3.1.3 Average Percentage of teachers awarded national/ international fellowship / Financial support for advanced studies / collaborative research / conference participation in Indian and overseas institutions.

Fellowship

KRISHNA INSTITUTE OF MEDICAL SCIENCES "DEEMED TO BE UNIVERSITY", KARAD

This is to certify that

Dr. Shrikant Dalal

is awarded the

Post Doctoral Fellowship in Spine Surgery

after successfully completing the program
at Krishna Institute of Medical Sciences, Karad
from 5th August 2016 to 4th August 2017.

Karad

neelimalele
Vice-Chancellor

PRN FS201601
24th August, 2018

KRISHNA INSTITUTE OF MEDICAL SCIENCES "DEEMED TO BE UNIVERSITY", KARAD

This is to certify that

Dr. Karankumar Singla

is awarded the

Post Doctoral Fellowship in Minimal Access Surgery

after successfully completing the program
at Krishna Institute of Medical Sciences, Karad
from 16th August 2017 to 15th August 2018.

Vice-Chancellor

PRN FS201701
24th August, 2018

KRISHNA INSTITUTE OF MEDICAL SCIENCES "DEEMED TO BE UNIVERSITY", KARAD

This is to certify that

Dr. Vinit Choudhary

is awarded the

Post Doctoral Fellowship in Echocardiography

after successfully completing the program
at Krishna Institute of Medical Sciences, Karad
from 16th August 2017 to 15th August 2018.

Vice-Chancel

PRN FS201702
24th August, 2018

D Y PATIL
DEEMED TO BE
UNIVERSITY
NAVI MUMBAI
(Established under section 3 of the UGC Act, 1956) Re-accredited by NAAC with 'A' Grade

FFO1718029

Certificate

We the Chancellor, Vice Chancellor, and Members of the Board of Management on the recommendation of the Academic Council, Certify that

Dr. Prashant Ashok Punde

has satisfactorily completed the necessary requirements to receive the

Fellowship Program in Forensic Odontology

for the academic year November 2017 - October 2018.

The said Fellowship Certificate has been conferred on his on the 27th Day of October 2018.

In Testimony whereof are set the Seal of the University and the Signatures of the Vice Chancellor and the Program Director.

Program Director

Vice Chancellor

Heart Rhythm Society℠

APHRS

CERTIFICATE *of* COMPLETION

The Heart Rhythm Society and the Asia Pacific Heart Rhythm Society

CERTIFY THAT

Abhijeet Shelke

HAS PARTICIPATED IN AND COMPLETED THE ACTIVITY TITLED

APHRS-HRS Immersion Program

Aurora Health Center
Milwaukee, WI

May 2019

Andrea M. Russo, MD, FHRS
President
Heart Rhythm Society

Chu-Pak Lau, MD
President
Asia Pacific Heart Rhythm Society

APHRS-HRS U.S. Immersion Program 2020 [Closed]

"U.S. Immersion Program - Global Approach to Arrhythmia Expertise"

Heart Rhythm Society℠ (http://www.hrssessions.org/)

Program:

A two-week observational program for established medical doctors with experience in CRM devices and/or ablation, looking to expand their device and ablation expertise.

To be held at a medical institution in the United States, selected by Medtronic, immediately prior to, or post the Annual Heart Rhythm Society Meeting, May 6-9, 2020 in San Diego.

This initiative is co-sponsored by Medtronic and HRS, who have joined together with APHRS to provide this opportunity for Asia-Pacific electrophysiologists. International travel and accommodation at the host centre will be provided by Medtronic. Travel to/from the host centre, accommodation, and registration to the Heart Rhythm 2020 will be provided by HRS.

Eligibility:

- Must be physician in the Asia-Pacific region
- Must be a Regular Member of APHRS

https://aphrs.org/fellowships/aphrs-hrs-immersion-program

Collaborative Research

महाराष्ट्र MAHARASHTRA

AZ 979170

दुय्यम निबंधक कार्यालय, कराड
वि.नं. ५४५५ ता. २६/२/२०१४ किंमत रु. ५०/-
श्री KRISHNA INSTITUTE OF MEDICAL SCIENCES DEEMED UNIVERSITY, KARAD.
Tal. Karad, Dist. Satara. Maharashtra. (India)
☎. 02164 - 241555 to 58
राजाराम भा. पाटील
मुद्रांक विक्रेता, कराड. परवाना क्र. २३०३००६/९८
रा. नांदलापूर, ता. कराड

SUB. TREASURY OFFICE KARA
20 FEB 2014
SUB TREASURY OFFICER KARAD

PPP INTEGRATED COUNSELING AND TESTING CENTRES (ICTCs)

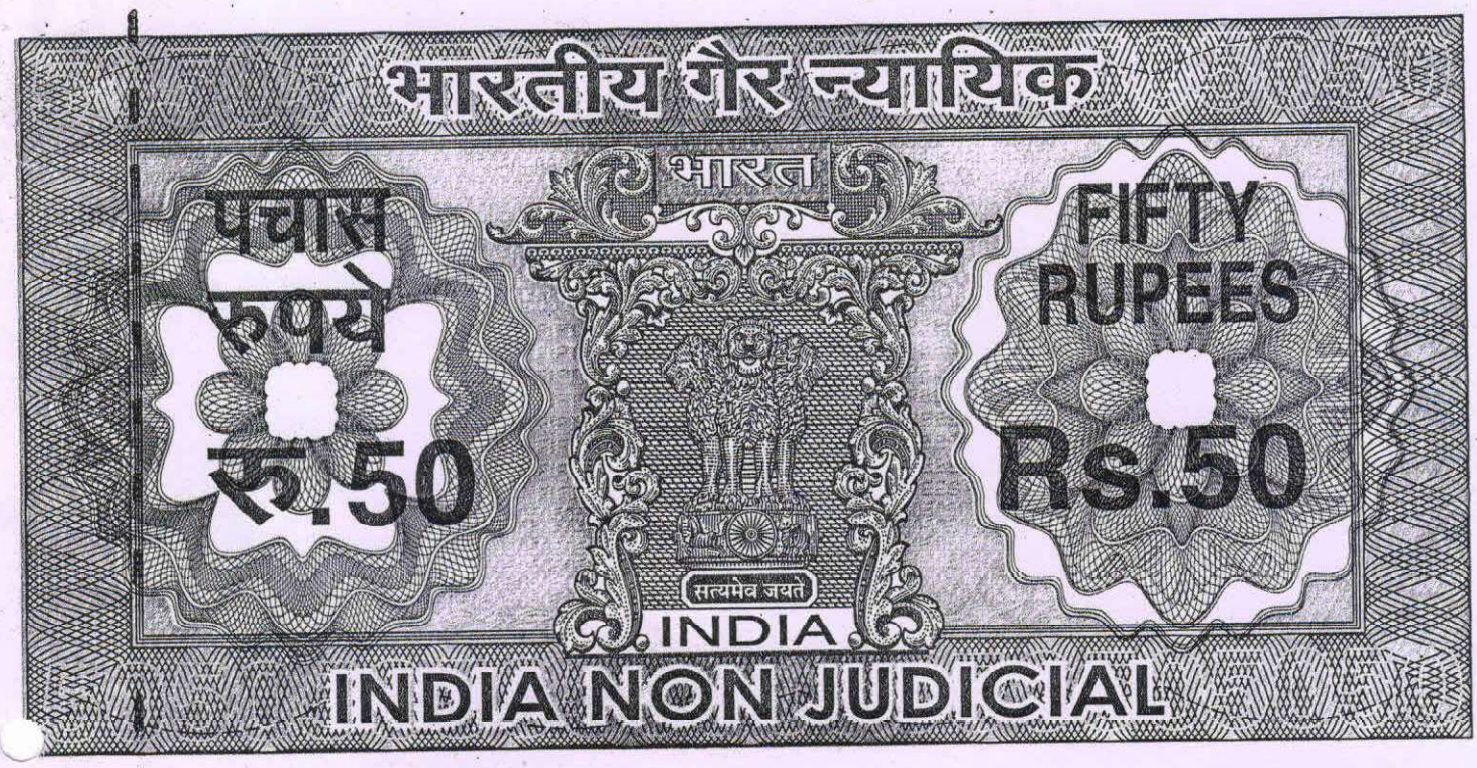
Memorandum of understanding (MOU)
Between
Krishna Institute of Medical Sciences Deemed University, Karad.
&
National AIDS Control Organisation (NACO)
Government of India,

This Memorandum of Understanding is made on 26th **Feb 2014** by and between the Director General, National AIDS Control Organization, Department of Health, Ministry of Health and Family Welfare, Government of India, 9th & 6th Floor, Chandralok Building, 36, Janpath, New Delhi 110 001 (herein referred to as "NACO") on behalf of Project Director of Maharashtra State AIDS control Society, (hereafter referred to as "MSACS"), Dr. Govind Raj, I.A.S, Project Director, Acworth complex, R.A. Kidwai Marg, Wadala, Mumbai -400031

AND

REGISTRAR
Krishna Institute of Medical Sciences,
Deemed University, Karad

Disrtict Programme Officer
DAPCU, Satara.



महाराष्ट्र MAHARASHTRA AZ 979169

दुय्यम निबंधक कार्यालय, कराड
वि.नं. ५४५५ ता. २८/२/२०१४ किंमत रु. ५००
श्री. KRISHNA INSTITUTE OF MEDICAL SCIENCES DEEMED UNIVERSITY, KARAD.
Tal. Karad, Dist. Satara.
Maharashtra. (India)
☎ 02164 - 241555 to 58
राजाराम भा. पाटील
मुद्रांक विक्रेता, कराड. परवाना क्र. २३०३००६/९८
रा. नांदलापूर, ता. कराड

SUB. TREASURY OFFICE KARAD
दस्त सादरीकरण 28 FEB 2014
SUB TREASURY OFFICER KARAD
उप कोषागार अधिकारी

Krishna Institute of Medical Sciences Deemed University, Karad, a facility having its office at Karad in Satara District, acting through **Dr. M.V. Ghorpade, The Registrar, Krishna Institute of Medical Sciences Deemed University, Karad** the authorized signatory, hereinafter referred to as PPP implementer, which expression shall, unless repugnant to the context, include its successor in business, administrators, liquidators and assigns or legal representatives.

I. PURPOSE OF THE COLLABORATIVE PROJECT

The purpose of the agreement is to set up NACO certified facility integrated counseling and testing centre for HIV counseling and testing in a private sector/not for profit /non governmental organizations run health facility through a public private partnership. The aim is to provide access to quality HIV counseling and testing services to clients who access private/not for profit health care system in both urban and rural areas of the country.

REGISTRAR
Krishna Institute of Medical Sciences
Deemed University, Karad

Disrtict Programme Officer
DAPCU, Satara.

It is agreement between NACO (through MSACS), and **Krishna Institute of Medical Sciences Deemed University, Karad** to scaling up Integrated Counseling and Testing Centers (ICTC) / Prevention of Parent To Child Transmission of HIV centers (PPTCT) in state and Private Health facilities (private sector/not for profit /non governmental organizations run health facility Hospitals and nursing homes).

II. RESPONSIBILITIES OF THE SACS / DAPCU:

1. To supply rapid HIV diagnostic kits (3 different antigens/ principles) in quarterly advance as per annual requirement to **Krishna Institute of Medical Sciences Deemed University, Karad** subject to availability of above kits with SACS. While every effort will be made to provide uninterrupted supply of above kits, SACS will not be held responsible for any shortage of above kits due to unforeseen circumstances.
2. To provide training of staff of ICTC (staff of facility) in HIV counseling and testing in NACO approved centers. If required more than one training will be provided by the SACS.
3. To supply protective kits for delivery of HIV positive pregnant woman as per requirement to **Krishna Institute of Medical Sciences Deemed University, Karad.**
4. To provide TA/DA as per eligibility to ICTC staff of **Krishna Institute of Medical Sciences Deemed University, Karad** for attending review meeting conducted by SACS as well for collecting the HIV test kits, registers, formats etc. from the office of the SACS and for transport of coded blood sample or delivery of blood test records from **Krishna Institute of Medical Sciences Deemed University, Karad** to the SRL (State Reference Laboratory-State/district ICTC management authority) under the external quality assurance schemes (EQAS) as laid out in "Operational guidelines for Integrated Counseling and Testing Centre" published by NACO, Ministry of Health & Family Welfare, Govt. of India in July, 2007 or any newer version thereof
5. To supply PEP (Post-exposure Prophylaxis) drugs for protection of staff of ICTC in the event of accidental exposure to **Krishna Institute of Medical Sciences Deemed University, Karad** as per requirement.
6. To supply IEC material required for an ICTC such as flip charts, posters, condom demonstration models, take home materials to **Krishna Institute of Medical Sciences Deemed University, Karad** as per requirement.
7. To supply condoms required for demonstration and distribution to clients coming to the ICTC as per requirement.
8. To supply prophylactic ARV drugs for prevention of transmission from HIV positive mother to their new born babies as per national protocol.
9. To evaluate the performance of the ICTC periodically as per monitoring and evaluation tools developed by NACO/SACS.
10. To provide Registers and Formats as per "Operational guidelines for Integrated Counseling and Testing Centre" published by NACO, Ministry of Health & Family Welfare, Govt. of India in July, 2007 or any newer version thereof.
11. To provide capacity building to the staff of private sector involved in ICTC/PPTCT.
12. Monitoring support whenever required, to ensure smooth functioning of ICTC/ PPTCT in private sector. Nevertheless, also ensure the quality parameter.
13. Support Private Sector ICTC/PPTCT team in record keeping and provide the necessary information to MSACS which can be fed into CMIS format of NACO.

REGISTRAR
Krishna Institute of Medical Sciences,
Deemed University, Karad

Disrtict Programme Officer
DAPCU, Satara.

III. Responsibilities of Krishna Institute of Medical Sciences Deemed University, Karad:

1. To provide a room with suitable, sufficient and convenient space to be used for counseling purpose with adequate furniture, lighting and privacy and any other infrastructure required.
2. To provide a laboratory equipped with refrigerator, centrifuge, micropipette, needle cutter, etc for HIV testing & blood sample storing facility.
3. To designate existing staff or appoint new staff for the posts of counselor and laboratory technician in the ICTC. To also designate an existing Medical Officer as ICTC Manager.
4. To provide consumables such as needles, gloves, syringes, serum storage vials, microtips, etc. of standard quality required for HIV testing to the ICTC.
5. To provide counseling and testing services in the ICTC to any client who approaches the ICTC without discrimination **either freely or on receipt of a charge not exceeding Rs. 75/-** as per protocol laid out in the guideline text per "Operational guidelines for Integrated Counseling and Testing Centre" published by NACO, Ministry of Health & Family Welfare, Govt. of India in July, 2007 or any newer version thereof. The charge will be used to defray cost for provision of the above services.
6. To entirely bear the costs related to staff salary, infrastructure and consumables required for the ICTC.
7. To respect the privacy of clients and maintain confidentiality. Provide data protection systems to ensure that records of all those who are counseled and tested are not accessible to any unauthorized person.
8. **Stand Alone PPP-ICTC (who are conducting three test, both screening and confirmatory test) will do 100% ART linkages of cases found HIV positive in facility.**
9. **Stand Alone PPP-ICTC will follow all ICTC guidelines/ instructions of NACO which ever recently published.**
10. **To provide linkages and referral facilities to all HIV positive cases detected in Stand Alone PPP ICTC center.**
11. To maintain quality assurance at the service delivery especially in HIV testing services as provided in the guideline text "Operational guidelines for Integrated Counseling and Testing Centre" published by NACO, Ministry of Health & Family Welfare, Govt. of India in July, 2007 or any newer version thereof. **Krishna Institute of Medical Sciences Deemed University, Karad** will be accountable for any substandard delivery of services.
12. To participate in EQAS (External Quality Assessment Scheme) as laid out in the above mentioned guideline text. Laboratory In charge, **Krishna Institute of Medical Sciences Deemed University, Karad** will send samples in the first week of every quarter, for cross checking to the SRL (state reference laboratory-state/ district ICTC management authority) once every quarter. The laboratory technician designated by **Krishna Institute of Medical Sciences Deemed University, Karad** to ensure that these samples are collected in the first week of January, April, July and October & sent to the SRL.
13. To provide data and information to the coordinating agency to perform their duties as per the instruction and direction from SACS
14. To send monthly report to the SACS/DAPCU in CMIS format by 5th of every month in registers and records supplied by the SACS.

