiated by the First party will be borne by the same (First party).
12. The Vice-Chancellor of First Party and the Director of Second Party will mutually coordinate to oversee the implementation and any other issues arise out of this agreement.

IN WITNESS Whereof the parties herein above have signed and executed the above MOU on the 11th day of June Month, Year 2016 here in above mentioned in the presence of following witnesses.

FIRST PARTY

PROF. B.G.MULIMANI
Hon'ble Vice-Chancellor,
BLDE, University, Vijayapura.

SECOND PARTY

PROF. PRAMOD B. GAI
Hon'ble Director
Karnataka Institute for DNA Research
Dharwad, Karnataka-580003.

WITNESS 1

Dr. M.S.Biradar
Dean, Faculty of Medicne & Principal
BLDE, University,
Vijayapura-586103.

BLDE UNIVERSITY, VIJAYAPURA

WITNESS 2

Dr. Suyamindra S. Kulkarni
Scientist "C"
Karnataka Institute for DNA Research
(KIDNAR)- Dharwad, Karnataka-580003.

Karnataka Institute for DNA Research
Government of Karnataka
Dharwad

BLDE UNIVERSITY, VIJAYAPURA

KARNATAKA INSTITUTE FOR DNA RESEARCH, DHARWAD

COLLABORATIVE RESEARCH PROJECT

FOR

MOLECULAR DIAGNOSIS OF HUMAN BRUCELLOSIS BY REAL TIME PCR

DEPARTMENT OF MICROBIOLOGY,
Shri B M Patil Medical College,
BLDE University, Vijayapura, Karnataka

WITH

DEPARTMENT OF BIOTECHNOLOGY
Akkamahadevi Women's University,
Vijayapura- Karnataka

August 2017

COLLABORATIVE RESEARCH PROJECT

(2017-2020)

DEPARTMENT OF MICROBIOLOGY,
Shri B M Patil Medical College,
BLDE University, Vijayapura, Karnataka

with

DEPARTMENT OF BIOTECHNOLOGY
Akkamahadevi Women's University,
Vijayapura- Karnataka

AUGUST 2017

TITLE OF THE STUDY

"**MOLECULAR DIAGNOSIS OF HUMAN BRUCELLOSIS BY REAL TIME PCR"**

Brucellosis is a zoonotic disease produced by Brucellae, Gram-negative bacteria that cause major worldwide economic losses due to infection of livestock. The pathogenesis of the resulting disease, called brucellosis, is mostly linked to the ability of Brucella to survive and replicate intracellular in host cells by expressing several cell envelope molecules that contribute to the control of the intracellular trafficking of the pathogen. Brucellosis in humans is almost always associated with infected domestic and wild animals or their products and poses more risk to farmers, animal handlers, abattoir workers and veterinarians. It causes a debilitating disease with unspecific symptoms comparable to other febrile conditions such as malaria, which may be chronically disabling. Treatment of human brucellosis is long and costly.

NEED FOR THE STUDY:

The laboratory investigation for brucellosis is usually by isolation of the bacteria or detection of anti-Brucella antibodies. Although isolation of the bacteria is the "gold standard", it requires long incubation periods and is seldom successful. Since the identification and differentiation of Brucella are laborious and time consuming, molecular approaches have been explored to overcome these problems. The conventional polymerase chain reaction (PCR) and multiplex PCR typing are capable of identifying Brucella up to species level.

METHODOLOGY:

Extraction and Testing for Presence of Brucella DNA from Serum Samples

To test directly from clinical material, DNA was extracted from 200 µL of serum using the DNeasy Blood and Tissue kit (Qiagen, Hilden, Germany) following the kit protocol. Conventional PCR based on the Brucella spp. specific target IS711 (O'Leary et al., 2006) was performed for the detection of Brucella. The PCR reaction mixture was prepared with a final volume of 25 µL. FastStart 1x PCR buffer with MgCl2 (Roche), 0.4 mM dNTPs, 800 nM of both forward and reverse primers, 1 unit FastStart Taq DNA polymerase (Roche) with 5 µL template DNA (from DNeasy extraction). The following oligonucleotide forward (5´ GACGAACGGAATTTTTCCAATCCC-3´) and reverse (5´

TGCCGATCACTTAAGGGCCTTCAT-3′) primers were used during the reaction. Thermocycler parameters used were as follows: pre-incubation at 94°C for 5 min, 40 cycles of 94°C for 30 sec for heating, 63°C for 30 sec for annealing and 72°C for 1 min for extension and final extension step of 72°C for 5 min. We spiked an aliquot of each sample with 1 µL of a 1 ngmL-1 dilution of Brucella spp. genomic DNA obtained through phenol chloroform extraction (Sambrook et al., 1989) to check for possible inhibition or false negatives through PCR. The products of amplification were visualized using a 2% agarose gel and a size marker of 1 kb, with a fragment size of 498 bp corresponding to the desired IS711 target (O'Leary et al., 2006). Each sample was tested in duplicate and only those that generated a product of the correct size on both occasions were identified as Brucella positive.

MOLECULAR IDENTIFICATION

The extracted DNA was subjected to real time PCR for the Brucella spp. specific targeting IS711. Primers and probe were developed by using different tools and positive results of the experiments were recorded.

BRUCE-LADDER ANALYSIS

Species-level molecular identification was undertaken by multiplex PCR (Bruce-ladder) which was performed as described with the following conditions: Step 1: 95 °C 15 min, Step 2: 94 °C 30 s, Steps 3: 58 °C 90 s, Step 4: 72 °C 3 min, Step 5: 72 °C 10 min. Step 2, 3 and 4 was repeated in 25 cycles. The size of the PCR products was analyzed by capillary electrophoresis with Bioanalyzer ®, Agilent Technologies, Santa Clara, CA, USA.

IMPORTANCE OF THE STUDY:

The determination of Brucella spp.would facilitates the investigation and adopt innovative strategies for prevention of spread of the disease in human and animal. This assay can be used for rapid detection of infection, which will greatly help in the investigation and management of sporadic cases and outbreaks. The species identification of Brucella is also essential for epidemiological studies of brucellosis.

Principal Investigator
Dr. P. R. SHAHAPUR
Professor and Head, Microbiology,
Shri B. M. Patil Medical College
BLDE University, Vijayapura

Co-Principal Investigator
Dr. S. B. MADAGI
Professor and Chairman
Department of Biotechnology
and Bioinformatics,
Akkamahadevi Women's
University, Vijayapura

DEAN
Faculty of Science & Technology.
Karnataka State Women's University.
Vijayapura-586109.

Registrar
BLDE University,
Vijayapura

REGISTRAR
BLDE University, Vijayapura.

Registrar
Akkamahadevi Women's University,
Vijayapura

BLDE UNIVERSITY, VIJAYAPURA

DEPARTMENT OF BIOTECHNOLOGY

Akkamahadevi Women's University,
Vijayapura- Karnataka

MEMORANDUM OF UNDERSTANDING

(MoU)

FOR

UTILISING FACILITIES FOR RESEARCH AND SKILLS LABORATORY

MoU

Between

BLDE UNIVERSITY

The Constituent College

Shri B. M. Patil Medical College, Hospital and Research Centre, Vijayapura

AND

GADAG INSTITUTE OF MEDICAL SCIENCES, GADAG

March 01, 2017

MEMORANDUM OF UNDERSTANDING

(MoU)

FOR

UTILISING FACILITIES FOR RESEARCH AND SKILLS LABORATORY

Between

BLDE UNIVERSITY

The Constituent College

Shri B.M.Patil Medical College, Hospital & Research Centre, Vijayapura

AND

GADAG INSTITUTE OF MEDICAL SCIENCES, GADAG

March 01, 2017

This agreement is made on March 1, 2017 between Gadag Institute of Medical Sciences, Gadag and BLDE University, Vijayapura are hereafter individually referred to as 'party' and collectively as the 'parties'.

WHEREAS

1. Gadag Institute of Medical Sciences, Gadag (hereafter referred as GIMS) is an autonomous medical college under Ministry of Medical Education, Government of Karnataka.

2. BLDE University, Vijayapura (hereafter referred as BLDEU) is a deemed University.

3. GIMS, Gadag desires to utilize the facilities available at BLDE University for research, Ph.D. work and Skill Laboratory.

NOW THE AGREEMENT WITNESSETH AND IT IS HEREBY AGREED BY AND BETWEEN THE PARTIES HERE TO AS FOLLOWS:

ARTICLE 1: DEFINITIONS

1.1 Party shall mean GIMS or BLDEU separately and parties shall mean GIMS and BLDEU collectively.

1.2 Term shall mean the duration of the agreement which shall be FIVE years from the date of signing the Agreement and subsequent Extension mutually agreed.

1.3 Facilities mean research laboratories of all the departments and their equipments and the skill lab at BLDEU.

ARTICLE 2: SCOPE OF ENGAGMENT AND OBLIGATIONS OF THE PARTIES.

2.1 The parties agree that for the terms and conditions set forth herein, BLDEU permits GIMS students and faculties to utilize the facilities.

2.2 BLDEU shall recognise the eligible Teachers of GIMS as PhD guides.

2.3 PhD registrants from GIMS at BLDE University will work under the guide and co-guide representing parties. There shall be a Co-ordinating Committee, comprising Guide, Co-guide, Concerned HoD and Prinipal of GIMS along with representatives of BLDEU. This Committee shall oversee the progress of GIMS candidates and report to the PhD Committee of the BLDEU.

2.4 PhD registrants from GIMS will carry out their experimental work at BLDEU facilities. The cost for the reagents, consumables, materials etc., will be borne by the PhD candidate. In case of any breakages or damages to the instruments while using, the candidate shall follow the rules laid by BLDE University or respective laboratory / department.

2.5 BLDE shall provide assistance, train the candidate in techniques and guidance for research free of cost. However, the PhD candidate shall oblige to pay the fees as per PhD rules of the University.

2.6 The procedures laid by BLDE University for the course work, thesis work, report submission etc., will be adhered to by the PhD candidate. BLDE shall provide the accommodation and boarding facilities to the PhD Candidate during course work, at BLDEU. The cost for the same shall be borne by the candidate.

2.7 Parties shall include the names of the respective institutes, departments and the personnel involved in any of the publications, presentations etc.,

2.8 Students (UG and PG) from GIMS shall get the training at skills lab at BLDEU. The prescribed fee by BLDEU for the training shall be borne by GIMS or the students.

2.9 During training sessions at skills lab, BLDEU shall provide the assistance, training and monitor the progress of the students from GIMS. Further, the BLDEU shall communicate the attendance and progress of the students to the Principal, GIMS.

ARTICLE 3: INITIAL TERM AND RENEWAL TERM:

The term of agreement shall comprise of the initial FIVE years from the date of signing this agreement.

Parties may, at their option continue the agreement on the same terms and conditions as a set for herein mutually agreed upon further period of FIVE years immediately after completion of the initial term.

ARTICLE 4: INDEMNIFICATION

Both the parties agree to indemnify and hold each other harmless against any loss or damages with either party may incur due to acts or omission arising out of the activities of the other party. The parties indemnify and hold each other harmless from any loss and damages by reason of or arising out of their proven or wilful misconduct.

4.1 In no event shall either party be liable for indirect, special or consequential damages which may arise under agreement.

4.2 The indemnify contained in this article shall not prejudice either party from exercising additional or alternative remedy or applicable rights under the law and or the party shall take indemnity insurance cover to protect each other and from any third party against the risk of compensation claim by the third party / court of law.

IN WITNESS WHEREOF THE PARTIES HAVE CAUSED THE AGREEMENT TO BE EXECUTED BY THER DULY AUTHORISED REPRESENTATIVES AS OF THE DATE, MONTH AND YEAR HERE IN ABOVE WRITTEN

Dr. P. S. Bhusaraddi
Director
Gadag Institute of Medical Sciences,
GADAG

01-3-17

Dr. M.S. Biradar
Vice-Chancellor
BLDE University
VIJAYAPURA

BLDE UNIVERSITY, VIJAYAPURA

Dr. S. R. Deshapande
Principal
Gadag Institute of Medical Sciences,
GADAG

Dr. S. P. Guggarigoudar
Dean, Faculty of Medicine
& Principal, BLDEU's SBMPMCH&RC,
VIJAYAPURA

BLDE UNIVERSITY, VIJAYAPURA

GADAG INSTITUTE OF MEDICAL SCIENCES, GADAG

MEMORANDUM OF UNDERSTANDING

(MoU)

FOR

UTILISING FACILITIES OF LIBRARY AND CLINICAL SKILLS LABORATORY

MoU

Between

BLDE UNIVERSITY'S SHRI B. M. PATIL MEDICAL COLLEGE, HOSPITAL & RESEARCH CENTRE, VIJAYAPURA

AND

GOVERNMENT DISTRICT HOSPITAL, VIJAYAPURA

March 24, 2017

MEMORANDUM OF UNDERSTANDING

(MoU)

FOR

UTILISING FACILITIES OF LIBRARY AND CLINICAL SKILLS LABORATORY

MoU

BETWEEN

BLDE UNIVERSITY'S SHRI B. M. PATIL MEDICAL COLLEGE, HOSPITAL AND RESEARCH CENTRE, VIJAYAPURA

AND

GOVERNMENT DISTRICT HOSPITAL, VIJAYAPURA GOVERNMENT OF KARNATAKA

April 24, 2017

PREAMBLE:

Under the National Health Mission, the Ministry of Government of India, would encourage and support the State and UT Governments in Developing and adopting innovative solutions to improve Healthcare Services Delivery Systems, addressing the shortage of Specialists and strengthening District Hospital to provide quality care.