REGISTRAR
Krishna Institute of Medical Sciences
Deemed University, Karad

District Programme Officer
DAPCU, Satara.

15. To use all the IEC materials, condoms, items required for laboratory use, protective kits for delivery, PEP (post exposure prophylaxis) drugs supplied by the SACS at the service delivery purpose by **Krishna Institute of Medical Sciences Deemed University, Karad.**
16. To maintain stock records for the all items and drugs provided by the SACS.
17. To maintain quality waste management of disposable items that is used in HIV testing.
18. To ensure that staff working in the blood collection room and laboratory will observe universal safety precaution (USP).
19. To ensure that ICTC staff are aware of the PEP procedure and display the name and contact information of the PEP focal point/ person as well as the location where the PEP drugs are stored.
20. To follow the national protocol for ARV prophylaxis for prevention of parent to child transmission of HIV (PPTCT).
21. To attend coordination/review meetings conducted by SACS.
22. To ensure that no research or clinical trials are done on the clients who visit the ICTC or based on data of clients who visit the ICTC's.
23. To attend review meetings at the district level and SACS level as per the supervisory protocol that is provided in the "Operational guidelines for Integrated Counseling and Testing Centre" published by NACO, Ministry of Health & Family Welfare, Govt. of India in July, 2007 or any newer version thereof. To allow access to authorized NACO/SACS/DAPCU staffs who visit the ICTC to the premises and records of the ICTC.
24. To permit SACS to periodically test designated counselor and Lab. Technician for their knowledge, attitude and skills.
25. To follow the testing methodology & algorithm as mentioned in the "Operational guidelines for Integrated Counseling and Testing Centre" published by NACO, Ministry of Health & Family Welfare, Govt. of India in July, 2007 or any newer version thereof, in the laboratory by **Krishna Institute of Medical Sciences Deemed University, Karad**
26. To follow National AIDS Control Policy & State HIV/AIDS policy.
27. Test kits supplied by MSACS not to be used for routine screening of surgical patients of the facility.

IV. COMMENCEMENT

1) This Memorandum of Understanding shall become effective upon signature by the parties and certification of the facility site. It shall remain in full force and effect for a period of one year thereafter.
2) Further, the certification of the site of the collaborative testing project as "NACO/SACS designated HIV counselling and testing centre" shall run concomitantly with the present Memorandum of Understanding.
3) DAPCU will support the private sector in commencement and closely coordinate for smooth rollout.

REGISTRAR
Krishna Institute of Medical Sciences,
Deemed University, Karad

Disrtict Programme Officer
DAPCU, Satara.

V. RENEWAL OF AGREEMENT

1) This Memorandum of Understanding is renewable at the option of **Krishna Institute of Medical Sciences Deemed University, Karad/SACS.**
2) Three months prior to the expiry of the Memorandum of Understanding due to efflux of time SACS shall intimate **Krishna Institute of Medical Sciences Deemed University, Karad** if it intends to renew or not to renew the Memorandum of Understanding.
3) In the event that SACS decides not to renew the Memorandum of Understanding, **Krishna Institute of Medical Sciences Deemed University, Karad** shall give notice to the patients regarding the cancellation of its certification. In the event that SACS decide to renew the Memorandum of Understanding, the terms and conditions of this Memorandum of Understanding, as may be amended, will apply.

VI. TERMINATION OF AGREEMENT

1) Any party may terminate this Memorandum of Understanding after giving three months notice to the other party at the address provided in this Memorandum of Understanding for correspondence or the last communicated for the purpose and acknowledges in writing by other party.

VII. BREACH BY The Registrar, KIMSDU, Karad

1) In case **Krishna Institute of Medical Sciences Deemed University, Karad** is not able to provide services as per agreement or defaults on the provision of this agreement or declines the patient to provide HIV counselling and testing services, it shall be liable for breach of agreement and breach of trust and other consequences which may include black listing with SACS, NACO, MOHFW, Ministry of Home affairs and external affairs.

VIII. SETTLEMENT OF DISPUTES:

1) Any dispute or difference or question arising at any time between the parties hereto arising out of or in connection with or in relation to this agreement shall be referred to and settled by arbitration under the provisions of the Indian Arbitration and Conciliation Act, 1996 or any modification or replacement thereof as applicable for the time being in India.
2) The arbitration shall be referred to an arbitrator nominated by Secretary Department of Legal Affairs, Ministry of Law and Justice, Govt. of India, Delhi. The arbitrator, if he so feels necessary, seek opinion of any healthcare personnel with experience of working in the field of HIV and care and treatment of PLHAs.
3) The place of arbitration shall be either New Delhi or the site of the collaborative laboratory, which shall be decided by the arbitral tribunal bearing in mind the convenience of the parties.
4) The decision of the arbitrator shall be final and binding on both the parties.

REGISTRAR
Krishna Institute of Medical Sciences
Deemed University, Karad

Disrtict Programme Officer
DAPCU, Satara.

VIII. LAW APPLICABLE:

This Memorandum of Understanding shall be construed and governed in accordance with the laws of India.

IX. ADRESSES FOR CORRESPONDENCE

In witness thereof, the parties herein have appended their respective signatures the day and the year above stated.

Signed For and on behalf of The Registrar, Dr. M.V. Ghorpade Krishna Institute of Medical Sciences Deemed University, Karad. Signature ..... Date...26/10/2014 REGISTRAR Krishna Institute of Medical Sciences, Deemed University, Karad In the presence of Name: - Mrs. Bhakti Joshi. Signature Date 26/10/2014	Signed For and on behalf of NACO CS/DPO, DAPCU, _____ MSACS District Programme Officer DAPCU, Satara. Signature ..... Date.....28/10/2014. In the presence of Name Pundlik N. Patil Dist supervisor Signature Date.....28/10/14

KRISHNA INSTITUTE OF MEDICAL SCIENCES "DEEMED TO BE UNIVERSITY", KARAD.

(Declared U/s 3 of UGC Act, 1956 vide Notification No. F.9-15/2001-U.3 of the Ministry of Human Resource Development, Govt. of India.)

Karad, Dist. Satara (Maharashtra State) Pin: 415 110 **Tel: 02164 -241555-58 Fax: 02164 243272/242170**

Website: www.kimsuniversity.in E-mail: contact@kimsuniversity.in

Dr. Asha J. Jadhav
Program Director,
PPTCT-ICTC KIMSDU,
Karad.

This is to certify that following is the financial support for ICTC program at KIMSDU, Karad under PPTCT Program by Maharashtra State AIDS Control Society (MSACS) Mumbai, that is through District AIDS Prevention Control Unit (DAPCU) Satara for the year 2015-2016

Sr. No	Post	Year	Monthly Salary	Yearly Salary	Total Expenses
1	Counselor	2015-2016	14500	174000	174000
2	Lab Technician	2015-2016	12800	153600	153600
3	Kit Use Rs. 205.75*4615	2015-2016	-	-	949536.25
	Total		27300	327600	1277136.25

Jadhav

Program Director,
PPTCT-ICTC KIMSDU,
Karad.

KRISHNA INSTITUTE OF MEDICAL SCIENCES "DEEMED TO BE UNIVERSITY", KARAD.

(Declared U/s 3 of UGC Act, 1956 vide Notification No. F.9-15/2001-U.3 of the Ministry of Human Resource Development, Govt. of India.)

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Sr. No	Post	Year	Monthly Salary	Yearly Salary	Total Expenses
1	Counselor	2016-2017	15500	186000	186000
2	Lab Technician	2016-2017	13000	156000	156000
3	Kit Use Rs. 205.75*5728	2016-2017	-	-	1178536
	Total	2016-2017	28500	342000	1520536

Program Director,
PPTCT-ICTC KIMSDU,
Karad.

KRISHNA INSTITUTE OF MEDICAL SCIENCES "DEEMED TO BE UNIVERSITY", KARAD.

(Declared U/s 3 of UGC Act, 1956 vide Notification No. F.9-15/2001-U.3 of the Ministry of Human Resource Development, Govt. of India.)
Karad, Dist. Satara (Maharashtra State) Pin: 415 110 **Tel: 02164 -241555-58 Fax: 02164 243272/242170**

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Sr. No	Post	Year	Monthly Salary	Yearly Salary	Total Expenses
1	Counselor	2017-2018	16275	195300	195300
2	Lab Technician	2017-2018	13650	163800	163800
3	Kit Use Rs. 205.75*7397	2017-2018	-	-	1521932.75
	Total	2017-2018	29925	359100	1881032.75

Program Director,
PPTCT-ICTC KIMSDU,
Karad.

KRISHNA INSTITUTE OF MEDICAL SCIENCES "DEEMED TO BE UNIVERSITY", KARAD.

(Declared U/s 3 of UGC Act, 1956 vide Notification No. F.9-15/2001-U.3 of the Ministry of Human Resource Development, Govt. of India.)

Karad, Dist. Satara (Maharashtra State) Pin: 415 110 **Tel: 02164 -241555-58 Fax: 02164 243272/242170**

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Dr. Asha J. Jadhav
Program Director,
PPTCT-ICTC KIMSDU,
Karad.

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Sr. No	Post	Year	Monthly Salary	Yearly Salary	Total Expenses
1	Counselor	2018-2019	17500	210000	210000
2	Lab Technician	2018-2019	15200	182400	182400
3	Kit Use Rs. 205.75*9225	2018-2019	-	-	1898043.75
	Total	2018-2019	32700	392400	2290443.75

Program Director,
PPTCT-ICTC KIMSDU,
Karad.

KRISHNA INSTITUTE OF MEDICAL SCIENCES "DEEMED TO BE UNIVERSITY", KARAD.

(Declared U/s 3 of UGC Act, 1956 vide Notification No. F.9-15/2001-U.3 of the Ministry of Human Resource Development, Govt. of India.)

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Dr. Asha J. Jadhav
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Karad.

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Sr. No	Post	Year	Monthly Salary	Yearly Salary	Total Expenses
1	Counselor	2019-2020	20700	248400	248400
2	Lab Technician	2019-2020	16200	194400	194400
3	Kit Use Rs. 205.75*7188	2019-2020	-	-	1478931
	Total	2019-2020	36900	442800	1921731

Jadhav
Program Director,
PPTCT-ICTC KIMSDU,
Karad.

Memorandum of Understanding
for
NARI-AIDS Rural Research in Maharashtra (Project: NARRIM)

This Memorandum of Understanding is drawn between the National AIDS Research Institute, a premier institute devoted to research on HIV infection and AIDS, with its office at G 73 MIDC, Bhosari, Pune, Maharatshtra. (ICMR-NARI) and Krishna Institute of Medical Sciences, deemed to be university, with its office at Karad (KIMSDU) on 19th November 2018.

Title of the Project:
NARI-AIDS Rural Research in Maharashtra (Project: NARRIM)

Genesis
Maharashtra is one of the earliest states to be affected by HIV/AIDS in India and one of the first to be considered as a high prevalence State. The State has a high influx of in-migration from other Indian states and 32 of its 35 districts are 'Category A' districts, connoting high prevalence of HIV and AIDS in the State. Further, while 72% of Indians dwell in rural areas, where the estimated HIV prevalence is only slightly lower than in urban areas and awareness on HIV and related issues is precariously low. Thus, the NARRIM project has been conceptualized to decentralize HIV prevention efforts in rural areas and expand research capacities in these areas.

Brief Description
The Research Project will establish a HIV research centre as an extension of ICMR-NARI in rural Maharashtra in collaboration with local organizations and government bodies to address various aspects of HIV Prevention and Prevention research.

Aims and Objectives

- Build HIV research capacity of ICMR-NARI through:
  - Establishment of Research Centres in the rural areas in collaboration with the State Government offices, NGOs, Medical colleges and State AIDS Control Society
- Study the socio-behavioral and cultural determinants of HIV infection
- Site, community, epidemiology and research preparedness for feasibility of conducting research related to New Biomedical Tools for Prevention of HIV (e.g. Preventive vaccine) in the near future when available.
- Study the transmission dynamics of HIV and immune-pathogenesis among AIDS patients in rural Maharashtra

Term:
This Statement of Work is effective for 5 years and will terminate after the present work-scope.
Total Duration: from 19th November 2018 to 18th November 2023

Collaborating Institutes:

- National AIDS Research Institute (ICMR-NARI), Pune, India
- International AIDS Vaccine Initiative (IAVI), USA

REGISTRAR
Krishna Institute of Medical Sciences
"Deemed To Be University", Karad

DIRECTOR
National AIDS Research Institute
PUNE - 411 026.

NATIONAL AIDS RESEARCH INSTITUTE * I.C.M.R. * PUNE - 411 026.

- Site Medical colleges and research institutions

Project Management and Implementation

Project Overseeing Group (POG)

- Director, ICMR-NARI - (1)
- Country Director, IAVI - (1)
- DG's Nominee, ICMR - (1)
- DG's Nominee, National AIDS Control Organization (NACO) - (1)
- Representatives from Local Partner Research Institutes - (2)

Study Investigators

- Principal Investigator (PI), Dr Seema Sanay ICMR-NARI;
- Co Investigator, Shweta Charath, IAVI;
- Site Principal Investigator (Site PI) Karad site: Dr. Asha Jadhav

Responsibilities

ICMR

- Financial support of the project
- Appoint representatives in the Project Overseeing Group for advisory roles to the project

ICMR-NARI

- Technical leadership of the Research Project
- Establishment of the ICMR-NARI-Rural Research Centres
- Hiring and training of Staff at the Rural Research Centre
- Training of the Research Project Staff for successful implementation of activities for project deliverables
- To establish linkages with local ICTC, ART Centres, DAPCU and NGOs
- Community engagement

IAVI

- Financial support of the project
- Provide technical assistance in :
  - Community Mobilization
  - Interfacing with key local influencers and stakeholders
  - Preparation of Community engagement and Education plans
  - Interacting with General Population, mapping of Most at Risk Population Groups
  - Training of the Research Project Staff
  - Preparation of IEC materials for research literacy

REGISTRAR
Krishna Institute of Medical Sciences
"Deemed To Be University", Karad

DIRECTOR
National AIDS Research Institute
PUNE - 411 026.

NATIONAL AIDS RESEARCH INSTITUTE * I.C.M.R. * PUNE - 411 026.

Local medical colleges

- Provide space for the Research Centre/Clinic at KIMSDU, Karad
- Recruitment of clinical, paramedical and socio-behavioral staff for the centre jointly with ICMR-NARI
- Management of the Research Centre and its day to day activities (data collection, sample collection processing and transport to ICMR-NARI and patient management)
- Provide guidance in procurement of accredited equipments
- Study key behavioral and biological indicators among high risk groups and the general population, with support from ICMR-NARI and IAVI
- With support from ICMR-NARI and IAVI develop
    - informed consent for HIV VCT
    - informed consent process for both literate and illiterate population
    - SOPs for key processes
- With support from ICMR-NARI and IAVI come out with the
    - List of Most at risk and hard to reach population groups
    - Size estimation of these groups
    - Number of geographical pockets for high risk groups and hard to reach populations identified
    - Data and information related to Knowledge, attitude, behaviour and practice of general population in the context of HIV and STI collected.
    - HIV prevalence details among most at risk and general populations in and around Udgir drawn out
- With supervision from ICMR-NARI and IAVI do data collection and management of the above studies
- With ICMR-NARI and IAVI support, generate report and disseminate findings

Outcome/project deliverables

a. Establish the Project Overseeing Group
b. Build sustainable partnerships and collaborations with rural research Institutions, local NGOS and CBOs, existing ICTC and ART Centres and DAPCU.
c. Formation of local Ethics Committee and Community Advisory Boards
d. Development and Implementation of Community Education and Engagement Plans including IEC and BCC materials.
e. Establish a Rural Research Centre with linkages to NACO ART and ICTC centres, with capacity and capability for conducting HIV prevention research.
f. Map most at risk population and develop database on knowledge in rural Maharashtra on attitude, behaviors and for HIV prevention and perceivable issues for research and introduction of New Biomedical Tools for HIV prevention and output of the research literacy conducted.

Indemnities: Neither ICMR-NARI nor KIMSDU will be responsible for omission or commission by the staff associated with respective organizations

REGISTRAR
Krishna Institute of Medical Sciences
"Deemed To Be University", Karad

Krishna Institute of Medical Sciences "Deemed To Be University", Karad

DIRECTOR
National AIDS Research Institute
PUNE - 411 026.

NATIONAL AIDS RESEARCH INSTITUTE * I.C.M.R. * PUNE - 411 026.

Budget and Payment Terms:

National AIDS Research Institute, Pune, India

- Expenditure of NARRIM project will be coordinated by National AIDS Research Institute, Pune, India.
- Purchase of equipment etc for the sites will be done by National AIDS Research Institute, Pune, India.
- Salaries of the staff will be paid from National AIDS Research Institute, Pune, India on 7th working day of each month
- Contingency advance of Rs. 15,000/- will be transferred to the site by ICMR-NARI.
- Contingency bills will be reimbursed to the site against bills/ receipt/ vouchers by the last working day of each month

KRISHNA INSTITUTE OF MEDICAL SCIENCES "DEEMED TO BE UNIVERSITY", KARAD (KIMSDU)
~~Krishna Institute of Medical Sciences, (KIMSDU)~~

- KIMSDU will submit Bills/receipts against contingency advance should reach National AIDS Research Institute, Pune by 25th date of each month for reimbursement of contingency.
- Salary bills and leave details of staff would be submitted by site KIMSDU to ICMR-NARI, Pune, by 25th date of every month.

Any Other Terms

IN WITNESS WHEREOF, the Parties agree to the above stated Program for the Research Project.

For: ICMR – ICMR-NARI

Name: Dr. Samiran Panda
Title: The Director
Date: 27/Dec/2018

डॉ. समीरन पांडा
Dr. SAMIRAN PANDA
निदेशक / Director
राष्ट्रीय एड्स अनुसंधान संस्थान
National AIDS Research Institute
पुणे–411 026. / Pune-411 026.

For: KIMSDU

Name: Dr. M. V. Ghorpade,
Title: The Registrar,
Date

REGISTRAR
Krishna Institute of Medical Sciences
"Deemed To Be University", Karad

NATIONAL AIDS RESEARCH INSTITUTE ★ I.C.M.R. ★ PUNE - 411 026.

REGISTRAR
Krishna Institute of Medical Sciences
"Deemed To Be University", Karad

Krishna Institute of Medical Sciences "Deemed To Be University", Karad

AO
29.3.17

27/3/17

e-75162

INDIAN COUNCIL OF MEDICAL RESEARCH
V. Ramalingaswami Bhawan, Ansari Nagar, New Delhi – 110 029
Phone : 26588980, 26588707, 26589336, 26589745, 26589873
FAX: 011-26588662, 26589791, GRAM : SCIENTIFIC, Web-site:
www.icmr.nic.in, e-mail: icmrhqds@sansad.nin.in

NATIONAL AIDS RESEARCH INSTITUTE ICMR * BHOSARI, PUNE-411 026 *
27 MAR 2017
Inward No. 2865

No.HIV/51/297/2015/ECD-II

Dated: 22/3/17

Subject: Payment of 1st and final installment of grant in aid for the research scheme entitled, "Promoting HIV vaccine Research and Development through tech-transfer and capacity building for HIV immune pathogenesis studies (PHV-NARRIM)" under Dr.Seema Sahay, Scientist F, –

MEMORANDUM

Reference this office letter of even number dated NIL.

The Director General, ICMR sanction the payment of **Rs.25,50,470/- (Rupees Twenty Five Lakh Fifty Thousand Four Hundred and Seventy only)** as the **1st** and final installment of the grant for incurring expenditure in connection with the above mentioned research scheme. The amount **Rs.25,50,470/-** may be debited from the provision of **Rs.25,50,470/-** made for the above research scheme for the current financial year.

A formal bill for **Rs.25,50,470/-** is sent herewith for payment by RTGS to The Director, National AIDS Research Institute, Pune-411026 (Mandate Form is enclosed herewith).

(ARTI CHAWLA)
Administrative Officer
For Director General

Accounts Section- V, ICMR

Copy to: The Director, National AIDS Research Institute, G Block, Plot No.73, MIDC, Bhosari, Pune-411026. An amount of **Rs.25,50,470/-** as the **1st** and final installment will be sent to you by RTGS in due course.

2. IRIS Section
3. Dr.Seema Sahay, Scientist F, National AIDS Research Institute, G Block, Plot No.73, MIDC, Bhosari, Pune-411026
4. Mrs.Vandana, DEO

(ARTI CHAWLA)
Administrative Officer
For Director General

INDIAN COUNCIL OF MEDICAL RESEARCH
V. Ramalingaswami Bhawan, Ansari Nagar, New Delhi – 110 029
Phone : 26588980, 26588707, 26589336, 26589745, 26589873,
FAX: 011-26588662, 26589791, GRAM : SCIENTIFIC, Web-site:
www.icmr.nic.in, e-mail: icmrhqds@sansad.nin.in

No.HIV/51/297/2015/ECD-II

Dated: 22/3/17

NATIONAL AIDS RESEARCH INSTITUTE ★ BHOSARI, PUNE-411 026 ★ 2017 Inward No. 2866

To

The Director,
National AIDS Research Institute,
G Block, Plot No.73, MIDC,
Pune-411 026.

Subject: Sanction of budget allotment for the ICMR Task Force / adhoc New Scheme entitled, "Promoting HIV vaccine Research and Development through tech-transfer and capacity building for HIV immune pathogenesis studies (PHV-NARRIM)": Phase-II Study" under Dr.Seema Sahay, Scientist F,

Dear Sir,

The Director General of the Council sanctions the above mentioned research scheme initially for a period of one year from **25.03.2017** subject to extension up to the total duration specified in para 3 (3) below:

The Director General of the Council also sanctions the budget allotment of **Rs.25,50,470/-** as detailed in the attached statement for one year period ending on **24.03.2018.**

The grant in aid will be given subject to the following conditions:

1. The payment of the grant will be made in lump sum to the Head of the Institute. The first Installment of the grant will be paid generally as soon as report regarding the commencement of the project and appointment of the staff is received by the Council. The demand for payment of the subsequent instalment of the grant should be placed with the Council in prescribed format attached.

2. The staff appointed on the project should be paid as indicated in the budget statement attached.

3. The approved duration of the research scheme is **TWO YEAR**. The annual extension will be given after review of the work done on the research scheme during the previous years.

4. Thirty copies of the annual progress report of work done be submitted to the Council every year after completion of ten months of the project. Failure to submit the report in time may lead to termination of the project.

5. The Institute will maintain a separate account of the receipts and expenditure incurred on the research scheme and will furnish a utilization certificate and an audited statement of the accounts pertaining to the grant.

6. The other terms & condition are indicated on ICMR ***website***.

7. The receipt of the letter may please be acknowledged.

Yours faithfully,

(ARTI CHAWLA)
Administrative Officer
For Director General

1. Copy together with a copy of the budget statement forwarded for information to : Dr.Seema Sahay, Scientist F, National AIDS Research Institute, G Block, Plot No.73, MIDC, Bhosari, Pune-411026
2. Copy together with one copy of the budget statement forwarded to the Account Section – V for information and necessary action.
3. Copy together with copy of the budget forwarded to budget section (Fin.) ICMR for Compilation of the Council's Budget. The **RFC No. ECD/Adhoc/78/2016-17 Dated: 20.3.2017**
4. IRIS Cell No.
5. Mrs.Vandana, DEO

(ARTI CHAWLA)
Administrative Officer
For Director General

"Promoting HIV vaccine Research and Development through tech-transfer and capacity building for HIV immune pathogenesis studies (PHV-NARRIM)": Phase-II Study" under Dr.Seema Sahay, Scientist F,

BUDGET STATEMENT
25.03.2017 TO 24.03.2018
(2016-17)

Sl.No.	Item	1st Year
I.	Staff	Amt. in Rs.
1.	Research Assistant@ Rs.31000/- p.m.x12x2	744000
2.	Staff Nurse @ Rs.31500/- p.m.x12x1	378000
3.	Lab. Technician @ Rs.18000/- p.m.x12x1	216000
4.	Field Worker @ Rs.18000/- p.m.x12x1	216000
5.	MTS @ Rs.15800/- x12x1	189600
II.	Consumables	
1.	Vaccutainers, needles etc. blood drawing cost	532500
2.	Clinic consumables – gloves	121870
3.	Laboratory consumables	152500
	Total	**2550470**

No. ECD/Adhoc/78/2016-17
Dated: 20.3.2017
No.HIV/51/297/2015/ECD-II

E/A13 26/3/18

A/o & Dr Seema Sahay for attention & necessary action

e-75162

INDIAN COUNCIL OF MEDICAL RESEARCH
V. Ramalingaswami Bhawan, Ansari Nagar, New Delhi – 110 029
Phone : 26588980, 26588707, 26589336, 26589745, 26589873,
FAX: 011-26588662, 26589791, GRAM : SCIENTIFIC, Web-site:
www.icmr.nic.in, e-mail: icmrhqds@sansad.nin.in

No.HIV/51/297/2015/ECD-II Dated: 22/3/18

Subject: Payment of 1st installment of grant in aid for the research scheme entitled, "Promoting HIV vaccine Research and Development through tech-transfer and capacity building for HIV immune pathogenesis studies (PHV-NARRIM)" under Dr.Seema Sahay, Scientist F –

NATIONAL AIDS RESEARCH INSTITUTE ICMR ★ BHOSARI, PUNE-411 026. ★ 26 MAR 2018 Inward No. 3424

MEMORANDUM

Reference this office letter of even number dated NIL.

The Director General, ICMR sanction the payment of **Rs.23,63,800/- (Rupees Twenty Three Lakh Sixty Three Thousand Eight Hundred only)** as the **1st** installment of the grant during the 3rd and final year for incurring expenditure in connection with the above mentioned research scheme. The amount **Rs.23,63,800/-** may be debited from the provision of **Rs.26,63,800/-** made for the above research scheme for the current financial year.

An amount of **Rs.16,08,237/-** is already available with the PI as unspent balance of the grant released during the previous year. A formal bill for **Rs.23,63,800/-** is sent herewith for (i) adjustment of **Rs.16,08,237/-** (ii) for payment of **Rs.7,55,563/-** by RTGS to The Director, National AIDS Research Institute, Pune-411026 (Mandate Form is enclosed herewith).

(ARTI CHAWLA)
Administrative Officer
For Director General

Accounts Section- V, ICMR

Copy to: The Director, National AIDS Research Institute, G Block, Plot No.73, MIDC, Bhosari, Pune-411026. An amount of **Rs.23,63,800/-** as the **1st** installment will be sent to you by RTGS in due course.

2. IRIS Section
3. Dr.Seema Sahay, Scientist F, National AIDS Research Institute, G Block, Plot No.73, MIDC, Bhosari, Pune-411026
4. Mrs.Vandana, DEO

(ARTI CHAWLA)
Administrative Officer
For Director General

INDIAN COUNCIL OF MEDICAL RESEARCH
V. Ramalingaswami Bhawan, Ansari Nagar, New Delhi – 110 029
Phone : 26588980, 26588707, 26589336, 26589745, 26589873,
FAX: 011-26588662, 26589791, GRAM : SCIENTIFIC,
Web-site: www.icmr.nic.in, e-mail: icmrhqds@sansad.nin.in

No.HIV/51/297/2015/ECD-II

Dated: 22/3/16

To

The Director,
National AIDS Research Institute,
G Block, Plot No.73, MIDC,
Pune-411 026.

Subject: Sanction of continuation with budget allotment for the ICMR adhoc Scheme entitled, "Promoting HIV vaccine Research and Development through tech-transfer and capacity building for HIV immune pathogenesis studies (PHV-NARRIM)": Phase-II Study" under Dr.Seema Sahay, Scientist F,

Dear Sir,

The Director-General of the ICMR accords sanction for adhoc continuation with an allotment of **Rs.26,63,800/- (Rupees Twenty Six Lakh Sixty Three Thousand and Eight Hundred only)** as detailed in the attached budget statement for the above mentioned project for a period w.e.f. **25.03.2018 to 24.03.2019** during the year 2017-18 subject to the following conditions :-

1. The grant will be released to the head of the Institute in two instalments during the financial year on receipt of the demand in the prescribed from (Appendix-I) as indicated below :-

1st instalment	**Rs.23,63,800/-**	
2nd instalment	**Rs. 3,00,000/-**	**(The 2nd and final instalment will be released on receipt of final SOE/Final report)**
Total	**Rs.26,63,800/-**	

While asking for the release of the instalment, it may be ensured that the amount for the pay and allowances of the staff who are actually in position is included. The unspent balance available as on 24.3.2018 out of the funds paid during the year 2016-2017 should be intimated. This will be adjusted against the current year's grant.

A separate account for the grant received and expenditure incurred shall be maintained. The account will be subjected to audited by the authorized auditors of the Institute. In case, facilities are not available for such auditing, the account will be audited by the Council's own internal auditors. Latest by the end of December, following the financial year for which the grant is paid, and audit certificate from the auditors to the effect that the accounts have been audited

and that the money was actually spent on the objects for which it was sanctioned shall be submitted to the Council alongwith a list of non-expendable articles purchased out of the grant during the year. Any unspent balance would be refunded to the ICMR on termination of the scheme.

Further grants will be stopped unless audited statements of accounts and utilization certificates are received within a period of the year after the end of the financial year for which grant was sanctioned.

3. The last instalment of the grant will be paid on receipt of the audited certificate which should include all the liabilities of last year, expenditure incurred before but the defrayed after termination of the scheme. The prior to which the expenditure pertains should be shown clearly.

4. The grant will not be regarded as a subvention, towards the normal work of the Institution but should be exclusively utilized for the research activity for which it has been sanctioned.

5. Expenditure should on no account exceed the allotment sanctioned for the enquiry. Expenditure incurred over and above the sanctioned amount against one or more subheads of expenditure such as pay, allowances, contingencies etc. shall be met without reference to the ICMR by re-appropriation of savings under remaining sub-heads provided that the total expenditure incurred during the financial year.