The Department of Health and Family Services, Government of Karnataka is facing an acute shortage of Specialists in its Districts, Taluka and Community Health Institutions. To address this issue and an order to make use of existing Clinical Services and Infrastructure, the Government identified 7 District Hospitals, one of them being Vijayapura District Hospital for starting DNB Courses.

In view of this the Government requested the BLDE University's Shri B. M. Patil Medical College, Hospital and Research Centre, Vijayapura to provide the required services to District Hospital, Vijayapura to fulfil the requirement of DNB Courses through an MoU (D.O.No.:HFW/281/PRS/2017, Dtd.17-04-2017).

The Government District Hospital requested the BLDE University's Shri B. M. Patil Medical College, Hospital and Research Centre, Vijayapura, to provide Library and Clinical Skills Laboratory Facilities for DNB Students. (Ref. No.:DHV/DNB/02/17-18/97, Dtd.18-04-2017)

This Agreement made on 24th April, 2017 between BLDE University's Shri B. M. Patil Medical College, Hospital & Research Centre and Government District Hospital, Vijayapura hereafter called individually as "Party" and collectively as "Parties".

WHEREAS

1. Government District Hospital, Vijayapura is a Government Hospital under the Ministry of Health and Family Welfare, Government of Karnataka.
2. BLDE University's Shri B. M. Patil Medical College, Hospital & Research Centre is the Constituent College of BLDE University.
3. Ministry of Health and Family Welfare, Government of Karnataka, desires to utilise Library facilities and Skills Laboratory for DNB students of Government District Hospital, Vijayapura.

NOW THE AGREEMENT WITNESSETH AND IT IS HEREBY AGREED BY AND BETWEEN THE PARTIES HERE TO AS FOLLOWS:

ARTICLE 1: DEFINITIONS

1.1 Party shall mean Government District Hospital, Vijayapura or BLDE University's Shri B. M. Patil Medical College, Hospital and Research Centre separately and Parties shall mean District Hospital, Vijayapura and BLDE University's Shri B. M. Patil Medical College, Hospital & Research Centre, collectively.

1.2. The Term shall mean the duration of agreement which shall be for FIVE YEARS from the date of signing the Agreement and subsequent extension mutually agreed upon.

1.3 Facilities mean facilities in the Library and Clinical Skills Laboratory of BLDE University's Shri B. M. Patil Medical College, Hospital and Research Centre, Vijayapura.

ARTICLE 2: SCOPE OF ENGAGEMENT AND OBLIGATIONS OF THE PARTIES

2.1 The Parties agree that for the terms and conditions set forth herein, BLDE University's Shri B. M. Patil Medical College, Hospital & Research Centre permits DNB students studying in District Hospital to utilise facilities in its Library and Clinical Skills Laboratory.

2.2 BLDE University's Shri B. M. Patil Medical College, Hospital & Research Centre will set rules and charge prescribed fees for the utilisation of said facilities, which would be mutually agreed upon, changing from time to time and paid by the Government District Hospital, Vijayapura or the student/s.

2.3 During training in Clinical Skills Laboratory BLDE University's Shri B. M. Patil Medical College, Hospital & Research Centre will provide assistance and training to DNB students of Government District Hospital. It will also monitor the attendance and progress of the students communicated to the District Surgeon, Government District Hospital, Vijayapura.

ARTICLE 3: INITIAL TERM AND RENEWAL TERM

The term of agreement shall comprise of the initial period of FIVE YEARS from the date of signing this agreement.

Parties may at their option continue the agreement on the same terms and conditions for further period of FIVE YEARS.

ARTICLE 4: INDEMNIFICATION

Government District Hospital, Vijayapura or its students will indemnify any loss or damages caused to its properties by its students.

ARTICLE: 5: MODIFICATION/DURATION/TERMINATION:

This MOU will be effective when signed by both the parties. This MOU may be amended at any time by the mutual written consent of the parties. This MoU may be terminated by either party at anytime by one party notifying the other party in writing, 90 days in advance of the termination date.

IN WITNESS WHEREOF THE PARTIES HAVE CAUSED THE AGREEMENT TO BE EXECUTED BY THEIR DULY AUTHORISED REPRESENTATIVES AS OF THE DATE. MONTH AND YEAR HERE IN ABOVE WRITTEN.

24/4/17

Dr. S.P. Guggarigoudar
Principal & Dean, Faculty of Medicine,
BLDE University's Shri B.M. Patil
Medical College, Hospital and Research
Centre, Vijayapura

24/4/17

Dr. Dasharath
District Surgeon,
District Hospital,
Vijayapura

B. L. D. E. UNIVERSITY VIJAYAPUR

Witness:

24/4/17

Dr. Vijayakumar Kalyanappagol
Medical Superintendent,
BLDE University's Shri B.M. Patil
Medical College, Hospital and Research
Centre, Vijayapura

24/04/17

Dr. Anand Zalaki
Coordinator,
District Hospital,
Vijayapura

ಕರ್ನಾಟಕ ಸರಕಾರ
ಆರೋಗ್ಯ ಮತ್ತು ಕುಟುಂಬ ಕಲ್ಯಾಣ ಸೇವೆಗಳ ಇಲಾಖೆ

ದೂರವಾಣಿ ಸಂಖ್ಯೆ : 08352-270009 Fax:270009
Email: dsbijapur@gmail.com

ಜಿಲ್ಲಾ ಶಸ್ತ್ರಚಿಕಿತ್ಸಕರ ಕಾರ್ಯಾಲಯ
ಜಿಲ್ಲಾ ಆಸ್ಪತ್ರೆ ವಿಜಯಪುರ

Refr No.: DHV/DNB/04/17-18 /97

Date : 18/04/2017

To,

The Principal
BLDEA'S University
Vijayapura

Respected sir

Sub : Regarding requesting for MOU for DNB Courses.

Ref No. : Letter from Principal Secretary to Government HFW Dept letter No.HFW/281/PRS 2017 Date 17/04/2017.

****

With reference to above mentioned subject, To improve health care services and delivery system addressing the shortage of specialist an d strengthen the District Hospital to provide Quality care. In address the same issue we are starting DNB courses at District Hospital Vijayapura.

In view of the above I request you to provide the required services to District Hospital Vijayapura for DNB student to utilize Library and Skill Lab facility from Shri B.M. Patil Medical college , Hospital and research center vijayapura.

With warm regards

Yours sincerely

District Surgeon Vijayapura

18/4/17

Dr. SHALINI RAJNEESH, I.A.S.,
Principal Secretary to Government
Health and Family Welfare Department

Tel:080-2225 5324
080-2203 4284
Fax: 080-2235 3916
E-mail: prs-hfw@karnataka.gov.in
Room No. 105, First Floor
Vikasa Soudha, B.R. Ambedkar Veedhi
Bengaluru-560 001

D.O.No :HFW 281 PRS 2017

Dear Dr. Guggari Goudar ,

Date : 17.04.2017

Sub : Providing Services for Starting of DNB courses in District Hospitals and General Hospitals of Karnataka.

Ref : 1. Letter from Joint Secretary MoHFW GOI No:Z-18015/12/2015-NRHM-II, Dated : 11/04/2016.
2. Letter No: HFW/347/PRS/2016, Dated : 18/08/2016 and 26/12/2016 of Principal Secretary HFW Department.

** ** **

Under the National Health Mission the Ministry of Government of India, would encourage and support the State and UT Governments in Developing and adopting innovative solutions to improve Healthcare Services Delivery Systems, addressing the shortage of Specialists and strengthening District Hospital to provide quality care.

The Department of Health and Family Services Government of Karnataka is facing an acute shortage of specialists in its District, Taluka and Community Health Institutions. To address this issue and in order to make use of the existing Clinical Services and Infrastructure, we have identified 7 District Hospitals (Bagalkot, Chitradurga, Dharwad, Kalburgi, Kolar Tumkur, Vijayapura) and 2 General Hospitals of Bengaluru (KCG Hospital and Jayanagara General Hospital) for starting DNB courses for Departmental and Private Candidates. This would help us in augmenting the shortage of specialists serving the Hospitals of the Health Department.

The Diplomate of National Board (DNB) course requires that one of the faculty member from Medical College would need to serve as adjunct faculty in each of the Speciality under DNB programme, Hence tie-up with Medical College is required for the purpose of utilizing facilities for Basic Science teaching, Research Methodology, Thesis Guides, Ethical Committee, Skill Lab and Library facilities of the Medical College.

In view of the above I request you to provide the required services to **District Hospital, Vijayapura** in **General Medicine General Surgery, OBG & Anaesthesia** to fulfill the requirement of DNB courses through an Agreement/ MoU between District Surgeon and Dean/ Principal of B.M. Patil Medical College, Hospital and Research Center, Vijayapura.

With Warm regards,

Yours Sincerely

Shals

(Dr. Shalini Rajneesh)

Dr. Guggari Goudar,
Principal & Dean,
B.M. Patil Medical College,
Hospital and Research Center, BLDE University,

BLDE UNIVERSITY, VIJAYAPURA

GOVERNMENT DISTRICT HOSPITAL, VIJAYAPURA

MEMORANDUM OF UNDERSTANDING (MoU)

BETWEEN

ASIAN INSTITUTE OF GASTROENTEROLOGY

AND

FACULTY OF MEDICINE, BLDE UNIVERSITY
(Deemed to be University)

October 5, 2017

MEMORANDUM OF UNDERSTANDING

(MoU)

BETWEEN

ASIAN INSTITUTE OF GASTROENTEROLOGY

AND

FACULTY OF MEDICINE, BLDE UNIVERSITY

(Deemed to be University)

October 5, 2017

The administration of the Asian Institute of Gastroenterology, Hyderabad and the **faculty of Medicine, BLDE University,** Vijayapura, Karnataka agree to enter this Memorandum of Understanding (MoU) based on a foundation of trust for the mutual benefit and development of the two institutes.

A. Background:

I. The parties seek to demonstrate by signing this Memorandum their commitment to co-operation in terms of common interest through the development of collaboration between Asian Institute of Gastroenterology, Hyderabad, India and Faculty of Medicine, BLDE University, Vijayapura, India.

II. The parties recognize the mutual benefit each will gain from working together and the value this will add to the promotion of not only medical science research but also overall impact on health sectors.

B. Scope of co-operation & activities:

Asian Institute of Gastroenterology and the Faculty of Medicine, BLDE University desire to explore and promote **some or all** the following activities based on their respective academic and research needs, which may be formally developed through a separate legally binding agreement between the parties:

I. Exchange of research materials, publications and research information.

II. Organization of joint research programmes.

III. Video conference programs by faculty of Asian Institute of Gastroenterology.

IV. Live telecasting of Endoscopy and operative procedures.

V. Posting of Post graduates & undergraduates to learn advances in Gastroenterology.

VI. Certificate courses and fellowships in medical and surgical Gastroenterology.

VII. Exchange programmes in basic sciences like Pathology, Microbiology and Nutrition.

VIII. Exchange of research students (Doctoral & Post doctoral) of basic science & clinical medicine.

IX. Training of nursing staffs of BLDE University.

C. Management of Co-operation:

I. The implementation of exchange based on the MoU shall be separately negotiated and determined by both Institutes.

II. Nothing shall diminish the full autonomy of either institute, nor will any constraint or financial obligations be imposed by either upon the other in carrying out MoU.

III. The parties acknowledge that this MoU does not involve the transfer of monies between the parties. The parties further acknowledge that no sponsor funding exists regarding activity contemplated by this MoU.

IV. Any notice required to be given under this agreement by either party will be in writing and sent to the other party by either hand delivery or certified mail return receipt requested as follows:

1. If to Asian Institute of Gastroenterology: Faculty to Medicine, Asian Institute of Gastroenterology 6-3-661, Somajiguda, Hyderabad - 500 082, Telangana, India Phone: 91-40-2337 8888, Fax: 91-40-2332 4255, Email: aigindiainfo@yahoo.co.in

2. If to BLDE University Faculty to Medicine, BLDE University, Smt. Bangaramma Sajjan Campus, Vijayapura - 586103, Karnataka, India Tel:+918352-262770, Fax: + 918352-263303 Email: registrar@bldeuniversity.ac.in

D. Terms and Termination:

I. The MoU will be valid for **three (3) years** from the Effective Date. Thereafter, renewal of the MoU will be subject to the written agreement of both parties.