No expenditure shall however, be incurred by re-appropriation of savings on items not sanctioned by the Council i.e. non-consumable equipment, stores not sanctioned by the Council savings shall also not be re-appropriated for meeting on incurring expenditure on staff that has not been sanctioned by the Council.

6. The grant paid by the Council shall be refunded in full by the institute if and when the grantee concerned discontinuous a scheme midway or does not follow the detailed technical programme laid down and approved.

7. Receipt, released by the Project Officer on behalf of ICMR project, if any, will be remitted to the Council as miscellaneous receipt and not utilized for meeting expenditure of the project.

8. All facilities for conduct of the research scheme basic equipment and ordinary laboratory chemicals, glassware, furniture and other assistance, as may be required for the smooth working of the research scheme, shall be provided by the Institute.

9. The stores purchased out of the grant of the Council shall be entered in the property/stock register and presented auditors for check and endorsement. The usual forms used for these registers and all purchases made in accordance with the procedure in vogue in your institution.

10. Only such equipment for which provision has been made in the budget shall be purchased.

11. All the non-expendable articles purchased out of the funds of the Council will be the property of the Council and will not be disposed of without their concurrence.

staff:

12. The staff employed on the research schemes will not be the Council's employee but for all purposes be treated as employees of the Institute and will be subject to the rules and administrative control of the Institute.

The scales of pay, allowances etc. applicable to the staff of the schemes will be the same as admissible under the rules of the grantee Institution.

Prior approval of the Council will however, be necessary if any higher than that admissible under the rules of the Institution is sought to be given e.g. by grant of advances increments or ad-hoc increase.

13. The council will not be liable to bear any expenditure pension/provident fund contribution and or leave salary contribution incurred or committed by the grantee for persons appointed on deputation from any other organization.

Report of Work Done

14. The grant is being sanctioned on the condition that reports on the progress of work done on the research scheme will be submitted by you to the Council as and when called for. Normally a progress report of work done on the enquiry is to be submitted to the Council as and when required, the enquiry may be discontinued immediately unless there is sufficient justification for non-submission of the report of work done on the research scheme.

Publication

15. The financial assistance rendered by the Council will be acknowledge in any published account of work for which the grant is given.

16. A list of papers published based on the work carried out on enquiry under the auspices of the ICMR shall be submitted annually alongwith reprints of the papers. Prior permission of the Council shall be obtained before publication of any such paper in a foreign journal.

Patents

17. The Council shall have the right to take out patent in respect of invention/discoveries made under schemes project financed by the Council. The Officer-in-Charge or the staff employed on ICMR scheme shall not apply or obtain patents for any invention/ discovery made by them without prior approval of the Council.

18 All the patents will be registered in the name of the Indian Council of Medical Research Termination of Research Scheme

19. Prior permission of the Council shall be obtained if the investigator desires to discontinue the research scheme. The reasons for discontinuing the scheme should invariably be stated.

20. A final report is required to be submitted within one month from the date of termination of the research.

21. A list(in duplicate) of non-expendable and expendable article together with property registers and suggestions for disposal of the articles should be sent to the Council within a month from the date of termination of the research scheme.

The receipt of this letter may kindly be acknowledged.

Yours faithfully,

(ARTI CHAWLA)
Administrative Officer
For Director General

1. Copy together with a copy of the budget statement forwarded for information to : Dr.Seema Sahay, Scientist F, National AIDS Research Institute, G Block, Plot No.73, MIDC, Bhosari, Pune-411026
2. Copy together with one copy of the budget statement forwarded to the Account Section – V for information and necessary action.
3. Copy together with copy of the budget forwarded to budget section (Fin.) ICMR for Compilation of the Council's Budget. The **RFC No. ECD/Adhoc/78/2016-17 Dated: 20.3.2017**
4. IRIS Cell No.
5. Mrs.Vandana, DEO

(ARTI CHAWLA)
Administrative Officer
For Director General

HIV/AIDS/ADHOC

"Promoting HIV vaccine Research and Development through tech-transfer and capacity building for HIV immune pathogenesis studies (PHV-NARRIM)": Phase-II Study" under Dr.Seema Sahay, Scientist F,

BUDGET STATEMENT
25.03.2017 TO 24.03.2018
(2016-17)

Sl.No.	Item	1st Year
I.	Staff	Amt. in Rs.
1.	Research Assistant@ Rs.32350/- p.m.x12x2	776400
2.	Staff Nurse @ Rs.32890/- p.m.x12x1	394680
3.	Lab. Technician @ Rs.18800/- p.m.x12x1	225600
4.	Field Worker @ Rs.18800/- p.m.x12x1	225600
5.	MTS @ Rs.16500/- x12x1	198000
II.	Consumables	
1.	Vaccutainers, needles etc. blood drawing cost	553400
2.	Clinic consumables – gloves	126620
3.	Laboratory consumables	163500
	Total	2663800

No. ECD/Adhoc/78/2016-17
Dated: 20.3.2017
No.HIV/51/297/2015/ECD-II

KRISHNA INSTITUTE OF MEDICAL SCIENCES "DEEMED TO BE UNIVERSITY", KARAD.
(Declared U/s 3 of UGC Act, 1956 vide Notification No. F.9-15/2001-U.3 of the Ministry of Human Resource Development, Govt. of India.)
Karad, Dist. Satara (Maharashtra State) Pin: 415 110 Tel: 02164-241555-58 Fax: 02164 243272/242170
Website: www.kimsuniversity.in E-mail: contact@kimsuniversity.in

PHV Project: - Promoting of HIV Vaccine Research and Development through tech-transfer and capacity building for HIV Immune-Pathogenesis Studies.

Project initiated in year 2017-2018 at KIMSDU, Karad for 5 years.

Project continued in year 2017-2018, 2018-2019.

The project was funded by IAVI, ICMR-NARI Budget was sanctioned as Rs.25,50,470 and Rs. 26,63,800/- which was received at NARI Pune, KIMSDU being the implementing partner for this project program.

The project was terminated in 2019 since it was continued as COHRPICA study Principal Investigator, Dr. Jadhav and Co-PI Dr. Karande – Microbiology copy of the sanctioned budget is enclosed herewith.

Site Principal Investigator

NATIONAL REFERRAL CENTRE FOR LEAD PROJECTS IN INDIA

ST JOHNS NATIONAL ACADEMY OF HEALTH SCIENCES
BANGALORE 560035

Ref: NRCLPI/RC/PROJ/02/2014 Date: 12 / 08 / 2014

To:
Dr. Arun J. Patil
Professor in Biochemistry
Krishna Institute of Medical Sciences "Deemed To Be University", Karad

Subject: Disbursement of Research Project Fund

Dear Dr,

I am pleased to inform you that UNDERWRITERS LABORATORIES (UL), USA has sanctioned an amount of Rs. 25 Lacs for Lead project in India [Estimation of lead from water, cosmetics, paints and traditional medicine and this amount will be equally disbursed to the following five Lead Referral Laboratories with a share of 5 lacs for each of the laboratories in stages with the progress made by each of the centre.

1. South Central at NRCLPI Chief Dr. Anita Bijoor, PhD HOD Biochemistry,
2. South Western at Karad in Maharashtra Dr. Arun Patil, PhD
3. Central at Lucknow, Dr. Abbas at KGMU PhD
4. Northern at Delhi, Dr. L. M. Srivastava is the chief coordinator PhD
5. North Western sector at AIIMS Jodhpur, Dr. Praveen Sharma PhD is the chief coordinator

With regards

Prof. Thuppil Venkatesh, Chairman
National Chairman "Indian Society for Lead Awareness & Research" [InSLAR], Lucknow
National Director "National Referral Center for Lead Projects in India" [NRCLPI], Bengaluru
Bengaluru

Govt.of Maharashtra, Health Services
Jt.Director of Health Services (Leprosy & TB)
"AROGYA BHAVAN" Opp. Vishrantwadi Police Station,
Alandi Road, Yerwada, Pune-411006.

Jt.Director - ☎ (020) 26686955
Dy.Director - 26686951
Office - 26686952-54
Fax – 26686956

Section wise e-mail
TB section- stomh@rntcp.org
Lep section - jtlepnms@rediffmail.com
Est section - jdhsest99@gmail.com

No.Jt.DHS/TB&L/ Desk-RNTCP/OR Proposal/ 24325-30
Date 11/8/2016

To,
The Dean,
Krishana Hospital and Medical Research Centre,
Karad

Sub:- Sanction of grant-in-aid for Operational Research proposal of Dr. Vijay D. Nair, Assistant Professor Under RNTCP.

Ref:- The State Operational Research Committee meeting held on 23rd April, 2016 at Disha Hall, Parivartan Building, Arogya Bhavan, Pune.

The following Operational Research proposal submitted by the Principal Investigator (PI) of your institute was discussed in State Operational Research Committee Meeting held on 23rd April, 2016 under RNTCP and it has been approved.

Sr. no	Name of the PI	Name of the Department & Medical College	Topic
1	Dr. Vijay D. Nair, Assistant Professor	Department of Medicine, Krishana Hospital and Medical Research Centre, Karad	Cross sectional study on the health related quality of life in patients who complete treatment for pulmonary TB.

The Principal Investigator (PI) will sign a Memorandum of Undertaking (MOU) with the TB programme manager on behalf of the society for the release of funds. The MOU will include the objects for which he will utilize the funds and the timeline for the study. It will also include the commitment from him to return the funds if the study cannot be taken up due to any reason, and other relevant causes. Funds will be released on the name of the institution of the Principal Investigator, so that the College / Department can ensure the study of its completion / return the funds in the event that the Principal Investigator is moved from the college during the course of the study. A Grant-in-aid of **Rs. 24,720 (Rs. Twenty Four Thousand Seven hundred twenty only)** for the above OR proposal will be released from the "Medical College Budget Head" from RNTCP funds by District TB Officer, Satara. 50% of the grant-in-aid will be released initially and remaining 30% after

receiving the report of data analysis and 20% will be released after receipt of the four hardcopies of the final documents.

Joint Director of Health Services
(Leprosy & TB) Pune

Copy to –

1. The DTO Satara– To follow up with the respective medical college & Principal Investigator and release the grant-in-aid amount from the "Medical College Budget Head" from RNTCP funds as per the guidelines.

2. The Principal Investigator–
   Dr. Vijay D. Nair, Assistant Professor, Department of Medicine, Krishana Hospital and Medical
   Research Centre, Karad
3. The RNTCP Medical Consultants by email – mhconsultants@rntcp.org
4. The OR Committee Members ..—(All)

Copy with complements to –
Dr. N. N. Ramraje, HOD & Professor Dept of Chest and TB, J. J. Hospital Mumbai & State Task Force Chairperson, Maharashtra.

Govt.of Maharashtra, Health Services
Jt.Director of Health Services (Leprosy & TB)
"AROGYA BHAVAN" Opp. Vishrantwadi Police Station,
Alandi Road, Yerwada, Pune-411006.

Jt.Director - ☎ (020) 26686955
Dy.Director - 26686951
Office - 26686952-54
Fax – 26686956

Section wise e-mail
TB section- stomh@rntcp.org
Lep section - jtlepnms@rediffmail.com
Est section - jdhsest99@gmail.com

No.Jt.DHS/TB&L/ Desk-RNTCP/OR Proposal/ /16
Date 11/8/2016
24331-36

To,
The Dean,
Krishana Hospital and Medical Research Centre,
Karad

Sub:- Sanction of grant-in-aid for Operational Research proposal of Dr. Asha Prathinidi, Director of Research Under RNTCP.

Ref:- The State Operational Research Committee meeting held on 23rd April, 2016 at Disha Hall, Parivartan Building, Arogya Bhavan, Pune.

The following Operational Research proposal submitted by the Principal Investigator (PI) of your institute was discussed in State Operational Research Committee Meeting held on 23rd April, 2016 under RNTCP and it has been approved.

Sr.no	Name of the PI	Name of the Department & Medical College	Topic
1	Dr. Asha Prathinidi Director of Research	Department of Medicine, Krishana Hospital and Medical Research Centre, Karad	Identifying predictors of treatment outcome in TB.

The Principal Investigator (PI) will sign a Memorandum of Undertaking (MOU) with the TB programme manager on behalf of the society for the release of funds. The MOU will include the objects for which she will utilize the funds and the timeline for the study. It will also include the commitment from her to return the funds if the study cannot be taken up due to any reason, and other relevant causes. Funds will be released on the name of the institution of the Principal Investigator, so that the College / Department can ensure the study of its completion / return the funds in the event that the Principal Investigator is moved from the college during the course of the study.

A Grant-in-aid of **Rs. 1,26,100 (Rs. One lac Twenty Six Thousand One Hundred only)** for the above OR proposal will be released from the "Medical College Budget Head" from RNTCP funds by District TB Officer, Satara. 50% of the grant-in-aid will be released initially and remaining 30% after

receiving the report of data analysis and 20% will be released after receipt of the four hardcopies of the final documents.

Joint Director of Health Services
(Leprosy & TB) Pune

Copy to –

1. The DTO Satara – To follow up with the respective medical college & Principal Investigator and release the grant-in-aid amount from the "Medical College Budget Head" from RNTCP funds as per the guidelines.
2. Dr. Asha Prathinidi, Director of Research, Department of Medicine, Krishana Hospital and Medical Research Centre, Karad
3. The RNTCP Medical Consultants by email – mhconsultants@rntcp.org
4. The OR Committee Members ..... (All)

Copy with complements to –
Dr. N. N. Ramraje, HOD & Professor Dept of Chest and TB, J. J. Hospital Mumbai & State Task Force Chairperson, Maharashtra.

Govt.of Maharashtra, Health Services
Jt.Director of Health Services (Leprosy & TB)
"AROGYA BHAVAN" Opp. Vishrantwadi Police Station,
Alandi Road, Yerwada, Pune-411006.

Jt.Director - ☎ (020) 26686955
Dy.Director - 26686951
Office - 26686952-54
Fax – 26686956

Section wise e-mail
TB section- stomh@rntcp.org
Lep section - jtlepnms@rediffmail.com
Est section - jdhsest99@gmail.com

No.Jt.DHS/TB&L/ Desk-RNTCP/OR Proposal/ /16
Date - 12/04/2016
11181 24337-42

To,
The Dean,
Krishana Hospital and Medical Research Centre,
Karad

Sub:- Sanction of grant-in-aid for Operational Research proposal of Dr. Vaishali Raje, Professor Under RNTCP.

Ref:- The State Operational Research Committee meeting held on 23rd April, 2016 at Disha Hall, Parivartan Building, Arogya Bhavan, Pune.

The following Operational Research proposal submitted by the Principal Investigator (PI) of your institute was discussed in State Operational Research Committee Meeting on 23rd April, 2016 under RNTCP and it has been approved.

Sr.no	Name of the PI	Name of the Department & Medical College	Topic
1	Dr. Vaishali Raje, Professor	Dept. of Community Medicine, Krishana Hospital and Medical Research Centre, Karad	Tuberculosis case detection in high risk population in context to Migrants.

The Principal Investigator (PI) will sign a Memorandum of Undertaking (MOU) with the TB programme manager on behalf of the society for the release of funds. The MOU will include the objects for which she will utilize the funds and the timeline for the study. It will also include the commitment from her to return the funds if the study cannot be taken up due to any reason, and other relevant causes. Funds will be released on the name of the institution of the Principal Investigator, so that the College / Department can ensure the study of its completion / return the funds in the event that the Principal Investigator is moved from the college during the course of the study.