II. This MoU is subject to revision by mutual written agreement. It is also understood that either party may terminate the MoU for any reason and at any time upon thirty (30) days prior written notice to the other party; although such action will only be

taken after mutual consultation in order to avoid any possible inconvenience to all parties.

III. The MoU is effective when representatives of both institutions have signed and dated the document ("Effective Date").

AUTHORIZED TO SIGN FOR AND ON BEHALF OF ASIAN INSTITUTE OF GASRTOENTEROLOGY:

Signature: Date: 5/10/2017

D. NAGESHWAR REDDY
Name is Capitals:

Position in Organization:
CHAIRMAN

AUTHORIZED TO SIGN FOR AND ON BEHALF OF FACULTY OF MEDICINE, BLDE UNIVERSITY:

Signature: Date: 5-10-17

Name is Capitals: Dr. M. S. BIRADAR

Position in Organization:
Vice chancellor

BLDE UNIVERSITY, VIJAYAPURA

ASIAN INSTITUTE OF GASTROENTEROLOGY, HYDERABAD

United Nations
Educational, Scientific and
Cultural Organization

Network on Research and
Postgraduate Education in Biophysics,
Biotechnology and Environmental Health

AGREEMENT

BETWEEN

THE NETWORK ON RESEARCH AND POSTGRADUATE EDUCATION IN BIOPHYSICS, BIOTECHNOLOGY AND ENVIRONMENTAL HEALTH

AND

BLDE
(DEEMED TO BE UNIVERSITY)
SHRI B M PATIL MEDICAL COLLEGE HOSPITAL & RESEARCH CENTRE

CONCERNING THE ESTABLISHEMENT OF PARTNERSHIP WITHIN THE NETWORK ON RESEARCH AND POSTGRADUATE EDUCATION IN BIOPHYSICS, BIOTECHNOLOGY AND ENVIRONMENTAL HEALTH APPROVED IN UNESCO/UNITWIN COOPERATION PROGRAMME

AGREEMENT

between the Network on Research and Postgraduate Education in Biophysics, Biotechnology and Environmental Health and BLDE (Deemed to be University) Shri B M Patil Medical College Hospital & Research Centre

concerning the establishment of partnership within the Network on Research and Postgraduate Education in Biophysics, Biotechnology and Environmental Health APPROVED IN UNESCO/UNITWIN COOPERATION PROGRAMME

The International Network on Research and Postgraduate Education in Biophysics, Biotechnology and Environmental Health (hereinafter referred to as "the Network"), represented by its coordinator, Prof. Sinerik Ayrapetyan and composed of:

- Life Sciences International Postgraduate Educational Center, 31 Acharian St., Yerevan, 0040, Armenia , represented by its Director, Professor G. Ayrapetyan;
- Bogomoletz Institute of Physiology, Bogomoletz Str.4, Kyiv, 01024, Ukraine, represented by its Director, Professor Oleg Krishtal;
- Istanbul Medeniyet University, Dumlupınar Mahallesi, D-100 Karayolu No:98, 34000 Kadıköy, İstanbul, Turkey, represented by its Rector, Professor Dr. M. Ihsan Karaman;
- Jamia Hamdard, Mehrauli, Badarpur Road, Near Batra Hospital, Hamdard Nagar, 110062, New Delhi, Delhi, represented by its Chancellor, Dr. Habil Khorakiwala;

and,

BLDE (Deemed to be University) Shri B M Patil Medical College Hospital & Research Centre (hereinafter referred to as "BLDE"),, Smt. Bagaramma Sajjan Campus, Dr B M Patil Road (Solapur Road) Vijayapura (Bijapur)-586103, Karnataka, India, represented by its Vice Chancellor, Professor (Dr.) M.S. Biradar

Considering that one of the essential factors favouring development of biophysics, biotechnology and environmental health in developing countries is the exchange of experience and knowledge between universities and other higher education institutions;

Convinced that joint work by university teachers, researchers and administrators from different regions all over the world will provide important benefits for the entire academic community;

Have agreed as follows:

Article I **Purpose**

The Network and BLDE will establish and expand academic cooperation within Network on Research and Postgraduate Education in Biophysics, Biotechnology and Environmental Health approved in UNESCO/UNITWIN Cooperation Programme

.

Article II **Main objectives**

The main objectives of this Cooperation Programme are to:

- promote an integrated system of research, training, information and documentation activities on biophysics, biotechnology and environmental health ;

- support capacity enhancement in biophysics, biotechnology and environmental health in developing countries notably through the development of a specialized postgraduate programme that meets international standards, addresses social and economic needs, and gives education access to different social groups;

- foster research and innovation capacity in the fields of focus through the establishment of an exchange programme for PhD students and young researchers between the participant institutions, the organization of short-term training courses, summer schools and biannual research meetings;

- improve awareness on the network's activities and outreach to stakeholders to ensure sustainable use of the research results;

- facilitate collaborative work, knowledge and information sharing among students and researchers notably through the creation of a dedicated website, the organization of online libraries specialized in science literature at Network member institutions, as well as the publication and dissemination of brochures and other publications including a newsletter;

- facilitate collaboration between high-level, internationally-recognized researchers and teaching staff of the institutions that are members of the Network, as well as institutions outside the Network in other regions of the world.

Article III **Implementation of the Cooperation Programme**

1 The implementation of the Cooperation Programme will comprise two phases:

- phase one: establishment of direct contact between BLDE and the Network to determine the work plan for cooperation over the next four years;

- phase two: identification, in close collaboration with the members of the Network , of ways to extend the Network to include other participants and/or institutions.

Article IV **Contribution of each Party**

1 BLDE shall appoint its own Coordinator for implementation of the programme from their side and duly notify the others.

3 Subject to the terms of this Agreement, the each participant university within the Network shall assume their own expenses linked to the implementation of the Network activities.

4 Each Network member shall contribute the facilities, as well as the human and financial resources necessary to conduct the academic research and training activities in its fields and to make their results accessible online.

5 BLDE shall provide a mid-term progress report to the Network which will be added to the final mid-term progress report of the Network to be submitted to UNESCO. The report should describe the activities carried out by BLDE. The reports should comply with the UNESCO template.

Article V **Other Provisions**

1 Neither the Network nor any member of its staff employed for the implementation of the Cooperation Programme's activities shall be considered an agent, representative or member of UNESCO's staff, nor shall they enjoy any benefit, immunity, remuneration or reimbursement if not clearly foreseen in this Agreement; moreover, they shall not be authorized to present themselves as being part of UNESCO, nor make statements on UNESCO's behalf, nor commit UNESCO to any expense of any nature or to any other obligation.

2 BLDE shall be entirely responsible for taking any measures it deems necessary to insure itself against loss, injury or damage incurred during the implementation of these activities.

3 The present Agreement shall enter into force for a period of four (4) years on the date of all signatures having been appended. It may be cancelled by either Party subject to sixty (60) days' written notice to the other Party.

4 BLDE shall request the renewal of the present Agreement before its expiry date. Any renewal of the present Agreement shall be effected by an exchange of letters between the Parties, on condition that the Network meets its specific objectives as laid out in Article II, and provides detailed information on activities and budget secured for the period of renewal.

5 The Network may decide not to renew the present Agreement, or to terminate the it if BLDE fails to submit timely progress reports on its activities; the reports are negatively evaluated; or, the BLDE's activities do not correspond to the Network's strategic priorities.

6 In the event of a dispute, the Parties shall make a good faith effort to settle it amicably. If an amicable settlement cannot be reached, any dispute arising out of, or relating to, this Agreement shall be settled by a sole arbitrator appointed by mutual agreement or, failing this, by the President of the International Court of Justice at the request of either Party.

In witness whereof the undersigned, duly authorized to that effect, have signed 2 copies of the present Agreement in the English language.

For the Network on Research and Postgraduate Education in Biophysics, Biotechnology and Environmental Health

Prof. Sinerik Ayrapetyan
Coordinator

Date: **06.08.2018**

For BLDE (Deemed to be University)
Shri B M Patil Medical College Hospital & Research Centre

Dr. M.S. Biradar
Vice Chancellor

Date: **06.08.2018**

सत्यमेव जयते

INDIA NON JUDICIAL

Government of Karnataka

Rs. 100

e-Stamp

Certificate No.	:	IN-KA22264279433472R
Certificate Issued Date	:	21-Oct-2019 04:10 PM
Account Reference	:	NONACC (FI)/ kaksfcl08/ BIJAPUR/ KA-BJ
Unique Doc. Reference	:	SUBIN-KAKAKSFCL0864059459133748R
Purchased by	:	REGISTRAR BLDE DEEMED TO BE UNIVERSITY VIJAYAPUR
Description of Document	:	Article 12 Bond
Description	:	M O U
Consideration Price (Rs.)	:	0 (Zero)
First Party	:	REGISTRAR BLDE DEEMED TO BE UNIVERSITY VIJAYAPUR
Second Party	:	DEAN RC AND RM I C T MUMBAI
Stamp Duty Paid By	:	REGISTRAR BLDE DEEMED TO BE UNIVERSITY VIJAYAPUR
Stamp Duty Amount(Rs.)	:	100 (One Hundred only)

सत्यमेव जयते

Authorised Signatory
For Siddhasiri Souharda
Sahakari Ltd. Branch, Vijayapura

IN-KA22264279433472R RS. 100 21-OCT-2019 04:10 PM

Please write or type below this line

MEMORANDUM OF UNDERSTANDING
BETWEEN
BLDE (DEEMED TO BE UNIVERSITY)
AND
INSTITUTE OF CHEMICAL TECHNOLOGY

..2

Statutory Alert:
1. The authenticity of this Stamp Certificate should be verified at "www.shcilestamp.com". Any discrepancy in the details on this Certificate and as available on the website renders it invalid.
2. The onus of checking the legitimacy is on the users of the certificate.
3. In case of any discrepancy please inform the Competent Authority.

This Memorandum of Understanding (MoU) is executed on this **22** Day of **October, 2019** between Indian Institute of Chemical Technology, Mumbai (hereafter referred to as ICT), a premier educational institution in Chemical Engineering, Chemical Technology and Pharmacy, and BLDE (Deemed to be University), Vijayapura, Karnataka (hereafter referred to as BLDE DU) which is a Single Faculty Medical Sciences Institution with Shri B. M. Patil Medical College, Hospital & Research Centre (established 1986) as its constituent college, for the purpose of:

1) Undertaking collaborative research in the areas of mutual interest, both in extent and scope through students enrolled in the partner institutes.

2) Faculty members/scientist from both the institutions may collaborate for the joint supervision of Ph.D. scholars, submission of research proposals, drafting of manuscripts, and other related activities.

3) Both the institutions of higher learning may jointly organize Seminars/Symposia/Conferences/Workshops.

4) Training and exchange of administrative professionals in terms of academic/scientific fields by both institutions.

5) The issues related with the Intellectual Property Right (IPR) with regard to the outcome of the collaborative research and the outcome of thesis/projects work carried out under the joint supervision of the faculty from the partner institutes shall be governed through mutual agreement and within the framework of IPR policies of both the institutes.

Implementation

This MoU becomes effective from the date it is signed by the partner institutes and will be valid for an initial period of five years. The agreement may be extended by mutual consent. The MoU may have the provisions for modification to facilitate the requirements of the both the institutes form time to time. It may not be a legally binding document but may be intended to provide an outline/framework for the promotion of co-operation and collaboration between ICT and BLDE (DU) in the best interest of the students and academic fraternity.

..3

For implementation of this MoU, the following will be the contact persons.

- From BLDE (DU) (i) Registrar, BLDE (DU)
- From ICT (i) Dean (Research, Consultancy and Resource Mobilization)

Signed on **22** Day of **October, 2019**

For and on behalf of:

.....

Registrar, BLDE (DU)
BLDE (Deemed to be University)

For and on behalf of:

.....

Dean (Research, Consultancy and Resource Mobilization)
Institute of Chemical Technology

Witnessed by:

Dr. Akram D. Harkandi
Dean (R&D)

DEAN RESEARCH AND DEVELOPMENT
BLDE (Deemed to be University)
Vijayapura-586103. Karnataka

Witnessed by:

Prof. Vikas N. Telvekar

BLDE (DEEMED TO BE UNIVERSITY) VIJAYAPURA

DEAN
(Research, Consultancy & Resource Mobilization)
INSTITUTE OF CHEMICAL TECHNOLOGY
(University under Section- 3 of UGC Act 1956)
Elite Status & Centre of Excellence - Govt. of Maharashtra
Matunga, Mumbai - 400 019.

भारतीय प्रौद्योगिकी संस्थान कानपुर
Indian Institute of Technology Kanpur

शैक्षिक कार्यालय
ACADEMIC AFFAIRS' OFFICE

डाकघर - आई. आई. टी., कानपुर - 208 016 (भारत)
Post Office : I.I.T. Kanpur - 208 016 (India)

कार्यालयः Office : (0512) 2597199, 2597288, 2597669 • ई-मेलः e-mail : doaa@iitk.ac.in

MoU/BLDE/2019-20
03rd February, 2020

BLDE (Deemed to be University)
REGISTRAR OFFICE
DATE : 11/02/2020
INWARD No. 4181

To,

The Registrar
BLDE (Deemed to be University)
Vijayapura - 586103
Karnataka

MoU between BLDE (Deemed to be University) and IIT Kanpur

Sir,

Reference is made to your office letter no. BLDE(DU)/REG/MoU/2019-20/3338 dated 16th January 2020.

Annexed along with this letter, please find a copy of MoU, between BLDE (Deemed to be University) and IIT Kanpur, duly signed by the Dean Academic Affairs, IIT Kanpur and witness signed by the Associate Dean Academic Affairs, IIT Kanpur. A signed copy of the MoU has been retained at this office for records.

Two unsigned copies of the MoU are hereby returned.

For your kind information please.

With regards,

Indian Institute of Technology Kanpur

Assistant Registrar 03.02.2020
Academic Affairs
सहायक कुलसचिव (शैक्षिक कार्य)
Assistant Registrar (Academic Affairs)
भारतीय प्रौद्योगिकी संस्थान, कानपुर
Indian Institute of Technology, Kanpur

Copy to: -

1.Dean of Academic Affairs, IIT Kanpur
2.Prof. Amitabha Bandyopadhyay, BSBE Dept, IIT Kanpur
3. Associate Dean, Academic Affairs, IIT Kanpur

MEMORANDUM OF UNDERSTANDING

(MoU)

FOR

EDUCATIONAL, RESEARCH AND ACADEMIC EXCHANGES

MoU

Between

BLDE

(Deemed to be University)

Constituent College:

Shri B. M. Patil Medical College, Hospital & Research Centre,
Vijayapura, Karnataka, India, PIN: 586103

AND

INDIAN INSTITUTE OF TECHNOLOGY, KANPUR

(IIT, KANPUR)

Kalyanpur, Kanpur, Uttar Pradesh, India, PIN: 208016

January 16, 2020

BLDE (Deemed to be University), Vijayapura, Karnataka State was established in 2008, is a single faculty medical sciences Institution with Shri B. M. Patil Medical College, Hospital & Research Centre (established 1986) as its constituent college. This University is sponsored by BLDE Association (established 1910), Vijayapura, Karnataka. BLDE [The vision of the BLDE (Deemed to be university)] and its constituent college is to be a leader and be recognized as an Institution striving for maintenance and enhancement of quality health sciences education and health care, agrees to enter into this Memorandum of Understanding.

with

Indian Institute of Technology Kanpur, Kanpur, Uttar Pradesh established in 1959, is one of the premier Institute of National importance established by the Government of India. The aim of the Institute is to provide meaningful education, to conduct research of the highest standard and to provide leadership in technological innovation. The vision of IIT Kanpur is to create, disseminate and translate knowledge in science, engineering and allied disciplines that will best serve society.

BLDE (Deemed to be University), Vijayapura, Karnataka State, India is hereinafter referred to as Party 1 and **Indian Institute of Technology Kanpur (IIT Kanpur),** Kanpur, Uttar Pradesh, India is hereinafter referred as Party 2. IITK and BLDE (Deemed to be University) are hereinafter referred to individually as the "Institute" and collectively as the "Institutes".

A. Background:

Indian Institute of Technology Kanpur (IIT Kanpur), Kanpur Uttar Pradesh and **BLDE (Deemed to be University)**, Vijayapura, Karnataka for the purpose of furthering cooperation through educational, research and academic exchanges, hereby affirm their intent to promote such cooperation activities as will be of mutual benefit for their respective institutions.

B. Scope of Co-operation & Activities:

1. Development of mutually beneficial academic programmes and courses.
2. Coordination of academic staff mobility for purposes of teaching, research and training.
3. Coordination of student mobility programmes for study and research;
4. Sharing of research facilities on mutually agreed terms.

5. Sharing of sophisticated instrumentation facilities. The facilities shall be used as per the prevailing guidelines of the Institutes.
6. Coordination of academic activities such as joint research, joint publication(s), origination of joint QIP (Quality Improvement Programme) and training programmes.
7. Exchange of research students (Doctoral & Post Doctoral), Postgraduate and undergraduate students of basic sciences and clinical medicine.
8. Both the Institutions mutually agree to take up and supervise or co-supervise doctoral research projects of all disciplines under health sciences to pool expertise. To strengthen the research ecosystem in both institutes, approved experts in both institutions may act as a co-supervisor for the research scholars.
9. Exchange of documents and research materials in fields of mutual interest provided that, to the best of knowledge of the respective Institution(s), in case there is no prohibition at law or otherwise against the exchange.
10. Other such activities as considered by the Institutes to be of mutual benefit towards furthering education and research programmes.

C. Management and Co-operation:

1. The implementation of exchange based on the MoU shall be separately negotiated and determined by both the Institutions.
2. Nothing shall diminish the full autonomy of either University / Institute nor will any constraint or financial obligations be imposed by either upon the other in carrying out MoU.
3. Any notice required to be given under this Agreement by either Institutes (1 & 2) will be in writing and sent to the other Institute by either hand delivery or by post.

D. Terms & Termination:

1. This MoU will be valid for a period of 5 years from the effective date. Thereafter, the renewal of the MoU will be subject to the written agreement between the Institutes.
2. The MoU is subject to revision by mutual written agreement by both the Institutes in writing.

3. Both the Institutes shall take necessary approvals from the competent authorities for fulfilling the scope of the program on case to case basis.
4. It is also understood that, either Institute may terminate the MoU for any reason and that any time upon thirty (30) days prior written notice to the other Institute; although such action will only be taken after mutual consultation in order to avoid any possible inconvenience to the Institutes.
5. The MoU is effective from the date of signing of documents by the representatives of both the Institutes.

AUTHORISE TO SIGN FOR AND ON BEHALF OF BLDE (Deemed to be University), VIJAYAPUR, KARNATAKA, INDIA

Signature: ..... Date: 16.01.2020.
Name in Capitals: **DR. M. S. BIRADAR**
Position in University/Institution: **VICE-CHANCELLOR**
Official Seal:

VICE-CHANCELLOR
BLDE (Deemed to be University)
Vijayapura-586103. Karnataka

AUTHORISE TO SIGN FOR AND ON BEHALF OF IIT KANPUR, KANPUR, UP, INDIA

Signature: ..... Date: 31/01/2020
Name in Capitals: **PROF.** Achla M. Raina.
Position in University/Institution: **DEAN,** Academic Affairs.
Official Seal:

अधिष्ठाता शैक्षिक कार्य
DEAN OF ACADEMIC AFFAIRS
भारतीय प्रौद्योगिकी संस्थान कानपुर-16
Indian Institute of Technology, Kanpur-16

WITNESS:

For **BLDE (Deemed to be University), Vijayapura, Karnataka, India**:

Name: **DR.ARAVIND V.PATIL**
Designation: Dean, Faculty of Medicine & Principal, Shri B.M.Patil Medical College, Hospital & Research Centre, BLDE (Deemed to be University), Vijayapur, Karnataka, India
Signature with date: 16-01-2020

For **IIT Kanpur, Kanpur, UP, India**:
Name: **Prof.** Nisarth N. Nair
Designation: Associate Dean, Academic Affairs
Signature with date: 30-01-2020

MEMORANDUM OF UNDERSTANDING (MoU)

Between

NIPER HYDERABAD
National Institute of Pharmaceutical Education and Research
HYDERABAD

BLDE
(Deemed to be University)

(2019-2024)

National Institute of Pharmaceutical Education and Research (NIPER),
Hyderabad, Telengana State, India

With

BLDE
(Deemed to be University)
The Constituent Collge:
Shri B. M. Patil Medical College, Hospital & Research Centre, Vijayapura, Karnataka,India

Date: 11-11-2019

National Institute of Pharmaceutical Education and Research (NIPER), Hyderabad is an "Institute of National Importance" with proclaimed objectives of becoming Centre of Excellence for advanced research in pharmaceutical sciences under the aegis of Department of Pharmaceuticals, Ministry of Chemicals and Fertilizers, the Govt. of India. The vision of NIPER Hyderabad is to serve as a leading global institution in the field of higher learning and research in Pharmaceutical Sciences and Management.

BLDE (Deemed to be University), Vijayapura, Karnataka State was established in 2008, is a single faculty medical sciences institution with Shri B. M. Patil Medical College, Hospital & Research Centre (established 1986) as its constituent college. The vision of the BLDE (Deemed to be University) and its constituent college is to be a leader and be recognized as an Institution striving for maintenance and enhancement of quality health sciences education and health care, agrees to enter into this Memorandum of Understanding.

National Institute of Pharmaceutical Education and Research (NIPER), Hyderabad, TS, India is referred to as Party 1 and **BLDE (Deemed to be University)**, Vijayapura, Karnataka State, India is referred to as Party 2.

A. Background:

National Institute of Pharmaceutical Education and Research (NIPER), Hyderabad, Telangana State and **BLDE (Deemed to be University)**, Vijayapura, Karnataka for the purpose of furthering cooperation through educational, research and academic exchanges, hereby affirm their intent to promote such cooperation activities as will be of mutual benefit for their respective institutions.

B. Scope of Co-operation & Activities:

1. Development of mutually beneficial academic programmes and courses;
2. Coordination of academic staff mobility for purposes of teaching, research and training;
3. Coordination of student mobility programmes for study and research;
4. Sharing of research facilities on mutually agreed terms.
5. Sharing of sophisticated high-cost instrumentation facilities. The facilities shall be used as per the prevailing guidelines of the institutes.
6. Coordination of academic activities such as joint research, joint publication(s), origination of joint QIP (Quality Improvement Programme) and training programmes.

7. Exchange of research students (Doctoral & Post Doctoral) of basic sciences, allied health sciences (Pharmacy).
8. Both the Institutions mutually agree to take up and supervise or co-supervise doctoral research projects of all disciplines under health sciences to pool expertise. To establish a research ecosystem in both Institutions, approved doctoral guides of BLDE (Deemed to be University) can act a Co-guides to NIPER Hyderabad and vice-versa.
9. Exchange of documents and research materials in fields of mutual interest provided that, to the best of knowledge of the respective institutions, there is no prohibition at law or otherwise against the exchange.
10. Other such activities as considered by the parties to be of mutual benefit towards furthering education and research programme.

C. Management of Co-operation:

1. The implementation of exchange based on the MOU shall be separately negotiated and determined by both the University/Institutions.
2. Nothing shall diminish the full autonomy of either University/Institute, nor will any constraint or financial obligations be imposed by either upon the other in carrying out MOU.
3. Any notice required to be given under this Agreement by either Party (1 & 2) will be in writing and sent to the other Party by either hand delivery or by certified postal mail.

D. Terms & Termination:

1. The MoU will be valid for a period of 5 years from the effective date. Thereafter, the renewal of the MoU will be subject to the written agreement between the parties.
2. The MoU is subject to revision by mutual written agreement.
3. Both parties shall take necessary approvals from the competent authority for fulfilling the scope of the program on case to case basis.
4. It is also understood that, either party may terminate the MoU for any reason and that any time upon thirty (30) days prior written notice to the other party; although such action will only be taken after mutual consultation to avoid any possible inconvenience to all parties.

5. The MoU is effective when representatives of both parties have signed and dated the document ("Effective Date").

AUTHORISE TO SIGN FOR AND ON BEHALF OF NIPER, HYDERABAD, TS, INDIA

Signature: . . . . . Date: 14-11-2019

Name in Capitals: **DR.SHASHI BALA SINGH**

Position in University/Institution: **DIRECTOR**

Official Seal: NIPER HYDERABAD

AUTHORISE TO SIGN FOR AND ON BEHALF OF BLDE (Deemed to be University), VIJAYAPUR, KARNATAKA, INDIA

Signature: . . . . . Date: 11.11.2019

Name in Capitals: **DR.M.S.BIRADAR**

Position in University/Institution: **VICE-CHANCELLOR**

Official Seal: VICE-CHANCELLOR
BLDE (Deemed to be University)
Vijayapura-586103. Karnataka

Witness: For **NIPER, Hyderabad**:

Name: **DR. N. SATHEESH KUMAR**
Designation: Assistant Professor, NIPER, Hyderabad, TS,India
Signature with date 11/11/19

Witness: For **BLDE (Deemed to be University), Vijayapura**:

Name: **DR.ARAVIND V.PATIL**
Designation: DEAN, Faculty of Medicine & Principal, Shri B.M.Patil Medical College, Hospital & Research Centre, BLDE (Deemed to be University),. Vijayapura, Karnataka, India
Signature with date: 11/11/19.