A Grant-in-aid of **Rs. 1,08,000 (Rs. One lac Eight Thousand only)** for the above OR proposal will be released from the "Medical College Budget Head" from RNTCP funds by District TB Officer, Satara.

50% of the grant-in-aid will be released initially and remaining 30% after receiving the report of data analysis and 20% will be released after receipt of the four hardcopies of the final documents.

Joint Director of Health Services
(Leprosy & TB) Pune

Copy to –

1. The DTO Satara – To follow up with the respective medical college & Principal Investigator and release the grant-in-aid amount from the "Medical College Budget Head" from RNTCP funds as per the guidelines.
2. Dr. Vaishali Raje, Professor Department of Medicine, Krishana Hospital and Medical Research Centre, Karad
3. The RNTCP Medical Consultants by email – mhconsultants@rntcp.org
4. The OR Committee Members ..... (All)

Copy with complements to –
Dr. N. N. Ramraje, HOD & Professor Dept of Chest and TB, J. J. Hospital Mumbai & State Task Force Chairperson, Maharashtra.

भारतीय गैर न्यायिक

भारत INDIA

रु. 500 FIVE HUNDRED RUPEES

पाँच सौ रुपये Rs. 500

सत्यमेव जयते

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Agmt

National Aids Research Inst

Vamp Sangli Bhosari Pune

Tumankahendra

500

3394 दि. 26.3.19

T. Chatendra

The Pune Lawyers Consumer's Co-op Society Ltd., Pune-5 LIC No.: 2201111

संमती पत्र (MOU)

दोघांमध्ये

राष्ट्रीय एड्स अनुसंधान संस्थान (ICMR-NARI)

आणि

वेश्या एड्स मुकाबला परिषद (VAMP)

एचआयव्ही / एड्स संशोधन आणि विकास क्षेत्रात सहकार्यासाठी

सदर संमती पत्र खालील / पुढील नमूद केलेल्या दोन संस्थांमध्ये आहे:

मायां ३/२४

Dr Seema Sahay WITNESS FROM ICMR-NARI & INVESTIGATOR COMPRICA

मायां ३/२४

Dr. Seema Sahay WITNESS FROM ICMR-NARI & INVESTIGATOR COMPRICA

आय.सी.एम.आर - राष्ट्रीय एड्स अनुसंधान संस्थान - (ICMR-NARI): जी-73, एमआयडीसी, भोसरी, पुणे, महाराष्ट्र येथील एचआयव्ही संसर्गावर आणि एड्सवर संशोधन करण्यासाठी समर्पित व अग्रणी असलेली संस्था.

<u>आणि</u>

वेश्या एड्स मुकाबला परिषद (VAMP): हि परिषद सध्या वेश्या अन्याय मुक्ती परिषद म्हणूनही ओळखली जाते, वाढत्या एचआयव्ही / एड्स चळवळीच्या अनुषंगाने, सन १९९६ मध्ये स्थापन झालेले हे संघटन वेश्या व्यवसाय करणाऱ्या महिलांसाठीचे आहे. या परिषदेचे कार्यालय बाल जगत, बालाजी नगर, कुपवाड रोड, सांगली, महाराष्ट्र येथे असून, हि परिषद या महिलांच्या प्रश्नांचे व अधिकारांचे सक्षमीकरण करण्याचा दृष्टीकोन बाळगते.

ICMR-NARI ची स्थापना ऑक्टोबर १९९२ मध्ये झाली आणि तेव्हापासून एचआयव्ही/एड्स विरुद्धच्या लढ्यात या संस्थेने गुणवत्तापूर्ण संशोधन करून वैद्यकीय अभ्यासांद्वारे उपचार आणि काळजीसाठी अनुकूलता निर्माण केली. भारतातील प्रचलित एचआयव्ही-१ उपप्रकार-सी संसर्गासंदर्भात, प्रतिबंधासाठी नवनवीन पद्धतींचा विकास आणि परीक्षण करून एचआयव्ही ची नवीन जीवशास्त्रीय माहिती सिद्ध केली आहे. ही संस्था आपल्या विविध उपक्रमांद्वारे, मुख्यतः देखरेख, क्षमता निर्मिती, प्रयोगशाळा सेवा व औषध प्रतिरोधनाच्या माध्यमातून राष्ट्रीय एड्स नियंत्रण कार्यक्रमास योग्य ती मदत करीत आहे.

संस्थेच्या संशोधन उपक्रमांचे मार्गदर्शन एका वैज्ञानिक सल्लागार समितीद्वारे केले जाते ज्यामध्ये विविध विषयांवरील प्रख्यात शास्त्रज्ञांचा समावेश आहे. ICMR-NARI ची संस्थात्मक नैतिक समिती संस्थेचे सर्व प्रकल्प काळजीपूर्वक अभ्यासते व मंजूर करते तसेच उच्च नीतिमत्तेच्या आधारावर संशोधनाच्या कार्याची पडताळणीही करते.

वेश्या एड्स मुकाबला परिषद (VAMP) हे वाढत्या एचआयव्ही / एड्स चळवळीच्या अनुषंगाने, सन १९९६ मध्ये स्थापन झालेले हे संघटन वेश्या व्यवसाय करणाऱ्या महिलांसाठीचे आहे जे या महिलांसाठी सामान्यत: साधनभूत दृष्टीकोन ठेवते. वेश्या व्यवसाय करणाऱ्या स्त्रियांची हळूहळू एक सामान प्रतिमा / ओळख बनविणे, त्यांना एकसंध / संघटित ठेवणे, त्यांच्या अधिकारांसंबंधी जागरूक करणे तसेच एचआयव्ही च्या संसर्गापासून स्वत:चा बचाव करण्यास सक्षम करणे असे उद्दिष्ट आहे.

येथून पुढे ICMR-NARI व VAMP ला एकवचनात "पार्टी" तर बहुवचनात "पक्ष" म्हणून संबोधले जाईल.

माया सुरत

Dr. Seema Sahay WITNESS FROM ICMR-NARI & INVESTIGATOR COURPICA

पार्श्वभूमी

भारत सरकारच्या विविध मंत्रालयांद्वारे राष्ट्रीय एड्स नियंत्रण संस्था (NACO), बायोटेक्नॉलॉजी विभाग (DBT) आणि ICMR विभाग यांच्या संयुक्त प्रयत्नांद्वारे भारताने एचआयव्ही-महामारी नियंत्रित करण्यासाठी लक्षणीय प्रयत्न केले आहेत. तरीसुध्दा महामारीच्या बदलत्या स्वरूपामुळे नवीन आव्हाने निर्माण झाली आहेत. प्रगती चालू ठेवण्यासाठी आणि महामारीचा उन्मूलन करण्याचा वेग वाढविण्यासाठी भारताने वैज्ञानिक प्रगती करणे आवश्यक आहे.

या दिशेने, 2017 साली भारतीय बाल व प्रौढांमध्ये एचआयव्ही प्रतिकार आणि प्रगती यांच्या अभ्यासासाठी (CoHRPICA) प्रोग्राम मधील कोहॉर्टस् द्वारे, भारतातील स्वारस्य असलेल्या एचआयव्हीच्या पद्धतशीर आणि संरचित अभ्यासाचे अशा प्रकारचे प्रथम राष्ट्रव्यापी प्रयत्न सुरू झाले. हा कार्यक्रम खुला-प्रतिसादात्मक अभ्यास (open-ended study) असून डी.बी.टी., आय.सी.एम.आर. आणि आय.ए.व्ही.आय. यांच्या नेतृत्वाने आणि NACO च्या सहभागाने केला जाणार आहे. या संशोधनात उत्कृष्ट दर्जाच्या आठ राष्ट्रीय संस्था एकत्र येणार आहेत. अति जोखमीचे वर्तन असणाऱ्या परंतु एचआयव्ही अबाधित प्रौढांचा आणि मुलांचा अनुकालिक अभ्यास गट (एचआयव्ही संपर्क आलेल्या सेरो-नेव्हिगेटसह) आणि एचआयव्ही बाधित व्यक्तींच्या गटाचा अभ्यास केला जाणार आहे (लहान वयातील एचआयव्ही संक्रमण, दुसऱ्या आजारांसह / शिवाय असलेला दीर्घकालीन संसर्ग आणि कोमॉरबिडिटीज आणि एचआयव्ही बाधित मुले, असा या अभ्यासाचा विस्तार असेल). प्रथम गटाचा अभ्यास समुदायांमधील शाखांमध्ये केला जाईल आणि दुसऱ्या गटाचा अभ्यास चिकित्सालयीन शाखांमध्ये केला जाईल. अभ्यासातील सहभागी व्यक्तींना आरोग्य-संबंधित माहिती दिली जाईल आणि रक्तद्रव्य / म्यूकोसल / पेशींचे नमुने नियमित वेळेवर घेतले जातील तसेच हे नमुने केंद्रीकृत राष्ट्रीय जैवविविधता संग्रहालयात संग्रहित केले जातील. यासंबंधित सर्व माहिती ही अतिप्रगत व अतिसुरक्षित गोपनीयतेच्या नियमानुसार राष्ट्रीय डेटाबेसशी (माहितीशी) संलग्न केली जाईल.

विविध शास्त्रज्ञ, संशोधक आणि समुदायाचे नेतृत्व करणाऱ्या संघटना यांमधील सहकार्य आणि सहयोगात्मक सहभाग यांद्वारे देशातील एचआयव्ही / एड्स च्या प्रभावी व्यवस्थापनासाठी नवीन साधने, हस्तक्षेप कार्यक्रम, उत्पादने आणि तंत्रज्ञान यांचा विकास केला जाऊ शकतो हे ओळखून या संमती पत्रात सहभागी होण्याचा हेतू असणारे सर्व पक्ष (पार्टी) त्यांच्या कार्यक्षमतेचा विस्तार आणि वापर करण्याचा उद्देश ठेवतील आणि संशोधन कार्याच्या सुलभतेसाठी त्यांच्या अनुभव आणि कौशल्यांचा वापर करतील. तसेच, विशिष्ट एचआयव्ही कोहॉर्ट्सच्या (गटाच्या) स्थापनेसाठी परस्पर सहकार्याने जनसमुदायाला संशोधनात सहभागासाठी सामील / संलग्न करून घेण्याच्या कृतीयोजनांची रचना आणि अंमलबजावणी करतील ज्यामुळे, भविष्यात एचआयव्ही / एड्स प्रतिबंध आणि उपचार यांवर संशोधन करण्यास मदत होईल.

माया 3/24

Dr. Seema Sahay WITNESS FROM ISNR-NARI & INVESTIGATOR COHRPICA

हे येथे सर्वांना मान्य आहे

1. पक्षांचे उद्दिष्ट:

येथे अटींच्या आधीन असलेले सर्व पक्ष या समजुती / संमती ज्ञापनाद्वारे पुष्टी करतात की, ते एचआयव्ही / एड्स संबंधित संशोधन आणि विकासासाठी त्यांचे अनुभव आणि संसाधने यांचे योगदान देण्याचा आणि त्यासाठी भागीदारी करण्याचा प्रस्ताव सादर करीत आहेत. **सर्व पक्ष त्यांच्या भागीदार नेटवर्कसह (सहभागी संघटनांसह) कार्य करण्याची पुष्टी करत आहेत - VAMP आणि त्याचे नेटवर्क्स (सहयोगी संघटना), क्लिनिकल रिसर्च सेंटर (वैद्यकीय संशोधन केंद्र) / ICMR-NARI सह संलग्न असलेले संशोधन उत्कृष्टतेचे केंद्रे जसे, कृष्णा इन्स्टिटयूट ऑफ मेडिकल सायन्सेस डीम्ड युनिव्हर्सिटी** (KIMSDU) आणि इतर, त्यांच्या क्षमता आणि कार्यकुशलता यांचे दृढीकरण आणि गुणवत्ता विकसन यांद्वारे देशातील विद्यमान संसाधनांचा महामारी विज्ञान, वर्तन, चिकित्सा आणि जैव-वैद्यकीय एचआईवी / एड्स प्रतिबंध आणि उपचार संशोधन यासाठी सहयोग करतील. एचआईवी / एड्स आजार व्यस्थापनासाठी सद्यस्थितीत अस्तित्वात असलेल्या आणि नवीन जैव-वैद्यकीय साधनांच्या विकासाठी तसेच त्यामधील प्रगतीची माहिती देण्यात सहयोग करतील. यामध्ये विशिष्ट एचआयव्ही कोहॉर्ट्सची (गटांची) स्थापना करणे समाविष्ट आहे जे विविध भविष्यलक्षी आणि पूर्वलक्षी एचआयव्ही संबंधित अभ्यासांमधून जैविक नमुन्यांचे जैविक संग्रहालय निर्माण करण्यास मदत करेल.

2. भूमिका आणि जबाबदाऱ्या

ICMR-NARI ची भूमिका आणि जबाबदाऱ्या

- आयसीएमआर- नारी केंद्रीय कारभार, प्रशिक्षण आणि CoHRPICA अभ्यासाच्या प्रोटोकॉलचे पालन करणाऱ्याबाबतच्या बाबींवरील व्यवस्थापन आणि समन्वय यासाठी जबाबदार असेल.
- संशोधन साहाय्यता निधी, व्यवस्थापन, अनुपालन आणि गुणवत्ता निकष यांच्यापुरते मर्यादित नसून कार्यक्रमात अपेक्षितलेले सर्व प्रकारचे साहाय्य प्रदान करेल..
- नियोजन, आराखडा आणि समाजाच्या सहभागाची अंमलबजावणी, संशोधनाची तयारी, सहभागी साधनांचा प्रसार आणि त्याचे मूल्यांकन याबाबत VAMP बरोबर एकत्रितपणे कार्य करेल.

KIMSDU च्या भूमिका

- ICMR-NARI च्या ग्रामीण पुढाकारांतर्गत सातारा आणि आसपासच्या जिल्ह्यामधील सर्व वैद्यकीय अभ्यासांसाठी ICMR-NARI सोबत असलेल्या कृष्णा आरोग्य विज्ञान विद्यापीठ (अभिमत) (KIMSDU), कराड, CoHRPICA अभ्यासा संबंधित सर्व बाबींची अंमलबजावणी व पूर्तता यासाठी जबाबदार असतील.

माया 3/24

Dr. Seema Sahay WITNESS FROM ICMR-NARI & INVESTIGATOR COHRPICA

- ICMR-NARI आणि VAMP सोबत नियोजन, आराखडा आणि समाजाच्या सहभागाची अंमलबजावणी, संशोधनाची तयारी, सहभागी साधनांचा प्रसार आणि त्याचे मूल्यांकन याबाबत एकत्रितपणे कार्य करतील.

VAMP ची भूमिका

- VAMP, त्यांच्या नेटवर्कच्या माध्यमातून CoHRPICA ला समान सहभागासाठी पाठिंबा देईल व त्यायोगे FSW चा संशोधनातील सहभाग वाढविण्यास मदत करेल. समूहप्रमुखांच्या सहकार्याने, नेटवर्कच्या माध्यमातून अधिकाधिक FSW पर्यंत पोहोचेल.
- ICMR-NARI सोबत समुदायातील सदस्य व नेत्यांसोबत सभा / मिटींग्ज करण्यासाठी सहकार्य करेल, ज्याद्वारे एचआयव्ही संशोधनाबाबत समाजाचे विचार समजून घेण्यास, आपआपसातील समज दृढ करण्यास आणि प्रभावी समुदाय सहभाग मिळवण्यासाठी मदत करेल.
- ICMR-NARI आणि KIMSDU यांच्यासोबत एकत्र नियोजन, आराखडा आणि संशोधनाची तयारी करताना समुदायाचा सहभाग दृढ करण्याची अंमलबजावणी आणि सहभागी साधनांचा प्रसार आणि त्याचे मूल्यांकन करण्यास सहकार्य करेल.
- सहभागीशी संपर्क कायम ठेवण्यासाठी आणि संपर्काचे संदर्भ आणि व्यवस्थापनामध्ये मदत करून CoHRPICA साठी अंमलबजावणी करण्यास पाठिंबा देईल.