PRINCIPAL
BLDE (Deemed to be University)
Shri B. M. Patil Medical College, Hospital &
Research Centre, Vijayapura-586103. Karnataka

MEMORANDUM OF UNDERSTANDING

Between

BLDE (Deemed to be University)
INDIA

and

Train and Help Babies (TaHB)
USA

The Administration of TaHB (Train and Help Babies), is a not for profit, 501c(3) IRS certified organization. The organization is volunteer based and strives to improve the healthcare delivery in India. Main Office is based in Texas, USA and the Faculty of Medicine, BLDE (Deemed to be University), Vijayapura, Karnataka State, INDIA agree to enter into this Memorandum of Understanding based on "A foundation of trust for mutual benefit and development and the promotion of International understanding and goodwill."

A. Background:

i) The parties seek to demonstrate by signing this memorandum their commitment to co-operation in terms of common interest through the development of collaboration between TaHB, USA and Faculty of Medicine, BLDE (Deemed to be University), INDIA.

ii) The parties recognized the mutual benefit each will gain from working together and the value this will add to the promotion of not only medical sciences research but also overall impact on health sectors globally.

B. Scope of co-operation and activities:

TaHB (Train and Help Babies), the Faculty of Medicine BLDE (Deemed to be University) desire to explore & promote some or all of the following activities based on the respective academic and research needs, which may be formally developed through a separate legally binding agreement between the parties:

i) To create a strong academic environment.

..2

ii) To improve the knowledge and skills of all healthcare providers.

iii) Organization of joint research programs.

C. Management of Co-operation:

i) The implementation of exchange based on the MoU shall be separately negotiated and determined by both the parties.

ii) Nothing shall diminish the full autonomy of either party, nor will any constraint or financial obligations we imposed by either upon the other in carrying out MoU.

iii) The parties acknowledge that this MoU doesn't involve the transfer of money between the parties. The parties further acknowledge that, no sponsor funding exists regarding activity contemplated by this MoU.

iv) BLDE (DU) and TaHB mutually agree to exchange research/training materials, publications and research / training information.

v) Any notice require to given under this agreement by either party will be in writing and sent to the other party by either hand delivery or certified mail return receipt requested as follows:

If to TaHB: Prakash M Kabbur, President, Train and Help Babies Organization,Texas,USA,Telephone:+1(808)2913162,email:kabburpm @yahoo.com,tahbtx@gmail.com,website:trainandhelpbabies.com.

If to BLDE (Deemed to be University): Faculty of Medicine and Principal, BLDE(DU), Smt. Bangaramma Sajjan Campus, VIJAYAPURA-586103,Karnataka,INDIA Telephone:+91 8352-262770, Fax:+918352-263303.email:registrar@bldedu.ac.in, website:www.bldedu.ac.in

D. Terms & Termination:

i) The MoU will be valid for 5 years from effective date. Thereafter, renewal of the MoU will be subject to the written agreement of both parties.

..3

ii) The MoU is subject to revision by mutual written agreement. It is also understood that, either party may terminate the MoU for any reason and that any time upon thirty (30) days prior written notice to the other party; although such action will only be taken after mutual consultation in order to avoid any possible inconvenience to all parties.

iii) The MoU is effective when representatives of both parties have signed and dated the document ("Effective Date").

E. ARTICLE: INDEMNIFICATION

i) The Details of training and schedule of visit to individual Institution such as BLDE (DU) will be mutually decided.

ii) BLDE (Deemed to be University) will make arrangement for logistics to and from Vijayapura within Karnataka and provide required equipment for training.

iii) The Coordinator to be nominated for all the TaHB activities.

iv) Two Postgraduate to be posted for the TaHB activities.

AUTHORISE TO SIGN FOR AND ON BEHALF OF TaHB, USA

Signature: ..... Date: 22/10/2018

Name in Capitals: **DR. PRAKASH M. KABBUR**
Position in Organization: PRESIDENT, TRAIN AND HELP BABIES ORGANIZATION, Texas, USA.

AUTHORISE TO SIGN FOR AND ON BEHALF OF BLDE (Deemed to be University)

Signature: ..... Date: 23-10-2018

Name in Capitals: **DR. S. P. GUGGARIGOUDAR**
Position in Organization: DEAN FACULTY OF MEDICINE AND PRINCIPAL, BLDE (DEEMED TO BE UNIVERSITY), VIJAYAPURA

PRINCIPAL
BLDE (Deemed to be University)
Shri B. M. Patil Medical College
Hospital & Research Centre,
VIJAYAPUR- 586103

SR.

Integrated Disease Surveillance Programme
National Centre for Disease Control
22, Sham Nath Marg, Delhi: 110054

Date-7th March,2019

To,

Dr. Shailaja S. Patil
Professor & Head
Dept. of Community Medicine
BLDE (Deemed to be University)
Shri. B. M. Patil Medical College,
Hospital & Research Centre,
Vijayapura-586103
Karnataka.
Phone No- 9901317974

8 MAR 2019

Subject- Regarding copy of signed MOU between Shri. B. M. Patil Medical College and MOHFW for IDSP programme to conduct trainings in session 2019-20.

Respected Ma'am,

I am enclosing herewith the original signed copy of the MOU between Shri. B. M. Patil Medical College and MOHFW for IDSP programme to conduct trainings in session 2019-20. Kindly retain this copy for your office records.

With regards,
Yours sincerely,

7/3/19

Isha Gupta
Training Manager
IDSP, NCDC
Delhi-110054

सत्यमेव जयते

INDIA NON JUDICIAL

Government of Karnataka

Rs. 100

e-Stamp

Certificate No.	:	IN-KA36523027720998R
Certificate Issued Date	:	25-Jan-2019 04:21 PM
Account Reference	:	NONACC (FI)/ kaksfcl08/ VIJAYAPURA/ KA-BJ
Unique Doc. Reference	:	SUBIN-KAKAKSFCL0806968063629141R
Purchased by	:	DEAN FACULTY OF MEDICINE AND PRINCIPAL BLDE
Description of Document	:	Article 12 Bond
Description	:	BOND
Consideration Price (Rs.)	:	0 (Zero)
First Party	:	DEAN FACULTY OF MEDICINE AND PRINCIPAL BLDE
Second Party	:	DIRECTOR N C D C NEW DELHI
Stamp Duty Paid By	:	DEAN FACULTY OF MEDICINE AND PRINCIPAL BLDE
Stamp Duty Amount(Rs.)	:	100 (One Hundred only)

सत्यमेव जयते

For. Bijapur Totagarika Souharda Sahakari Niyamit, Vijayapura

Authorised Signatory

RS. 100 25-JAN-2019 04:21 PM

Please write or type below this line

MEMORANDUM OF UNDERSTANDING

PRINCIPAL
BLDE (Deemed to be University)
Shri B. M. Patil Medical College
Hospital & Research Centre,
VIJAYAPUR- 586103

MEMORANDUM OF UNDERSTANDING

BETWEEN

Integrated Disease Surveillance Programme
(Ministry of Health and Family Welfare,
Government of India)

And

BLDE
(Deemed to be University)
VIJAYAPURA

JANUARY 2019

Memorandum of Understanding (MoU)

WHEREAS the **Integrated Disease Surveillance Programme (IDSP)**, under MoHFW has been launched in 2004 by the Government of India in all States and Union Territories (UTs).

AND WHEREAS the main objectives of the Integrated Disease Surveillance Programme are:

1. To strengthen/maintain a decentralized laboratory based IT-enabled disease surveillance system for epidemic prone diseases to monitor disease trends and to detect and respond to outbreaks in early rising phase through trained Rapid Response Teams.
2. To establish a functional mechanism for inter-sectoral coordination to tackle the Zoonotic diseases.

The Programme components of the Integrated Disease Surveillance Programme are:

1. Integration and decentralization of surveillance activities through establishment of surveillance units at Centre, State, and District level.
2. Human Resource Development – Training of State Surveillance Officers, District Surveillance Officers, Rapid Response Team and other Medical and Paramedical staff on principles of disease surveillance.
3. Use of Information Communication Technology for collection, collation, compilation, analysis, and dissemination of data.
4. Strengthening of public health laboratories.
5. Inter sectoral Co-ordination for zoonotic diseases

The criteria for an Epidemiology training College/institute:

a) Recognised training institutions with experience in post-graduate teaching in the field of community medicine/Public Health.
b) Adequate training infrastructure and equipment including residential facility.
c) Key resource person in the area of epidemiology who are willing to be resource person for training.
d) Ability to facilitate field visits.
e) Preferably experience in health surveillance activities.

The criteria for a Microbiology training College/institute:

a) Training institutions with experience in the field of Microbiology.
b) Adequate training infrastructure and equipment including residential facility.
c) Key resource person in the area of microbiology who are willing to be resource person for training.
d) Preferably experience in health surveillance activities.

The criteria for an Entomological training College/institute:

a) Recognised training institutions with experience in the field of Entomology related to Human diseases.
b) Adequate training infrastructure and equipment including residential facility.
c) Key resource person in the area of entomology who are willing to be resource person for training.
d) Ability to facilitate field visits.
e) Preferably experience in entomological surveillance activities.

PRINCIPAL
BLDE (Deemed to be University)
Shri B. M. Patil Medical College
Hospital & Research Centre,
VIJAYAPUR- 586103

AND WHEREAS the IDSP and the BLDE (Deemed to be University)'s Shri B. M. Patil Medical College, Hospital & Research Centre, Vijayapura shall be parties to this Memorandum of Understanding.

NOW THEREFORE, below are the terms and conditions under which signatories to this MoU, IDSP and BLDE (Deemed to be University)'s Shri B. M. Patil Medical College, Hospital & Research Centre, Vijayapura, have agreed to set out as herein below;

1. Duration of MOU

This MOU will be operative with effect from the date of signature of both the parties concerned and **will remain in force till March 31st 2020**. This MOU may be terminated before the expiry of its term by the mutual consent of the parties concerned.

2. The commitments of IDSP

i. Provide Course curriculum
ii. Provide guidelines/modules
iii. Liaison with State/UTs and provision of training load.
iv. Provision of funds in the form of GIA to the training college/Institute.

Funds provided by IDSP are to be utilized as per table below:

For FETP Training: An amount of up to Rs. **16,91,140/- (Rupees Sixteen Lakh Ninety One Thousand One Hundred and Forty only)** is the approved budget for Field Epidemiologists Training Programme (FETP) under IDSP. The amount mentioned herein will be exclusive of all types of admissible /enforceable taxes across India.

Sl. No.	Budget Head	Proposed Norm for FETP (13 Days)	Amount (Rs.)
1	Travel Cost of Participants	As per the entitlements, subject to government norms}	5,00,000/-*
2	Honorarium (DA) to Trainee	Rs.700/- per participant per day	1,82,000/- (700x20x13)
3	Honorarium to guest faculty at Regional/State/National level. Nominated by CSU.	Rs.1500/- for 01 person and 02 days	3,000/- (1500x1x2)
4	Honorarium to External Resource Persons	Rs.1500/- per person per day for 13 days**	39,000/- (1500x2 x 13 days)
5	Honorarium to In-house faculty per day	Rs.1000/- per person per day for 13 days**	26,000/- (1000x2personsx13)
6	Working Lunch	Rs.350x (20participants+8 faculties/Assistants) x13 days)	1,27,400/- (350x28x13, subject to actual)
7(a)	Accommodation for participants	Rs.2000/participant/dayx20 persons x 13 dyas, subject to actual) This is the max. limit & subject to production of receipt(s)	5,20,000/- (2000x20x13, subject to actual)
7(b)	Accommodation for two (2) external resource persons	Rs.2000/participant/day x 02 persons x 13 days, (subject to actual). This is the max. limit & subject to production of receipt(s)	52,000/- (2000x2x13)
8	Incidental expenditure, photocopying, job aids, flip charts, LCD etc.	Rs. 300 per day per participants for 13 days, subject to keeping it to minimum	78,000/- (300x20x13)
9	Venue Hiring	10,000/-	10,000/-
10	Institutional Overhead & for use of Institutional facilities	@ 10% of total training expenses	1,53,740/-
	Total Cost/Batch of 20 participants		**16,91,140/-**

PRINCIPAL
BLDE (Deemed to be University)
Shri B. M. Patil Medical College

Note:

* Travel as per the entitlement and subject to Government norms, however, travel cost has been taken tentatively as Rs.5,00,000/- for 20 participants.

**Subject to two lectures/Guest faculty/day

- In-house Faculty: Faculty members of training institutions and attached clinical training site/District hospitals will be considered as In-house faculty.
- Guest Faculty: All other trainers/resource persons not failing under the above mentioned criteria will be considered as Guest Faculty.

3. The Medical College/Institute Commitments

i. Designate a dedicated focal point, a permanent faculty of the same department, who would be responsible for IDSP training related activities and will liaison with IDSP focal person Name, contact number and email of focal point:
DR.PRAVEEN GANGANAHALLI, Assistant Professor, Community Medicine, Mob.No.-09901317974, Email id - dr.pravin2000@gmail.com

ii. Follow-up and coordination with participants after provision of training load from CSU, IDSP.

iii. Shall arrange and conduct training as per the norms provided.

iv. Shall ensure that the training is conducted with utmost professional manner.

v. Submit consolidated participant's feedback on training to IDSP after the end of each training programme.

vi. Responsibility of the participants during the training period.

4. Set out below are the **terms and conditions** under which **BLDE (Deemed to be University)'s Shri B. M. Patil Medical College, Hospital & Research Centre, Vijayapura** agrees to carry out the above mentioned assignment.

i. For administrative purpose, Programme Director, IDSP who is also Director NCDC has been assigned to administer the assignment and to provide **BLDE (Deemed to be University)'s Shri B. M. Patil Medical College, Hospital & Research Centre, Vijayapura** with relevant information needed to carry out the assignment.

ii. The IDSP may, if find necessary, postpone or cancel the assignment and/or shorten or extend its duration. However, every effort will be made to give **BLDE (Deemed to be University)'s Shri B. M. Patil Medical College, Hospital & Research Centre, Vijayapura** early as possible, notice of any changes. In the event of termination, the **BLDE (Deemed to be University)'s Shri B. M. Patil Medical College, Hospital & Research Centre, Vijayapura** shall be paid for the services rendered for carrying out the assignment to the date of termination, and the **BLDE (Deemed to be University)'s Shri B. M. Patil Medical College, Hospital & Research Centre, Vijayapura** will provide the IDSP with any reports thereof or any other information and documentation gathered under the Memorandum of Undertaking (MOU) prior to the date of termination.

iii. Whereas, this Memorandum of Undertaking (MOU), its meaning and interpretation and relation between the parties shall be governed by the Laws in force of Union of India.

iv. Whereas all final plans, drawings, specification, designs, reports and other documents or software submitted by the **BLDE (Deemed to be University)'s Shri B. M. Patil Medical College, Hospital & Research Centre, Vijayapura** in the performance of the services shall become and remain the property of the NCDC. **BLDE (Deemed to**

PRINCIPAL
BLDE (Deemed to be University)
Shri B. M. Patil Medical College
Hospital & Research Centre

v. **be University)'s Shri B. M. Patil Medical College, Hospital & Research Centre, Vijayapura** may retain a copy of such documents but shall not use them for purpose other than this Memorandum of Undertaking (MOU) without the prior written approval of IDSP.

vi. Whereas the **BLDE (Deemed to be University)'s Shri B. M. Patil Medical College, Hospital & Research Centre, Vijayapura** undertakes to carry out the assignment in accordance with the highest standards of professional and ethical competence and integrity, having due regards to thenature and purpose of the assignment and to ensure that the staff assigned to perform the services under the Memorandum of Undertaking (MOU), will conduct themselves in a manner consistent herewith.

vii. **BLDE (Deemed to be University)'s Shri B. M. Patil Medical College, Hospital & Research Centre, Vijayapura** shall deduct & pay the taxes, duty fees and other impositions levied under the admissible/enforceable tax across India.

viii. **BLDE (Deemed to be University)'s Shri B. M. Patil Medical College, Hospital & Research Centre, Vijayapura** also agrees that all knowledge and information not within the public domain which may be acquired during carrying out of this Memorandum of Undertaking (MOU), shall be for all times and for all purposes, regarded as strictly confidential and held in confidence and shall not be directly or indirectly disclosed to any person whatsoever, except with IDSP's written permission.

ix. The fund for this program will be transferred through PFMS before commencement of each training programme and **BLDE (Deemed to be University)'s Shri B. M. Patil Medical College, Hospital & Research Centre, Vijayapura** shall use the EAT module of PFMS for expenditure filling and submit statement of expenditure and utilization certificates within 15 days of the closure of each training programme. For the purpose of maintenance of accounts relating to above funds, College/institute shall open a separate savings bank account, maintain books of accounts separately and submit the audited accounts along with Statement of Expenditure, Bill wise summary Sheet of Expenditure and Utilization Certificate (in the attached format) after completion of each training programme to Central Surveillance Programme, Integrated Disease Surveillance, Delhi within 15 days. The expenditure will then be adjusted against the Grant in aid paid to the institute. The Audit Fees should be charged under the head of "Incidental Charge". The format of Utilization Certificate is attached as per GFR12-A of GFR rule, 2017.

x. The institutions should follow the General Financial Rules 2017 for procurement of Goods and services and deduct TDS while making various payments as per Income Tax Act/GST.

xi. Integrated Disease Surveillance Programme (IDSP)/National Centre for Disease Control (NCDC) will not be liable to pay any liability on account of non-fulfillment of Statuary rules/ obligations on the part of Training institution.

5. Redressal Mechanism

i. In case of any irregularity or dispute arising out of this MOU or interpretation of the terms and conditions of this MOU both the parties agree to settle the matter amicably through mutual discussion by Director, National Centre for Disease Control and the **Dean, Faculty of Medicine & Principal, BLDE (Deemed to be University)'s Shri B. M. Patil Medical College, Hospital & Research Centre, Vijayapura**, and on the failure of such discussions, the matter shall be referred to a sole arbitrator to be appointed by both the parties by mutual agreement. The decision of the arbitrator shall be binding on both the parties. The arbitration shall be subject to the provisions of the Arbitrations and Conciliation Act, 1996.

PRINCIPAL
BLDE (Deemed to be University)
Shri B. M. Patil Medical College,
Hospital & Research Centre,
VIJAYAPURA-586103

ii. Non-compliance of the commitment and obligations set out in the MOU, upon failureof **BLDE (Deemed to be University)'s Shri B. M. Patil Medical College, Hospital & Research Centre, Vijayapura** to make satisfactory progress may require IDSP and **BLDE (Deemed to be University)'s Shri B. M. Patil Medical College, Hospital & Research Centre, Vijayapura** to review the SITUATION COMMITTED THROUGH THIS MOU leading to suspension, reduction or cancellation thereof. In case of unsatisfactory progress in the project, every effort would be made by IDSP and **BLDE (Deemed to be University)'s Shri B. M. Patil Medical College, Hospital & Research Centre, Vijayapura** to bring the project back to rail through mutual consultations. In event of irretrievable situation, the funding may be suspended and MOU also be terminated as per procedure.

IN WITNESS WHEREOF, THE PARTIES HAVE EXECUTED THIS AGREEMENT ON THIS MONDAY DAY OF 28th JANUARY, 2019

For and on behalf of the Government of India, Ministry of Health & Family Welfare (through Director, NCDC & PD IDSP)	College/Institute (Through its Principal/Director)
Director, NCDC डॉ. सुजीत कुमार सिंह / Dr. Sujeet Kumar Singh निदेशक / Director भारत सरकार / Government of India रा.रोग.नि.केन्द्र / स्वा. एवं परिवार कल्याण मंत्रालय NCDC/Dte. GHS, Min. Health & F.W. 22, शाम नाथ मार्ग, दिल्ली- 54 22, Sham Nath Marg, Delhi-110054	**Dean, Faculty of Medicine & Principal** **BLDE (Deemed to be University)'s Shri.B.M.Patil Medical College, Hospital & Research Centre, Vijayapura. Karnataka** PRINCIPAL BLDE (Deemed-to be University) Shri B. M. Patil Medical College Hospital & Research Centre, VIJAYAPUR- 586103

MEMORANDUM OF UNDERSTANDING (MoU)

(2020-2025)

Between

BLDE
(Deemed to be University)

ICMR- National Institute of Traditional Medicine

Belagavi- 590010 (Karnataka), India

With

BLDE
(Deemed to be University)

The Constituent Collge:
Shri B. M. Patil Medical College, Hospital & Research Centre
Vijayapura, Karnataka, India

Date: 29-05-2020

National Institute of Traditional Medicine, Belagavi, one of the research centres of the **Indian Council of Medical Research,** a society established under the Societies Registration Act, 1860, an autonomous body under and fully funded by the Department of Health Research, Ministry of Health & FW, Govt of India, having its research facility at Nehru Nagar, Belagavi, and its head/registered office at V. Ramalingaswami Bhawan, Ansari Nagar, New Delhi-110 029 (hereinafter referred to 'ICMR-NITM' as the context permits).

BLDE (Deemed to be University), Vijayapura, Karnataka State, India was established in 2008, is a single faculty medical sciences institution with Shri B. M. Patil Medical College, Hospital & Research Centre (established 1986) as its constituent college. This University is sponsored by BLDE Association (established 1910), Vijayapur, Karnataka. BLDE (The vision of the BLDE (Deemed to be university) and its constituent college is to be a leader and be recognized as an Institution striving for maintenance and enhancement of quality health sciences education and health care, agrees to enter into this Memorandum of Understanding.

ICMR-NITM, Belagavi, Karnataka Sate, India is referred as Party 1 and **BLDE (Deemed to be University), Vijayapura, Karnataka State, India** is referred as Party 2.

A. Background:

ICMR-NITM, Belagavi, Karnataka Sate, India and **BLDE (Deemed to be University),** Vijayapura, Karnataka for the purpose of furthering cooperation through educational, research and academic exchanges, hereby affirm their intent to promote such cooperation activities as will be of mutual benefit for their respective institutions.

B. Scope of Co-operation & Activities:

1. Coordination of academic reserach staff mobility for purposes of teaching, research and training;
2. Sharing of research facilities on mutually agreed terms.
3. Sharing of sophisticated instrumentation facilities. The facilities shall be used as per the **prevailing guidelines of the institutes.**

4. Coordination of academic activities such as joint research, joint publication(s), origination of joint QIP (Quality Improvement Programme) and training programmes.
5. Training of research students (Doctoral & Post Doctoral), Postgraduate and undergraduate students of basic sciences and clinical medicine.
6. Both the Institutions mutually agree to take up and supervise or co-supervise doctoral research projects of all disciplines under health sciences to pool expertise. BLDE (DU) will recognize ICMR-NITM Scientists for Supervising/Co-supervising PG/PhD students as per the UGC guidelines (2016).
7. Conducting joint research projects especially in clinical reserach.
8. Exchange of documents and research materials in fields of mutual interest provided that, to the best of knowledge of the respective institutions, there is no prohibition at law or otherwise against the exchange.
9. Other such activities as considered by the parties to be of mutual benefit towards furthering education and research programme.

C. Management of Co-operation:

1. The implementation of exchange based on the MoU shall be separately negotiated and determined by both the University/Institutions.
2. Nothing shall diminish the full autonomy of either University/Institute, nor will any constraint or financial obligations be imposed by either upon the other in carrying out MoU.
3. Any notice required to be given under this Agreement by either Party (1 & 2) will be in writing and sent to the other Party by either hand delivery or by certified postal mail.

D. Terms & Termination:

1. The MoU will be valid for a period of 5 years from the effective date. Thereafter, renewal of the MoU will be subject to the written agreement between the parties.
2. The MoU is subject to revision by mutual written agreement.
3. Both parties shall take necessary approvals from the competent authority for fulfilling the scope of the program on case to case basis.

4. It is also understood that, either party may terminate the MoU for any reason and that any time upon thirty (30) days prior written notice to the other party; although such action will only be taken after mutual consultation in order to avoid any possible inconvenience to all parties.

5. The MoU is effective when representatives of both parties have signed and dated the document ("Effective Date").

AUTHORISE TO SIGN FOR AND ON BEHALF OF ICMR-NITM, BELAGAVI, KARNATAKA, INDIA

Signature: . . Chattopadhyay . . . . . Date: **29-05-2020**

Name in Capitals: DR. DEBPRASAD CHATTOPADHYAY

Position in University/Institution : **DIRECTOR**

Official Seal: डॉ. देबप्रसाद चट्टोपा... वैज्ञानिक-जी एवं निदेशक
Dr. Debprasad Cha... Scientist-G & Director
आयसीएमआर-राष्ट्रीय पारम्परिक चिकित्साविज्ञान संस्थान
ICMR-NATIONAL INSTITUTE OF TRADITIONAL MEDICINE
स्वास्थ्य अनुसंधान विभाग, भारत सरकार
Department of Health Research, Govt. of India
नेहरू नगर, बेलगावी-५९००१० Nehru Nagar, Belagavi-590010

AUTHORISE TO SIGN FOR AND ON BEHALF OF BLDE (Deemed to be University), VIJAYAPUR, KARNATAKA, INDIA

Signature: . . . . . Date: . . 29-5-2020.