3. VAMP चे लाभ:

VAMP भारत सरकारच्या नेतृत्वातील CoHPRICA कार्यक्रमात अधिकृत भागीदार म्हणून दाखल / सहभागी होईल आणि जनसमुदायाच्या संशोधनातील सहभागासाठी आणि समुदायाला संशोधनाबद्दल साक्षर करण्यासाठी तसेच या कार्यक्रमाविषयी माहिती प्रसारित करण्यासाठी सातारा आणि सांगली जिल्ह्यातील वेश्या व्यवसाय करणाऱ्या महिलांना संशोधनात सहभागी करून घेण्यासाठी ICMR-NARI आणि KIMSDU यांना मदत करण्यास जबाबदार असेल. बायोटेक्नोलॉजी विभाग आणि इंडियन कौन्सिल ऑफ मेडिकल रिसर्च यांचे अधिकृत भागीदार म्हणून ओळखले जाण्याव्यतिरिक्त VAMP संशोधन प्रक्रियेच्या कार्यक्रमात सामाजिक दृष्टीकोन बनविण्यासाठी अग्रणी असेल तसेच भारताच्या प्रमुख संशोधन संस्थांबरोबर भागीदार म्हणून कार्यरत असल्यामुळे देशात अधिक व्यापक स्वरूपात काम करेल.

4. समाजाला असणारे फायदे

सध्याच्या एचआयव्ही संशोधनातील काही प्रगत संकल्पनांची या समुदायास ओळख करून दिली जाईल त्यात, जसे विषाणू विविधता, व्यापक निष्प्रभावक प्रतिपिंड, HIV ची सुप्तता आणि सक्रियता इत्यादी विषयांचा समावेश असेल तसेच या सर्वांचे भारतातील सामाजिक आरोग्यावर होणारे परिणाम याचाही उल्लेख असेल.

Dr. Seema Sahay WITNESS FROM ICMR-NARI & INVESTIGATOR COHRPICA

सहभागी खेळ, संवादात्मक नाटक (थिएटर) आणि अनुभवात्मक शिक्षण क्रियांचा वापर करून संशोधन साक्षरतेसाठी नाविन्यपूर्ण पद्धतींचा वापर करून / करण्यासाठी त्यांना प्रशिक्षण देण्यात येईल.

5. अभ्यास माहितीची उपलब्धता (अभ्यास माहितीचा उपयोग करण्याची संधी)

कराड आणि सांगली येथील संशोधनातून VAMP यांच्या समर्थनाद्वारे प्राप्त झालेली संशोधन माहिती VAMP साठी उपलब्ध असेल.

6. संशोधन प्रकल्प/ शोध निबंधांचे लेखकत्व

VAMP सह भागीदारीतून संशोधनाद्वारे प्राप्त केलेल्या माहितीचा समावेश असलेल्या सर्व प्रकाशनांमध्ये VAMP ला योग्य श्रेय आणि ऋणनिर्देश दिले जातील ज्यात सह-लेखकत्वाचाही समावेश असेल.

7. शोधनिबंधांचे प्रकाशन

CoHRPICA प्रकल्पांतर्गत असलेल्या वैज्ञानिक आणि तांत्रिक समितीच्या पुनरावलोकनंतरच/समीक्षणानंतरच VAMP ला या प्रकल्पातून/अभ्यासातून त्यांचे स्वतंत्र संशोधन प्रकाशित करता येतील कारण CoHRPICA संशोधन प्रकल्पातून होणाऱ्या सर्व संशोधनांसाठी आणि त्यातून प्रकाशित होणाऱ्या सर्व प्रकाशनाचे संशोधन मानदंड / मूल्ल्यांना कायम ठेवण्यासाठी CoHRPICA कार्यक्रम/प्रकल्प जबाबदार आहे.

8. जबाबदाऱ्या

ICMR-NARI खालील बाबींसाठी जबाबदार राहणार नाही:

- VAMP च्या कोणत्याही कर्मचा-यांद्वारे केलेल्या रकमेची मागणी
- VAMP ने केलेली कोणतीही आर्थिक वचनबद्धता
- VAMP ने कोणत्याही प्रकारे सर्व हक्क राखीव (कॉपीराईट) चे आणि अन्य कायद्यांच्या उल्लंघनाची मागणी केल्यास, ज्याचा संमती पत्राच्या उद्देशाशी काही सबंध नाही.

9. VAMP ला लॉजिस्टिकल पाठिंबा

काही विशिष्ट परिस्थितींमध्ये ICMR-NARI, VAMP च्या टीम सदस्यांसाठीचे लॉजिस्टिकल खर्च सहन करण्यास सक्षम असू शकतात. तथापि, कोणतेही लॉजिस्टिकल खर्च करण्यापूर्वी, VAMP ला ICMR-NARI च्या संचालकांकडून पूर्व मंजुरी घ्यावी लागेल. VAMP टीमच्या सदस्यांद्वारे अभ्यास क्षेत्रासाठी होणाऱ्या लॉजिस्टिकल खर्चाची परतफेड ICMR-NARI कडून थेट VAMP टीमच्या सदस्यांना केली जाईल.

10. वैधता कालावधी

हा करार सुरुवातीला हस्ताक्षर केलेल्या तारखेपासून एक वर्षासाठी वैध असेल आणि नंतर दोन्ही पक्षांच्या परस्पर संमतीने या कराराचे नूतनीकरण केले जाईल.

Dr. Seema Sahay WITNESS FROM ICMR-NARI

11. VAMP आणि त्यांच्या समुदाय सदस्यांची माघार

VAMP आणि त्याचे समुदाय सदस्य कोणत्याही वेळी कोणतेही कारण न देता CoHRPICA अभ्यासासाठी त्यांनी दिलेला पाठिंबा काढून घेण्यास मोकळे / स्वतंत्र आहेत.

12. कराराचा भंग

करारात नमूद केल्याप्रमाणे, दोन पक्षांपैकी एक पक्ष जर समुदाय-सदस्यांचे साहाय्य मिळविण्यास असमर्थ ठरला किंवा करारातील व CoHRPICA अभ्यासातील प्रोटोकॉल मधील एखाद्या भागाचे / विभागाचे / विधानाचे उल्लंघन केल्यास किंवा समुदाय-सदस्यांचे शोषण / गैरवापर केल्यास किंवा कोणत्याही प्रकारे ICMR-NARI सोबतच्या भागीदारीचा गैरवापर केल्यास दोन्ही पक्षांना करार समाप्त करण्याचा अधिकार असेल.

13. करारातील दुरुस्ती

या करारात VAMP आणि ICMR-NARI च्या दायित्व / कर्तव्यांचे वर्णन केले गेले आहे. तथापि, कराराच्या प्रक्रियेदरम्यान अशी काही परिस्थितीही उद्भवू शकते की जी या करारात फेरफार किंवा फेरबदल / परिवर्तन करण्याची मागणी करू शकते. हे फेरबदल / परिवर्तन परस्पर चर्चा आणि लिखित स्वरुपात दोन्ही पक्षांकडून सहमत होतील.

14. नैसर्गिक आपत्ती

आग, युद्ध, दंगल, संप / बंद , नैसर्गिक आपत्ती इत्यादि कोणत्याही कारणामुळे कराराच्या अटी आणि नियमांची पूर्तता होत नसल्यास, VAMP किंवा ICMR-NARI किंवा KIMS कोणत्याही नुकसान किंवा परिणामी नुकसानासाठी जबाबदार राहणार नाही.

15. मध्यस्थता

या संगती पत्राच्या अंतर्गत प्रत्येक पक्ष भारतातील सर्व लागू राष्ट्रीय कायदे, धोरणे आणि नियमांचे पालन करून त्यांचे कर्तव्ये पार पाडेल. या कराराच्या कोणत्याही बाबी संबंधित उद्भवणारा कोणताही विवाद करार किंवा भारतीय कायद्यानुसार पक्षांद्वारे आप-आपसात सल्लामसलत आणि करारादवारे सोडविला जाईल.

वेश्या एड्स मुकाबला परिषद साठी	आयसीएमआर- नारी साठी
माधा २५/२१/१२	
(संचालक, वेश्या एड्स मुकाबला परिषद) संचालक	(संचालक, ICMR-NARI) संचालक

VESHYA AIDS MUKABLA PARISHAD * SANGLI * Regd. No. MAH 5879

* I.C.M.R. * NATIONAL AIDS RESEARCH INSTITUTE * PUNE-411 026

29/3/13

27 March 2013

Dr. Seema Sahay WITNESS

KIMSDU Financial information

Budget Head	Year 1	Year 2	Year 3	Year 4	Year 5	Total
Equipment	Nil	Nil	Nil	Nil	Nil	Nil
						Manpower
Doctor-1	826500	851700	876900	902100	927300	4384500
Counselor-1	372000	388200	404400	420600	436800	2022000
Field worker-1	216000	225600	235200	244800	254400	1176000
Total	1414500	1465500	1516500	1567500	1618500	**75,82,500**
Laboratory Tests & participant care cost	686125	1224333	1148916	644875	316183	**40,20,433**
Community engagement cost	500000	500000	500000	500000	500000	**25,00,000**
Shipment charges	25000	25000	25000	25000	25000	**1,25,000**
Travel						
Contingency	15000	15000	15000	15000	15000	**75,000**
Total	2640625					**1,43,02,933**

Annexure I – Financial Information

The Total Cost of the Project is INR 216685524 as per details given below (all costs in INR):

Institute	Year 1	Year 2	Year 3	Year 4	Year 5	Total
NARI	53552735	12336028	13850161	12486005	11804557	104029486
YRGCARE	7689832	10386503	9628764	7477819	5893511	41076429
NIRT	5211290	5749163	5336038	4800412	4304411	25401314
GHTM	2291344	2788275	2401217	2445617	2490018	12416471
IGICH	2511000	3039980	3145760	3197240	3248720	15142700
NIE	2306600	851800	877000	902200	927400	5865000
PCU	1985900	3270524	2605900	2665900	2225900	12754124
TOTAL	75548701	38422273	37844840	33975193	30894517	216685524

Institute-wise details

1. National AIDS Research Institute (NARI)
   - *Establishment of Cohorts of HIV-uninfected individuals at high-risk (including Exposed-seronegative and Early HIV-infection) and HIV-infected adults – with and without comorbidities;*
   - Establishment of the state-of-the-art biorepository

Budget Head	Year 1	Year 2	Year 3	Year 4	Year 5	Total
Equipment	42760000	0	0	0	0	42760000
Manpower	4932000	5126760	5321520	5515880	5710440	26606600
Laboratory tests, Participant Care and Community engagement costs (Cohorts)	4510735	6739268	6136641	4654125	3642117	25682886
Consumables (Biorepository)	1000000	100000	1000000	800000	800000	3700000
Shipment charges	200000	220000	242000	266000	292000	1220000

AMC for Biorepository Equipment	0	0	1000000	1100000	1210000	3310000
Travel	100000	100000	100000	100000	100000	500000
Contingency	50000	50000	50000	50000	50000	250000
TOTAL	**53552735**	**12336028**	**13850161**	**12486005**	**11804557**	**104029486**

1a. *Equipment*

Name of Equipment	No.	Cost
For Biorepository		
Bio Bank system (LN2)	2	30000000
LN2 shipment tank	2	2400000
70 freezer	2	2400000
Computer	1	60000
LN2 supply facility	1	500000
Sub-total		*35360000*
For Cohorts		
Tablet/Note book	4	100000
Upgradation of FACS Area	1	7300000
Sub-total		*7400000*
TOTAL		**42760000**

1b. *Manpower*

Head	No.	Monthly salary	Year 1	Year 2	Year 3	Year 4	Year 5	Total
For Biorepository								
Technical assistant	1	31000	372000	388200	404400	420600	436800	2022000
Technical Officer	1	32000	384000	400680	417360	434040	450720	2086800
Lab attendant	1	15800	189600	198000	206400	214800	223200	1032000
Sub-total			*945600*	*986880*	*1028160*	*1069440*	*1110720*	*5140800*
For Cohorts								
Scientist B (Medical) - For HIV uninfected cohorts	1	66250	795000	820200	845400	870400	895600	4226600

Scientist B (Non-Medical) – For HIV uninfected cohorts	1	52200	626400	651600	676800	702000	727000	3383800
Field Worker/Data Entry Operator – One each for HIV uninfected and HIV-infected Adult Cohort	2	18000	432000	451200	470400	489600	508800	2352000
Counselor – One each for HIV uninfected and HIV-infected Adult Cohort	2	31000	744000	776400	808800	841200	873600	4044000
Scientist B (Medical) – For HIV-infected Adult Cohort	1	66250	795000	820200	845400	870400	895600	4226600
Lab Technician (shared for HIV uninfected and HIV-infected Adult Cohort)	1	18000	216000	225600	235200	244800	254400	1176000
Staff nurse (shared for HIV uninfected	1	31500	378000	394680	411360	428040	444720	2056800

and HIV-infected Adult Cohort)							
Sub-total			3986400	4139880	4293360	4446440	4599720	21465800
TOTAL			**4932000**	**5126760**	**5321520**	**5515880**	**5710440**	**26606600**

1c. *Laboratory Tests, Community Engagement and Participant Care Costs for Cohorts*

	Year 1	Year 2	Year 3	Year 4	Year 5	Total
Laboratory Tests and Participant Care Costs						
HIV-uninfected cohorts	2058375	3673000	3446750	1934625	948550	12061300
Early HIV Infection cohorts	69516	180893	235974	187916	161984	836283
Exposed-seronegative cohorts				77667	77665	155332
HIV-infected Cohorts	882844	1385375	953917	953917	953918	5129971
Community Engagement Cost	1500000	1500000	1500000	1500000	1500000	7500000
TOTAL	**4510735**	**6739268**	**6136641**	**4654125**	**3642117**	**25682886**

2. Y.R. Gaitonde Center for AIDS Research and Education (YRGCARE)

- *Establishment of Cohorts of HIV-uninfected individuals at high-risk (including Exposed-seronegative and Early HIV-infection) and HIV-infected adults – with and without comorbidities*

Budget Head	Year 1	Year 2	Year 3	Year 4	Year 5	Total
Equipment	210000	0	0	0	0	210000
Manpower	2440500	2536980	2633460	2729940	2826420	13167300
Laboratory tests, Participant Care and Community engagement costs	4889332	7699523	6845304	4597879	2917091	26949129
Travel	100000	100000	100000	100000	100000	500000
Contingency	50000	50000	50000	50000	50000	250000
TOTAL	7689832	10386503	9628764	7477819	5893511	41076429

Cohorts for HIV Resistance and Progression in Indian Children and Adults (CoHRPICA)

Study Objectives

The specific objectives of the study are the following:

- Establish well-characterized cohorts of HIV-uninfected individuals at high-risk (including Exposed-seronegative) and HIV-infected individuals (including Early HIV-infection, HIV-infected adults – with and without comorbidities, and HIV-infected children)

- Establish a state-of-the-art biorepository of biological specimens collected from the above cohorts and other prospective and retrospective studies in India;

- Develop a national HIV/AIDS database (with clinical-laboratory-socio-demographic-and research data) to enable a singular digital platform for epidemiological analyses, generation of new researc

Objective A – Establishment of cohorts

CoHRPICA will be an open-ended, multi-center, prospective cohort study enrolling HIV-uninfected, at high risk, adults (including Exposed-seronegative, and HIV-infected individuals (including Early HIV-infection, HIV-infected adults – with and without comorbidities, and HIV-infected children) at the clinical Centers of Excellence across India.