Name in Capitals: DR. M. S. BIRADAR

Position in University/Institution: **VICE CHANCELLOR**

Official Seal: VICE-CHANCELLOR
BLDE (Deemed to be University)
Vijayapura-586103. Karnataka

MEMORANDUM OF UNDERSTANDING (MoU)

(2020-2025)

Between

BLDE
(Deemed to be University)

ICMR- National Institute of Traditional Medicine

Belagavi- 590010 (Karnataka), India

With

BLDE
(Deemed to be University)

The Constituent Collge:
Shri B. M. Patil Medical College, Hospital & Research Centre
Vijayapura, Karnataka, India

Date: 29-05-2020

National Institute of Traditional Medicine, Belagavi, one of the research centres of the **Indian Council of Medical Research,** a society established under the Societies Registration Act, 1860, an autonomous body under and fully funded by the Department of Health Research, Ministry of Health & FW, Govt of India, having its research facility at Nehru Nagar, Belagavi, and its head/registered office at V. Ramalingaswami Bhawan, Ansari Nagar, New Delhi-110 029 (hereinafter referred to 'ICMR-NITM' as the context permits).

BLDE (Deemed to be University), Vijayapura, Karnataka State, India was established in 2008, is a single faculty medical sciences institution with Shri B. M. Patil Medical College, Hospital & Research Centre (established 1986) as its constituent college. This University is sponsored by BLDE Association (established 1910), Vijayapur, Karnataka. BLDE (The vision of the BLDE (Deemed to be university) and its constituent college is to be a leader and be recognized as an Institution striving for maintenance and enhancement of quality health sciences education and health care, agrees to enter into this Memorandum of Understanding.

ICMR-NITM, Belagavi, Karnataka Sate, India is referred as Party 1 and **BLDE (Deemed to be University), Vijayapura, Karnataka State, India** is referred as Party 2.

A. Background:

ICMR-NITM, Belagavi, Karnataka Sate, India and **BLDE (Deemed to be University),** Vijayapura, Karnataka for the purpose of furthering cooperation through educational, research and academic exchanges, hereby affirm their intent to promote such cooperation activities as will be of mutual benefit for their respective institutions.

B. Scope of Co-operation & Activities:

1. Coordination of academic reserach staff mobility for purposes of teaching, research and training;
2. Sharing of research facilities on mutually agreed terms.
3. Sharing of sophisticated instrumentation facilities. The facilities shall be used as per the **prevailing guidelines of the institutes.**

4. Coordination of academic activities such as joint research, joint publication(s), origination of joint QIP (Quality Improvement Programme) and training programmes.
5. Training of research students (Doctoral & Post Doctoral), Postgraduate and undergraduate students of basic sciences and clinical medicine.
6. Both the Institutions mutually agree to take up and supervise or co-supervise doctoral research projects of all disciplines under health sciences to pool expertise. BLDE (DU) will recognize ICMR-NITM Scientists for Supervising/Co-supervising PG/PhD students as per the UGC guidelines (2016).
7. Conducting joint research projects especially in clinical reserach.
8. Exchange of documents and research materials in fields of mutual interest provided that, to the best of knowledge of the respective institutions, there is no prohibition at law or otherwise against the exchange.
9. Other such activities as considered by the parties to be of mutual benefit towards furthering education and research programme.

C. Management of Co-operation:

1. The implementation of exchange based on the MoU shall be separately negotiated and determined by both the University/Institutions.
2. Nothing shall diminish the full autonomy of either University/Institute, nor will any constraint or financial obligations be imposed by either upon the other in carrying out MoU.
3. Any notice required to be given under this Agreement by either Party (1 & 2) will be in writing and sent to the other Party by either hand delivery or by certified postal mail.

D. Terms & Termination:

1. The MoU will be valid for a period of 5 years from the effective date. Thereafter, renewal of the MoU will be subject to the written agreement between the parties.
2. The MoU is subject to revision by mutual written agreement.
3. Both parties shall take necessary approvals from the competent authority for fulfilling the scope of the program on case to case basis.

4. It is also understood that, either party may terminate the MoU for any reason and that any time upon thirty (30) days prior written notice to the other party; although such action will only be taken after mutual consultation in order to avoid any possible inconvenience to all parties.

5. The MoU is effective when representatives of both parties have signed and dated the document ("Effective Date").

AUTHORISE TO SIGN FOR AND ON BEHALF OF ICMR-NITM, BELAGAVI, KARNATAKA, INDIA

Signature: . . Chattopadhyay . . . . . Date: **29-05-2020**

Name in Capitals: DR. DEBPRASAD CHATTOPADHYAY

Position in University/Institution : **DIRECTOR**

Official Seal: डॉ. देबप्रसाद चट्टोपा... वैज्ञानिक-जी एवं निदेशक
Dr. Debprasad Cha... Scientist-G & Director
आयसीएमआर-राष्ट्रीय पारम्परिक चिकित्साविज्ञान संस्थान
ICMR-NATIONAL INSTITUTE OF TRADITIONAL MEDICINE
स्वास्थ्य अनुसंधान विभाग, भारत सरकार
Department of Health Research, Govt. of India
नेहरू नगर, बेलगावी-५९००१० Nehru Nagar, Belagavi-590010

AUTHORISE TO SIGN FOR AND ON BEHALF OF BLDE (Deemed to be University), VIJAYAPUR, KARNATAKA, INDIA

Signature: . . . . . Date: . . 29-5-2020.

Name in Capitals: DR. M. S. BIRADAR

Position in University/Institution: **VICE CHANCELLOR**

Official Seal: VICE-CHANCELLOR
BLDE (Deemed to be University)
Vijayapura-586103. Karnataka

MEMORANDUM OF UNDERSTANDING

(MoU)

FOR

CLINICAL APPLICATION FOR TRADITIONAL MEDICINE AS AN ADJUNCT WITH MODERN MEDICINE

BETWEEN

Morarji Desai National Institute of Yoga

(An autonomous organization under Ministry of AYUSH, Government of India)

New Delhi

And

BLDE

(Deemed to be University)

VIJAYAPURA, Karnataka

August 19, 2020

This MOU is made on this the 19th day of August 2020

BETWEEN

Morarji Desai National Institute of Yoga, a leading institute under Ministry of AYUSH, Government of India, having its registered Office at 68, Ashok Road, Near Gole Dak Khana, New Delhi -110001. (Hereinafter referred to as "MDNIY", which expression, unless repugnant to the context thereof, shall mean and include its successors and assignees) through its duly authorized representative, **Dr. I.V.Basavaraddi, Director as FIRST PARTY.**

AND

Sri B. M. Patil Medical College (Deemed to be University), is one of the reputed universities in Karnataka providing education in various medical courses, having its office and institute at Smt. Bagaramma Sajjan Campus, Dr B M Patil Road (Solapur Road), Vijayapura (Bijapur)-586103, Karnataka, INDIA. (Hereinafter referred to as "BLDE (DU)", which expression, unless repugnant to the context thereof, shall mean and include its successors and assignees) through its duly authorized representative, **Dr M.S.Biradar, Vice-Chancellor as SECOND PARTY.**

"MDNIY" and "BLDE (DU)" are referred to collectively as 'PARTIES' and individually as 'PARTY' as the context may require.

WHEREAS Morarji Desai National Institute of Yoga (MDNIY) is an autonomous organization under Ministry of AYUSH, Government of India. MDNIY is a focal Institute for Planning, Training, Promotion and Coordination of Yoga Education, Training, Therapy and Research in all its aspects. MDNIY has been designated as a WHO-CC for Traditional Medicine (Yoga) from April, 2013 and serving as a Yoga resource centre for information exchange on Yoga within the country and for other countries, assisting and working with WHO in developing standards for promoting rational use of Yoga. MDNIY aims to promote deeper understanding of Yoga philosophy and practices based on classical Yoga amongst people. The main Vision and Mission of the Institute is "Health, Harmony and Happiness for all through Yoga". Yoga, as union, implies perfect harmony of body and

mind. It implies the harmonious integration of personality. The most common benefit of Yoga practice is the sense of well-being at all levels of our existence. MDNIY conducts Undergraduate, Diploma for graduates and Certificate courses. Along with these MDNIY also conducts Foundation courses at MDNIY campus as well as SAI stadium and Amity University campus. MDNIY has its own OPD for therapeutic treatment through Yoga. MDNIY also conducts certificate courses for special interest group such as Paramilitary Forces and Delhi Police. Apart from these academic activities, MDNIY organizes Orientation lecture, Workshops, Seminars, International Yoga Fest, to popularize, promote Yoga to more peoples. MDNIY play a vital role in International Yoga Day to popularize, promote Yoga among the people.

WHEREAS BLDE (Deemed to be University) was established in 2008 is a single faculty medical sciences institution with Shri B. M. Patil Medical College, Hospital & Research Centre (established 1986) as its constituent college. The vision of the BLDE (Deemed to be University) and its constituent college is to be a leader and be recognized as an Institution striving for maintenance and enhancement of quality medical education and health care.

The University medical college has a unitary campus of 45 acres with 24 departments and a teaching hospital with 1080 beds. The teaching hospital is well equipped with advanced and sophisticated instruments for the student and patient care.

The University medical college has been offering: UG Programme-MBBS (with an intake of 150 students), B.Sc. (MIT), PG Programmes in 18 disciplines, M.Sc. (Medical), PG Super Specialty Programme in Urology (M.Ch.), Ph.D. Programme in 14 disciplines and Innovative courses like Fellowship, Diploma and Certificate Courses in Medical and Allied health sciences.

Research becomes the most important priority next to teaching curriculum and health care services, in the medical college on being conferred with the Deemed to be University status. The focus of medical research in BLDE (Deemed to be University) has lead to enhanced MoUs and Collaborations with national and international Universities and research institutes/organizations of repute. A good number of research projects addressing social health care problems for people of Vijayapura district, Karnataka have been taken up with the collaboration of WHO, Bill & Melinda Gate Foundation and NIH, USA, in this regard. To promote research culture in the University, BLDE (Deemed to be University) sponsors a

biannual health sciences journal entitled "*BLDE (Deemed to be University) Journal of Health Sciences* (BJHS)" since 2016 under USA publishing house Wolters Kluwer Ltd. The journal is currently indexed with, DOAJ and Index Copernicus.

BLDE (Deemed to be University) has a social commitment to provide health care facilities to socially backward sections in rural and urban areas of the district. It is worth mentioning that University has established a very well equipped Rural Health Centre in the nearby village from Vijayapur city named Ukkali and the District Disability Rehabilitation Centre (DDRC) is also functioning to help differently abled persons.

The Teaching Hospital is providing the services from Primary Health Care to Tertiary Health Care.

AND WHEREAS, both parties viz. **Morarji Desai National Institute of Yoga** and **BLDE (Deemed to be University)** realize that in the current context, working together is important to promote modern medical science research, Yoga Sciences and Philosophy using facilities and expertise at both the organization. Therefore, both parties are agreeable to enter into an MoU for working and cooperating with each other and using their respective expertise, knowledge, resources and infrastructure.

Article I: Principle of Cooperation

MDNIY and BLDE (DU) agree to develop their academic links especially in the fields of Health Care, Physical, Physiological Well-being, Diet & Nutrition and Life Sciences under the principles of mutual understanding, common interest and mutually complementary other activities:

1. To establish "**Advance Centre of Yoga for Cardiac Prevention and Rehabilitation**" in the premises of BLDE (DU), Smt. Bagaramma Sajjan Campus, Dr B M Patil Road (Solapur Road), Vijayapura (Bijapur)-586103, Karnataka, INDIA.
2. To initiate inter-disciplinary researches and Ph.D. in Allied health sciences (Yoga) and Faculty of medicine, under joint PhD supervision program.
3. To promote inter-disciplinary academic activities, certificate courses, diplomas, skill development etc.
4. To promote institutional and individual contacts among scholars, students and personnel of both the institutions.
5. To provide opportunities for both faculty, scientists, staff and students to make optimal use of the expertise and facilities available in both the organizations through training of faculty/students/staff and through

exchange of thoughts and ideas by brain storming sessions/ workshops/ seminars/ conferences and meetings etc.

6. To work jointly for the common research interest at national and international levels. This includes preparation of proposals and their implementation as per the National Health Priorities.
7. To support the exchange of academic, research and training material.
8. To share experiences, expertise and best practices concerning institutional administration and management.
9. To encourage any other activities that both the institutions/parties agreed upon for mutual benefits.

Article II: Areas of Cooperation

Scientists/Staff working in MDNIY or using MDNIY facilities may be enrolled as full time scholars for Ph.D. programs (Allied Health Sciences) to be awarded by BLDE (DU). The Thesis Supervisor will be a regular faculty of BLDE (DU) / Institute according to the UGC norms whereas Co-Supervisor may be from MDNIY or vice - versa as per recommendations and approval of Research Advisory Committee (SRC/DRC).

1. Research projects on thrust areas like Physical health improvements by Yoga, cope up with hypertension, obesity, cardiovascular disease by Yoga, prevent lifestyle disorders by Yoga, performance enhancement following Yoga, effects of Yoga on geriatric problems, and others related to physiology and allied sciences can be initiated by the proposed "Advance Centre of Yoga for Cardiac Prevention and Rehabilitation" with MDNIY faculty may be one of the principal investigator and one co-investigator from each institute, i.e. one from BLDE (DU) or Institute and other from MDNIY. Both organization design shall be jointly prepared any research project and submitted it to various funding agencies of Govt. of India and Abroad.

2. All eligible faculty members may be recognized as PhD research guide as per university and UGC norms and vice – versa.

3. Ph.D./PG or M Phil students working at BLDE (DU) may carry out a part of their research work in MDNIY institutes/centers and vice-versa depending upon requirements.

4. Ph.D. guides will be from BLDE (DU) and Co-Guides may be from MDNIY and vice–versa as per recommendations of PhD Committee,

BLDE (DU) and approval of BLDE (DU) within the guidelines of UGC, 2016, as amended from time to time.

5. Award of Academic/Research degree will be governed by UGC norms and regulations and BLDE's Act, Statutes, Regulations and Guidelines.

6. MDNIY students / staff and full time scholar working on proposed research center will be allowed to avail a fee concession equivalent to the concession offered to own full-time PhD Scholar of BLDE (DU), other institutes / labs having MoU with BLDE (DU).

7. Scientists and Faculty of BLDE (DU) may deliver lectures in areas of their specialization to students of MDNIY as Visiting Faculty and vice-versa on days and timings pre-arranged on mutual consent. Only TA/ Convenience and local hospitality shall be provided by the organizing Institute.

8. MDNIY/Proposed centers will provide regular short term project training to the students of BLDE (DU) in their areas of specialization and vice versa.

9. MDNIY graduates and postgraduates may visit the research Centre in the BLDE (DU) for Scientific Research Trainings and demonstrations.

10. Outcome of the research data will be shared by both organizations in the form of authorship contributions, joint application of intellectual property right and patenting (if any).

11. Outcome of the research data will be shared by both organizations in the form of authorship contributions, joint application of intellectual property right and patenting (if any).

Article III: Financial Obligation

1. Financial implication for engagement of manpower or research staff and faculty shall be decided mutually or on sharing basis as per financial Rules of Government of India. This would be subject to financial approval by the competent authority of the respective parties, if any required.
2. If fees to be charged to conduct any courses under the centre (s) and engagement of manpower shall be decided mutually.

Article IV: Duration and Termination of the MoU

1. This MoU is effective as of the date of signatures by the Authorities of MDNIY and BLDE (DU).
2. This MoU is valid from the Date of execution by the Parties and shall remain in effect initially for FIVE YEARS, and thereafter it can be renewed with mutual consent of both the parties.
3. This MoU may be amended at any time by written mutual consent.
4. This MoU may be terminated by either party by the provision of written notice of termination not less than three (3) months prior to the desired termination date. However, both parties agree that all continuing obligations to students, staff, funding bodies or other entities are met in full subsequent to the notice of termination.
5. The termination of this MoU shall not affect the rights or obligations of either party regarding any binding offer or firm obligation approved and agreed to either party prior to the termination date.
6. In event of any dispute/s arising between the parties hereto, it shall be endeavour of both the parties to first make an attempt to resolve the dispute amicably by mutual discussion and deliberation, falling which the dispute shall be referred to Arbitration. The Arbitration shall be conducted as per the provisions of Arbitration and Conciliation Act, 1996 and amendments thereto. The Arbitral Tribunal shall consist of Arbitrator(s), to be appointed mutually by both the parties. The Jurisdiction of Arbitration shall be New Delhi. The language of Arbitration shall be English. The Award of the Tribunal shall be final and binding on the both parties.
7. If any dispute arises in discontinue of the MOU, it shall be filed or raised before the Competent Court of Law within the Jurisdiction of Delhi.

Article V: Miscellaneous

1. If any provision of this Memorandum is held by any court or other competent authority to be illegal, void or enforceable in whole or in part, this Memorandum shall continue to be valid as to the other provisions therefore and the remainder of the effected provision.
2. Nothing in this MoU constitutes or to be construed a party as the partner, agent employee or representative of the other party. A party must not act independently of the other Party and does not have the right or power to commit the other Party on any matter or incur any obligation on behalf of or pledge the credit of the other Party without the prior written approval of the other Party.

3. The parties agree to comply with all laws applicable within the jurisdiction of the signatories below.
4. Data generated through such collaborative research will be published in scientific journals jointly.
5. Any IPR generated by collaborative research will be shared jointly.

IN WITNESS Whereof the parties hereto have executed this MoU or caused it to be executed in their names and on their behalf by their duly authorized representatives on the date set forth.

FOR & ON BEHALF OF MDNIY

(Dr. I. V. Basavaraddi)
(Dr. Ishwar V. Basavaraddi)
Director
निदेशक / Director
मोरारजी देसाई राष्ट्रीय योग संस्थान
Morarji Desai National Institute of Yoga
(आयुष मंत्रालय, भारत सरकार)
(AYUSH, Govt. of India)
68, अशोक मार्ग नई दिल्ली-110001
68, Ashok Road, New Delhi-110001

WITNESSES:

1. MD. TAHYAB ALAM, MDNIY

2. P. C. JOSHI
Yoga Officer (MDNIY)

FOR AND ON BEHALF OF BLDE

19-8-2020

(Dr. M. S. Biradar)
Vice-Chancellor
VICE-CHANCELLOR
BLDE (Deemed to be University)
Vijayapura-586103. Karnataka

1. 19/8/2020
Dr Arvind. V. Patil.
Principal
PRINCIPAL
BLDE (Deemed to be University)
Shri B. M. Patil Medical College
Hospital & Research Centre,
VIJAYAPURA-586103.

2.

Kusal K Das
Prof. Kusal K. Das PhD
Laboratory of Vascular Physiology & Medicine
Department of Physiology
BLDE(DU) Shri B M Patil Medical College
Vijayapur-586103 Karnataka India

सत्यमेव जयते

INDIA NON JUDICIAL

Government of Karnataka

Rs. 100

e-Stamp

Certificate No.	:	**IN-KA74895805977270S**
Certificate Issued Date	:	25-Nov-2020 11:38 AM
Account Reference	:	NONACC (FI)/ kacrsfl08/ HSR LAYOUT/ KA-BA
Unique Doc. Reference	:	SUBIN-KAKACRSFL08409251698909 56S
Purchased by	:	CENTER FOR HUMAN GENETICS BANGALORE
Description of Document	:	Article 37 Note or Memorandum
Description	:	MOU
Consideration Price (Rs.)	:	0 (Zero)
First Party	:	SHRI B M PATIL MEDICAL COLLEGE VIJAYAPURA KAR
Second Party	:	CENTER FOR HUMAN GENETICS BANGALORE
Stamp Duty Paid By	:	CENTER FOR HUMAN GENETICS BANGALORE
Stamp Duty Amount(Rs.)	:	100 (One Hundred only)

Authorised Signatory
Karnataka SDDM-CO-OP Society Ltd.
867 Hosa Road, Opp. Chennakeshava
School, Bangalore-560 100.
Mob : 9035304846

CENTER FOR HUMAN GENETICS BANGALORE IN-KA74895805977270S RS. 100 25-NOV-2020 11:38 AM

Please write or type below this line

MEMORANDUM OF UNDERSTANDING (MoU)

FOR
EDUCATIONAL, RESEARCH AND ACADEMIC EXCHANGES

BETWEEN

BLDE
(Deemed to be University)
Constituent College:
Shri B. M. Patil Medical College, Hospital and Research Centre, Vijayapura, Karnataka, India, PIN: 586103

And

CENTRE FOR HUMAN GENETICS
Biotech Park, Electronic City Phase I, Bengaluru 560 100

November 25, 2020

BLDE (Deemed to be University), Vijayapura, Karnataka State was established in 2008, is a single faculty medical sciences Institution with Shri B. M. Patil Medical College, Hospital & Research Centre (established 1986) as its constituent college. This University is sponsored by BLDE Association (established 1910), Vijayapura, Karnataka. BLDE [The vision of the BLDE (Deemed to be University)] and its constituent college is to be a leader and be recognized as an Institution striving for maintenance and enhancement of quality health sciences, education and health care, agrees to enter into this Memorandum of Understanding.

with

Centre for Human Genetics, Biotech Park, Electronic City Phase I, Bengaluru 560 100, registered as a Society under the Karnataka Societies Registration Act, 1960. The Centre for Human Genetics (CHG) is a premier research Centre, whose faculty and students carry out advanced research in different areas of human biology, especially in genetics as it relates to disease.

BLDE (Deemed to be University), Vijayapura, Karnataka State, India is hereinafter referred to as Party 1 and Centre for Human Genetics, Biotech Park, Electronic City, Phase I, Bengaluru is hereinafter referred to as Part 1

A. Background:

Centre for Human Genetics, Bengaluru and BLDE (Deemed to be University), Vijayapura, Karnataka to further cooperation through educational, research and academic exchanges, hereby affirm their intent to promote such cooperation activities as will be of mutual benefit for their respective institutions.

Genetic disorders constitute about 20 percent of pediatric dermatology clinics. Although, genetic disorders related to dermatology have been well characterized, structured clinics involving multi-disciplinary care have been limited in most parts of India. Most of these patients are sent home telling that they do not have a cure, which is actually true. However, most of them have associated medical issues that need to be addressed to have a good quality of life. There are some conditions that are potentially fatal like junctional epidermolysis bullosa, where prenatal testing and counseling becomes relevant. In such cases, it is pertinent to have a laboratory to collect blood and isolate DNA that can be stored for PCR and sequencing later to provide prenatal diagnosis. If this wouldn't be done we would lose the window of opportunity to provide normal babies to childless couples and to prevent such diseases from perpetuating over generations. Geographically, Bijapur is located in the zone where consanguinity is very high and such serious illnesses are highly prevalent. Additionally setting up of such services would bring a new dimension to the already established pediatric dermatology services in the department.

B. Scope of Co-operation & Activities:

1. Setting up of genetics clinic related to dermatology- Focus would be on disorders of keratinization, mechano-bullous diseases, neuro-cutaneous, photosensitivity and immunodeficiency disorders
2. Continuum of care for Genetic disorders through Multi-disciplinary care and sharing of expertise to accomplish the same.
3. In the event of an interesting and scientific project that emerge through this collaboration, BLDE university may consider funding the same

C. Management and Co-operation:

1. The implementation of exchange based on the MoU shall be separately negotiated and determined by both the parties
2. Nothing shall diminish the full autonomy of either University/Centre nor will any constraint or financial obligations be imposed by either upon the other in carrying out MoU.
3. Any notice required to be given under this Agreement by either University/Centre (1 & 2) will be in writing and sent to the other University by either hand delivery or by post.
4. Any collaboration project submitted by two institutions must be approved by the Ethics Committee and Biosafety Committee of both institutions.

D. Terms and Termination:

1. This MoU will be valid for 2 years from the effective date. Thereafter, the renewal of the MoU will be subject to the written agreement between the University and the Centre.
2. The MoU is subject to revision by mutual written agreement by both the parties in writing.
3. Both the parties shall take necessary approvals from the competent authorities for fulfilling the scope of the program on case to case basis
4. It is also understood that, either parties may terminate the MoU for any reason and that any time upon thirty (30) days prior written notice to the other University; although such action will only be taken after mutual consultation to avoid any possible inconvenience to the Universities.
5. The MoU is effective from the date of signing of documents by the representatives of both the University.

Authorise to sign for and on behalf of BLDE (Deemed to be University), Vijayapur, Karnataka, India

Signature:..... Date: 01-12-2020

Name in Capitals: Dr Prof M.S. BIRADAR

Positions in University/Institution: Vice Chancellor

Official seal: VICE-CHANCELLOR
BLDE (Deemed to be University)
Vijayapura-586103. Karnataka

Authorise to sign for and on behalf of Centre for Human Genetics, Biotech Park, Electronic City Phase I, Bengaluru 560 100

Signature:..... Date: 25/11/2020

Name in Capitals: PROF. H. SHARAT CHANDRA

Positions in University/Institution: DIRECTOR

Official seal: CENTRE FOR HUMAN GENETICS BANGALORE

Witness:

For **BLDE (Deemed to be University), Vijayapura, Karnataka, India**

Name: Dr. Aravind V. Patil

Designation: Dean, Faculty of Medicine and Principal

Signature with date: 1/12/20

For **Centre for Human Genetics, Biotech Park, Electronic City Phase I, Bengaluru**

Name: Dr Jayarama S. Kadandale

Designation: professor

Signature with date: Jayaramans