For HIV-uninfected cohorts, males and females 18 years and above, who are at-risk of HIV acquisition including

Men who have Sex with Men/Transgender people (MSM/TG),

Female Sex Workers (FSW), and

People who inject drugs (PWID))

will be screened through community outreach activities by the partner institutions/ link organizations as well as at targeted intervention sites of National AIDS Control Organization.

- For all the volunteers screened, basic demographic, clinical and behavioral data along with biological specimens will be collected and serum/plasma samples will be stored. No targets are set for the number of individuals to be screened, but the screening will continue until the desired number of enrolments happen in the 3 high-risk categories [FSW, MSM/TG and PWID; 350X3=1050].
- Of the individuals screened, those HIV-uninfected individuals (not exceeding 1050 i.e. 350 in each risk category) practicing high-risk behaviors (for example, multiple unprotected sex or needle sharing in last 3 months and infection with herpes simplex virus 2/hepatitis C) will be enrolled to be followed every 3 months for 3 years with systematic collection of data as well as biological specimens.
- Of these 1050 HIV-uninfected (at high risk) participants, those who continue to persistently remain seronegative (for a minimum period of 3 year) despite risk-behaviors, will be invited to join the sub-cohort of Exposed Sero-negative individuals (ESN) and will be followed up every 4 months for 2 years if the study duration permits.

Objective B – Establishment of the Biorepository -------NARI

Objective C – Development of National Database---------NIE

Design and Methodology	• In conjunction with the revised objective 1, the study design for establishment of cohorts has been modified (Sections 3.1 – 3.6). Briefly, the modifications include populations of interest and number of participants to be screened, enrolled and followed (including for data and sample collection) based on the current epidemiological status and global norms such as to aid in establishment of cohorts of ESN, EHI, HIV-infected adults (with or without co-morbidities), and HIV-infected children; • In alignment with Objective 2 in the revised protocol, the methodology for the biorepository has been detailed out (in Section 4.1) mentioning its potential expansion and linkages with other national and international Government of India-funded initiatives and towards enabling access of samples to a broader research fraternity; • Similarly, towards Objective 3 of the revised protocol, the methodology for the database has been explicitly defined (in Sections 5.1 – 5.3) to detail out its functionalities, processes related to its creation and management to enable integration of data for facilitating generation of new research questions and creation of an organized knowledge repository in India.		
Other Changes	Study Sites and their respective focus areas included 1. NARI - for establishment of adult LTNP cohorts and the national database and biorepository 2. YRGCARE - for establishment of ESN and adult LTNP cohorts 3. NIRT - for establishment of ESN cohorts among MSM population 4. GHTM - for establishment of ESN cohorts among sero-discordant couples 5. CSTM - for establishment of adult LTNP cohorts) 6. IGICH - for establishment of pediatric LTNP cohorts	Based on the modified objectives in the revised protocol and the capacity and capabilities of the participating institutes (in terms of access to relevant populations of interest for establishment of cohorts across geographies in India, and creation and maintenance of the biorepository and the database), following changes have been made in the revised protocol: • For some sites (NARI, YRGCARE, NIRT, GHTM, IGICH, and NIE), focus areas have been changed;	Study sites and their respective focus areas include 1. NARI – for establishment of cohorts of HIV-uninfected individuals (including ESN) and HIV-infected individuals – EHI, HIV infected adults with and without comorbidities, and establishment of the state-of-the-art biorepository. For establishment of HIV-uninfected cohorts at NARI, Krishna Institute Medical Science Deemed University (KIMSDU) will be the implementation partner; 2. YRGCARE - for establishment of cohorts of HIV-uninfected individuals (including ESN) and HIV-infected individuals – EHI, HIV infected adults with and without comorbidities;

KRISHNA INSTITUTE OF MEDICAL SCIENCES "DEEMED TO BE UNIVERSITY", KARAD.

(Declared U/s 3 of UGC Act, 1956 vide Notification No. F.9-15/2001-U.3 of the Ministry of Human Resource Development, Govt. of India.)

Karad, Dist. Satara (Maharashtra State) Pin: 415 110 **Tel: 02164 -241555-58 Fax: 02164 243272/242170**

Website: www.kimsuniversity.in E-mail: contact@kimsuniversity.in

CoHRPICA :- Cohort for HIV Resistance and Progression in Indian Children and Adults.

The Project Initiated in year 2019 for a period of 5 years.

The project is multi centric With 6 centers having different target population to be covered under this research program.

Project is funded by IAVI, ICMR-NARI and DBT.

KIMSDU is the implementing partner along with ICMR-NARI Pune.

Research Program is in initial phase where in clinics are set-up at karad and sangali.

Staff is appointed and has undergone training and orientation program in the community.

The sanctioned budget is 2 Cr. per year where in ICMR-NARI is mother institute and KIMSDU is the implementing partner for execution of community based research program.

Site Principal Investigator

KRISHNA INSTITUTE OF MEDICAL SCIENCES "DEEMED TO BE UNIVERSITY", KARAD.

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PHV Project: - Promoting of HIV Vaccine Research and Development through tech-transfer and capacity building for HIV Immune-Pathogenesis Studies.

Project initiated in year 2017-2018 at KIMSDU, Karad for 5 years.

Project continued in year 2017-2018, 2018-2019.

The project was funded by IAVI, ICMR-NARI Budget was sanctioned as Rs.25,50,470 and Rs. 23,63,800/- which was received at NARI Pune, KIMSDU being the implementing partner for this project program.

The project was terminated in 2019 since it was continued as COHRPICA study Principal Investigator, Dr. Jadhav and Co-PI Dr. Karande - Microbiology copy of the sanctioned budget is enclosed herewith.

Jadhav

Site Principal Investigator

KRISHNA INSTITUTE OF MEDICAL SCIENCES "DEEMED TO BE UNIVERSITY", KARAD.
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Site Principal Investigator

GREEN HEALTH FOUNDATION

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AQAR 18-19.

Date: 09th July 2019

Ref: GHF/SOL/2019/02

To
Department of Public Health Dentistry,
School of Dental Sciences,
Krishna Institute of Medical Sciences Deemed to be University, Karad,
Maharashtra.

WORK COMPLETION CERTIFICATE

This is to certify that School of Dental Sciences, Krishna Institute of Medical Sciences Deemed to be University, Karad has successfully completed the health survey which was one of the parts of a CSIR-NEERI project viz., ***Health study to assess the impact of Water pollution on Water borne diseases*** at the Ujani dam and Bhima river offered to Green Health Foundation, Dombivli.

The health survey part of the project has been carried out by School of Dental Sciences, Krishna Institute of Medical Sciences Deemed to be University, Karad for Green Health Foundation, Dombivli for the period of four months from January - April 2019 for the total amount including tax INR 353,110/- only.

Green Health Foundation

GREEN HEALTH FOUNDATION GHF

Rs. 30,000=00 (Balance)
(Yet Receive from GHF)

Study Title

Implementation and Evaluation of Community Based Intervention for Upliftment and Voluntary Participation in Biomedical Research Studies

Protocol No:_____

Study Investigators and Institutional Affiliations

KIMSDU	
Dr. Asha Jadhav ***Principal Investigator*** Director Extension Activities Krishna Institute of Medical Sciences, deemed to be University, Pune Bangalore Highway, Malkapur, Karad Dist .Satara 415110 Email: kimsdea@gmail.com Phone:9421576382	**Signature:** **Date:** 20/11/2019
NARI	
Dr. Seema Sahay ***Study Advisor*** Scientist-G, ICMR-National AIDS Research Institute, Pune-411026 Email: ssahay@nariindia.org Phone: 020-27331200	**Signature:** **Date:** 22.11.19

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Contents

Summary of the Study

Title:
Implementation and Evaluation of Community Based Intervention for Upliftment and Voluntary Participation in Biomedical Research Studies.

Purpose of the Study:

The current study aims at exploring ways to bring more high-risk population into the prevention and treatment space and increasing research preparedness through community messaging and literacy tools about HIV, Sexual and Reproductive Health and Biomedical Research.

Objectives:

- To assess awareness and enhance perception of risks posed by HIV and STIs to sexual & reproductive health;
- To understand the facilitators and barriers for adoption and uptake of protective interventions against HIV & STIs and strengthen uptake;
- To identify hidden populations who are at risk of HIV and STIs and do a comparative analysis of the factors responsible;
- To augment collectivization efforts and capacities for self-addressal of community concerns;
- To advance research literacy in communities and encourage informed and voluntary participation in clinical and biomedical research (BMR) studies (including the National HIV Cohort Study).

Methodology:
Study Duration: 1 year.

Study Partners: Krishna Institute of Medical Sciences Deemed University (KIMSDU); National AIDS Research Institute (NARI).

Study Sites: Karad, Ichalkaranji and Sangli in Maharashtra.

Study Populations: (a) General population focused on adolescent girls and adult women involved in risk behavior (b) Traditional high-risk populations like FSW, along with representation from other relevant populations (like truckers, migrants, students etc.) who interact with the above-mentioned focal groups.

Study Design:
This study has a two-pronged approach where efforts will be focused to reach out to the hard-to-reach high-risk populations to understand the factors affecting their participation in HIV care continuum and biomedical research as well as implement and assess novel community engagement tools towards enhancing research literacy for voluntary and informed participation in BMR. Towards this, the study will be conducted as the following:

(A) Research study to understand facilitators and barriers towards participation in biomedical research: The study will be conducted using a mixed methods study design.

- A quantitative questionnaire survey to provide an overall statistical picture of the factors affecting research participation at individual and community level.
- A qualitative semi-structured face-to-face interview and focus group discussions which will enable in-depth understanding of the community perspectives towards willingness to participate in HIV research;

(B) Designing, dissemination and evaluation of novel community engagement tools:
The community engagement tools and materials, developed based on formative research and peer discussions, will be rolled out into the community focused on women at-risk in general as well as FSW populations. Following this, evaluation of the tools will be conducted to assess their impact on HIV related knowledge and perception towards BMR participation.

Background and Rationale

India stands at the intersection in the response to its HIV epidemic and has made significant steps in controlling the same. New HIV infections and AIDS-related deaths have dropped by 46% and 22%, respectively, since 2010. The adult HIV prevalence at national level has continued its steady decline from an estimated peak of 0.38% in 2001-03 through 0.34% in 2007, 0.28% in 2012 and 0.26% in 2015 to 0.22% in 2017. However, despite strong programmatic efforts resulting in overall decline in HIV prevalence, HIV continues to be a public health issue with considerable inter-state variations in prevalence among certain populations at higher risk of HIV infection, called key populations (KPs) like, Men who have Sex with Men (MSM), Female Sex Workers (FSW), People Who Inject Drugs (PWID), Transgender Women (TGW), adolescents, migrants and truckers among others. The UNAIDS has set ambitious targets of 90-90-90 wherein 90% of HIV infected persons are aware of their status, 90% of those aware are on sustained Antiretroviral Therapy (ART) and 90% of those on ART achieve viral suppression. To achieve these global targets, the National Strategic Plan (NSP) for HIV/AIDS and STI released by National AIDS Control Organization (NACO), outlines a framework of strategies and activities to be implemented over the next seven years. In line with these, it becomes imperative to increase the HIV awareness in KPs, increase knowledge about their HIV status and bring them into the treatment and care continuum.

The HIV disease management landscape has also been evolving and newer advancements in the prevention and treatment methodologies have brought about a paradigm shift in approaches to address the global HIV disease burden. To value add to the existing disease management tools like combination antiretroviral therapies (cART), researchers are working towards enabling development and implementation of new tools for HIV prevention and treatment, for example, for pre-exposure prophylaxis (PrEP), microbicides, long-acting implantable anti-retrovirals, therapeutic and preventative broadly neutralizing antibodies etc. Towards design and development of interventions that are according to the population-specific needs, it becomes relevant to better understand of the complex interplay between host, virus and the environment. Long-term cohort studies across the globe have been instrumental in focusing on different aspects of the HIV-disease and in working towards a better disease management tool.

Relevant studies that KIMSDU and NARI have conducted

NARI's AIDS Rural Research Initiative in Maharashtra (NARRIM) - In order to generate data on HIV awareness, and HIV status in rural population and achieving the first goal of 90% of all people living with HIV knowing their HIV status, ICMR-NARI and IAVI through the support from USAID has established a project entitled, 'NARI's AIDS Rural Research Initiative in Maharashtra (NARRIM)', a rural research initiative, a clinic in collaboration with Krishna Institute of Medical Sciences, Deemed University, Karad in Satara district of Maharashtra. Under this project, a situational analysis was conducted for entire Satara district focusing on three Millennium Development Goals of reproductive and child health, HIV and tuberculosis and mapping of High-Risk Groups and vulnerable pockets of HIV and AIDS to facilitate comprehensive understanding of the Satara district to initiate future research studies on various socio-behavioural, cultural determinants and bio-medical research in both rural and urban areas.

PHV- NARRIM (Promoting HIV Vaccine (PHV) Research and Development Through Tech-transfer And Capacity Building For HIV Immune-pathogenesis Studies)- Subsequently, NARI initiated a community based open cohort (PHV Cohort) in the 65 clusters of Karad and

Patan block of Satara District. The objectives of this project were to explore the perceptions of the rural community regarding STIs, HIV, HIV testing and HIV prevention, to study the demographic, behavioral, biological and program factors which are deterministic of STI/ HIV vulnerability and risk among rural population and to identify potential studies pertaining to vaccine development.
175 health camps were conducted in 65 clusters of Satara district across Karad and Patan to recruit participants in the open community cohort. During the community engagement, multiple stakeholders in Karad and Patan blocks of Satara district were involved through meetings and a program alligned to 'one health' approach named "Arogya aplya Daari" focused on HIV counseling, testing, NCDs and hygiene was implemented. This approach also helped in mainstreaming HIV testing and no incidence of stigma was observed during HIV testing camps. This kind of effort would be critical for participation of both visible and hidden key populations not only in seeking care but also in participation in biomedical research studies which is otherwise seen with suspicion.

National HIV Cohort Study (CoHRPICA) – The National HIV Cohort Program (**Co**horts for HIV **R**esistance and **P**rogression in **I**ndian **C**hildren and **A**dults – CoHRPICA), supported by the Department of Biotechnology (DBT), Indian Council of Medical Research (ICMR) and IAVI, is focused on creating specific cohorts, biorepository and database to enable understanding of the disease and aid in development of new tools for disease management. Towards this, the Program aims to bring together multiple institutes with interdisciplinary expertise (clinical, socio-behavioral and biomedical) across India to establish a consortium that leverages on individual strengths to accelerate accelerate population-based studies in HIV/AIDS. As a part of this, NARI (in working with KIMSDU) is responsible for establishing HIV uninfected cohorts from high risk populations (including exposed seronegative cohorts), Early HIV infected individuals and also HIV infected cohorts with and without co-morbidities.

Current Need

A critical key to the success of achievement of 90-90-90 in India, the above-mentioned studies and also to other future HIV research studies or interventional trials is the participation of the relevant community in these efforts. Therefore, it becomes extremely pertinent to extend the knowledge of these developments to the relevant community, understand their perspectives and the community needs, and their social and behavioral practices.
Recent programmatic data from Integrated Counselling and Testing Centers (ICTC) highlight that during 2015-16 only 3% of the newly detected HIV cases were from Targeted Intervention (TI) program focused on key populations whereas, 84% of the newly detected cases were from a mixed pool of general population that need to be characterized by socio-demographic characteristics and risk behaviors. Also, the current trend in sexual network include non-traditional interactions like non-hotspot-based sex work, part-time and seasonal sex work and virtual soliciting involving adolescents, upper class drug users, migrants and homeless populations, among others. Given that a considerable proportion of key population is non-self-identified, the national priorities are now focused on adoption of a wider definition of vulnerability and risk to reach out to these people at risk who do not fall into traditional domain of key populations.
Therefore, there is a strong need to identify this hard to reach at-risk populations, understand their behaviors, practices and perceptions and have a comparative evaluation of these with the self-identified key populations to bring more of them into the prevention, treatment and care continuum. Towards this, national priorities include appropriate design for community interventions to outreach these hard-to-reach populations through integration with Sexual and

Reproductive Health education and greater convergence with the NHM adolescent programme As Maharashtra has the highest prevalence of HIV among the FSW population, this study is uniquely positioned to understand and compare the community perspectives of FSWs and that of the adolescent girls and women of reproductive age in general population. Also, integration of social and behavioral science and community perspectives early in idea generation and research study design is imperative for the successful conduct of biomedical studies/trials and for ensuring optimal data collection approaches necessary for the interpretation of findings.

Towards the above, the current study aims at exploring ways to bring more high-risk population into the prevention and treatment space and increasing research preparedness through community messaging and literacy tools about HIV, Sexual and Reproductive Health and Biomedical Research.

Study Objectives

The objectives of the current study are:

- To assess awareness and enhance perception of risks posed by HIV and STIs to sexual & reproductive health;
- To understand the facilitators and barriers for adoption and uptake of protective interventions against HIV & STIs and strengthen uptake;
- To identify hidden populations who are at risk of HIV and STIs and do a comparative analysis of the factors responsible;
- To augment collectivization efforts and capacities for self-addressal of community concerns;
- To advance research literacy in communities and encourage informed and voluntary participation in clinical and biomedical research (BMR) studies (including the National HIV Cohort Study).

Study Duration

The study will be over a period of 1 year which will enable collection of data to understand the community knowledge, awareness, perspectives and behaviors related to sexual and reproductive health (SRH), HIV and biomedical research (BMR); development of interventions to address the gaps – information, education and communication materials and tools; roll-out of these in the community and impact assessment.

Study Population

Given that women account for 41% of estimated PLHIV in India and recent evidences highlighting gender norms can impact access to services by affecting decision to seek testing, pursue ART or other health seeking and the national priorities discussed above, this study will be focused on adolescent and adult women of reproductive age (15 – 45 years) with risk behavior including the key population FSW. Also, efforts will be made to include additional participants from other relevant groups (like migrants, truckers, students, among others) who interact with the above-mentioned groups. These participants will be recruited through conduct of health camps as well as other relevant community engagement activities and service delivery based on specific needs.

Study Sites

The study will be conducted in Karad, Ichalkaranji and Sangli in Maharashtra.

Study Partners- Roles and Responsibilities

KIMSDU	NARI	CBO	IAVI
Alignment and agreement on goals; key issues to be addressed; relevant community insights; and appropriate messaging for addressing the identified issues			
Co-creation of interactive tools to deliver key messages through peer-led activities	Co-creation of interactive tools to deliver key messages through peer-led activities	Co-creation of interactive tools to deliver key messages through peer-led activities	Funding and technical support
Training of peer educators on interactive tools and how to effectively deliver them	Training of peer educators on interactive tools and how to effectively deliver them	Training of peer educators on interactive tools and how to effectively deliver them	
Testing, implementation, delivery, evaluation & continuous improvement of interactive tools in community learning and engagement program	Delivery, evaluation & continuous improvement of interactive tools in community learning and engagement program	Testing, implementation, delivery, evaluation & continuous improvement of interactive tools in community learning and engagement program	
Counseling, informed consent, screening and enrollment of potential research participants resulting from CE efforts			

Study Design and Methodology

(A) Understanding facilitators and barriers towards participation in biomedical research

The study will be conducted using a mixed methods study design.

Quantitative Component

A quantitative questionnaire survey will be administered to the participants from both general and FSW populations. This survey will aid in deriving a statistical picture of overall level of knowledge and perception of the community about Sexual and Reproductive Health (SRH), HIV risk and prevention as well as the factors affecting voluntary participation in Bio Medical Research (BMR) at both individual and community level.

Evaluation parameters

- Awareness about HIV, SRH and general health
- Perception about HIV and STI prevention
- Treatment/Health seeking behavior for HIV and SRH
- Biomedical Research preparedness and research literacy

Sample size for cross-sectional quantitative survey

The baseline comprehensive knowledge about HIV and its prevention and transmission in women is 22% in rural Maharashtra (NFHS 4, 2015-16). This was taken as participant awareness about HIV and BMR with an absolute precision of 5% and confidence interval of 95%.

Given that the combined population of Karad, Ichalkaranji and Sangli is around 9 lakhs, using the above parameters, the sample size calculated for the cross-sectional questionnaire survey came out to be 528 which was rounded off to 550. Design effect of magnitude 2 was assumed to account for intra-cluster correlations.

The formula that was used in sample size calculation is given below:

$$N = \frac{(Z\alpha)^2 \times p\,(1-p)}{d^2}$$

Where, Zα: Level of significance, p: Prevalence, d: Precision

Qualitative component

The quantitative survey will then be followed by qualitative data collection including in-depth interviews, key informant interviews and focus group discussions among high-risk women of reproductive age (15-45 years) including FSWs. It will aid in in-depth understanding about community's current knowledge, awareness, attitude and practice towards Sexual and reproductive health; HIV risk, prevention and transmission and mental health; community perspectives on HIV testing and other preventative and therapeutic interventions; perspectives about collectivization and empowerment of the vulnerable community; research preparedness and willingness to participate in Biomedical Research Studies. This will also aid in further developing community engagement strategies, communication materials and literacy tools for strengthening community research preparedness and research literacy. Towards these the tools deployed would borrow from 'Participatory Action Research'.

Data collection

Data collection method	Population	Sample Size	Focus of inquiry
In Depth Interview	Adolescent girls and adult women of reproductive age with risk behaviors visiting the health camps	20	• Awareness and perspectives about SRH; • HIV awareness: perception about risk and knowledge about prevention, testing and care; • Current practice and perspective about uptake of various HIV Px and Tx options; • Research literacy: knowledge about HIV science; need for blood draw, behavioral information and follow ups even if treatment is not required; • Facilitators and barriers towards willingness to participate in BMR; • Perspective about specific programs (HIV testing health camp; Arogya Aaplya Dari)
	Key population: FSW	10	
	Participants from other relevant population like truckers, migrants, students etc.	6	
Key informants' interview	• Medical officer • Staff nurse/ other health care staffs • CBO rep/ DAPCU rep • Research team members • Key stakeholders from villages-Panch/ ASHA workers	3 (each category)	How can effectively implement this program for more recruitments, which measures should have been adopted to reach vulnerable population, how this program benefited for high risk and vulnerable population, what additional health care should be added.
Focus Group Discussions	• Adolescent girls and adult women of reproductive age with risk behaviors • FSWs • Representative of relevant interacting population	4 (7-8 participant per FGD)	Perspectives about SRH; Perception about HIV risk and prevention; awareness about HIV testing and care; Research preparedness; Facilitators and barriers to novel biomedical interventions and BMR

Participant Sampling and Participant Recruitment

Towards the study, 4 focus group discussions (FGDs), 12-15 key informant interviews (KIIs) and 36 In-depth interviews (IDIs) will be conducted.

For the focus group discussions, diverse subgroups of high-risk population such as adolescents, FSWs (brothel-based, street-based, internet/social media-based), truckers, migrants would be recruited. Effort would be taken to have minimum 7-8 people in any FGD.

Any women between 15-45 years of age with high risk behavior and willing to participate in the study after well informed consent will be eligible for participation in the interviews.

(B) Designing, Dissemination and Evaluation of Community Engagement Tools

According to NFHS 4, only 22% women in Maharashtra have comprehensive knowledge about HIV. For success of any programmatic efforts towards HIV prevention and care among women in this setting, it will be critical to design and implement regionally effective outreach activities to improve community awareness. The national strategic priorities are now focused on differential approaches towards outreach and community services to make them relevant to specific populations and geography such that it can improve community ownership and engagement. Therefore, it will be imperative to design, implement and evaluate novel communication strategies to enhance community perception about HIV risk, prevention and care. The awareness about HIV science and research will also be critical for enhancing uptake of HIV services and upcoming interventions.

The current interventions will focus on creating safe spaces to strengthen community conversations and help create of an 'HIV competent Community' that would enable community members to support each other in achieving behavior change. Rooted in various theories of Social and Behavior Change Communication, the intervention aims to create strategies that would help support inclusive and meaningful community engagement. Towards this, the program would employ various interactive games, street play based acts, group meeting on specific subject so that community can attend and actively participate in it, it will also adopt method like theater activity, video presentation of any subject and through power point presentation of various modules.

In addition to these, with an intent to bring science closer to community and provide an equitable space for community to participate in research in meaningful manner, learning tools will be developed and implemented that will help break down scientific quests and help community vale and think critically about HIV research and need for innovation and also help make HIV research more people-centered.

Designing of the intervention

Exhaustive review of relevant literatures and discussions with relevant peers would inform the designing of interventions for community engagement and education. Communication materials would be designed and co-created in consultation with the community members, program experts and research staff to further strengthen communities understanding of HIV prevention, Sexually Reproductive Health, Human body system and general health issues (such as non-communicable diseases), health seeking options, disease prevention, and ongoing BMR.

The materials may include (but are not limited to) leaflets, brochures, and posters and also research literacy tools like Participatory Theatre Activity and Experiential Game towards explaining various scientific basics in layman language.

Dissemination of the intervention

The community engagement for this study will be done in selected area of Karad, Ichalkaranji and Sangli in Maharashtra. Mass level campaigning through IEC material, local level publicity and advertisements in general population as well as focused engagements in FSW populations through outreach meetings and service delivery camps based on specific community needs will be adopted for increasing awareness and participation from the community including high-risk women from both general population and FSW population.

Community sensitization will be undertaken in the selected sites. The community will be oriented about the project, activities, and programs. Different methods will be applied for community sensitization such as one to one session, group sessions, dissemination of information through audio-visual modes and others. The community leader or key people in case of high-risk population will be identified during the initial phase of the project for community engagement and active participation. Also, peer volunteer will be identified for supporting the community sensitization work as well as their active engagement for the screening of HIV testing.

The prospective plan for the community engagement activities are provided below:

Detailed CEP plan

Activity	Site	Number	Implementor	Purpose
Outreach meetings/ Service delivery to relevant populations	Karad Ichalkaranji Sangli	25-30 engagements	• Research Assistant (Interventionist) • Peers	The community will be oriented about the project activities, and programs. Community sensitization and dissemination of information through audio-visual modes and others. To understand the need of research and preparedness of research in HIV prevention
Participatory Theatre Activity	Karad Ichalkaranji Sangli			To give knowledge about the perception, facts about HIV, Govt facilities of health care services.
	Karad			

Experiential Game	Ichalkaranji Sangli			To understand the disease epidemiology, incidence, HIV testing, treatment outcome, adherence benefits, social and moral responsibility, stigma reduction

Evaluation of Community Engagement Tools

This phase will evaluate the impact of community education messages for HIV (epidemiology, testing, treatment, adherence and national programme), SRH, and biomedical research participation on high-risk women from general and FSW population. This will be questionnaire-based evaluations across all the selected study sites. A sub-sample of the population will be selected for administering the community engagement tools and the data will be compared with a control group from the same population. Both the groups will be assessed at the baseline (before communication engagement tools are administered) and at end-point (after the tools are administered). Relevant qualitative and quantitative tools for analyzing knowledge and perception will be adopted from appropriate 'Knowledge-Attitude-Practice' and other behavioral science framework.

Statistical Analysis

- The quantitative questionnaire survey will be analyzed to decipher the interplay between socio-demography, knowledge and perception about SRH, HIV and BMR participation using frequentist approaches;
- The level of significance will be taken at 0.05;
- The effect of community engagement tools will be measured by comparing the appropriate scores defined for this study across intervention and control groups.

The details of statistical analysis will be outlined in the Statistical Analytical Plan.

Implementation Plan

Respecting and Protecting Research Participants and Communities

Informed consent process

Informed consent will be obtained prior to any data collection. Participants in the interviews will be presented with an information letter that outlines the scope of the study and a consent form that provides options to sign or put initials. Given the potential low literacy levels of some participants, the research assistants will offer to read the information letter and consent form. Following this procedure, they will then ask the potential participant questions about the study to ascertain the participant's level of understanding.

As part of the informed consent process, all potential participants will be told that their participation or not in interviews will not affect the services they currently receive or may receive in the future from their respective community agencies.

Possible risks and measures to minimize risks

There is no direct or indirect harm to the any participant due to their participation in the survey study.

Administrative Procedures

Roles and responsibilities

The Principal Investigator will be responsible for all aspects of the study at the study sites. The Study Advisor will be responsible for overall technical appropriateness of the study. The study staff will be recruited by the PI with approval from the Study Advisor. The Advisor will be responsible for overseeing the staff training for data collection and data analysis.

Study Working Group (SWG)

At each site, a Study Working Group, consisting of the Principle Investigator, the study co-ordinators and research staff will meet regularly to discuss any study related issues and address them in working with the Study advisor. Additionally, teleconferences between members of the SWGs, Study Advisor and IAVI will be organized monthly to discuss the progress of the study and study related issues.

Study Monitoring

On-site monitoring will be conducted to ensure that the study is conducted according to the protocol and is in compliance with applicable regulations and guidelines, recorded and reported in accordance with the protocol, is consistent with locally-accepted practices and standard operating procedures.

The Investigators and volunteers, by giving consent, agree that the monitor may inspect study facilities and source records (e.g., informed consent documents, other source documents) as well as observe the performance of study procedures. Such information will be treated as strictly confidential and will under no circumstances be made publicly available. The Principal Investigator will permit inspection of the facilities and all study-related documentation by authorized representatives of IAVI and Government and Regulatory Authorities relevant to this study.

Study Deliverables

The key deliverables for all study sites would include submission of (a) monthly progress and site-specific performance reports including field events, photos from sites etc; (b) SOPs, intervention strategy and training resources developed including guidelines and manuals; (c) original raw data (including field notes, transcriptions) and compiled data with analysis (including computer programmes, source codes, and any written documentation) (d) power point presentation including top line findings and final report upon completion of the study (e) Baseline and endline report (f) Budget utilization certificate to IAVI. In addition, any publication/ submission of abstract/summary or presentations in national and international conferences/peer reviewed journals must have prior approval from IAVI.

Investigator's Records

The Investigator will maintain and store in a secure manner complete, accurate, and current study records throughout the study. Study records include administrative documentation, including reports and correspondence relating to the study, as well as documentation related to each participant and should be kept in a secure location.

Publications

Manuscripts will be developed from the study reports. All manuscripts, abstracts, reports will be reviewed and approved by the study PI, study advisor and in working with the study sponsors. The researchers along with other contributors from partner agencies (including IAVI), where appropriate, who have substantially contributed to the manuscript will be given a co-authorship in accordance with the standard publication ethics guidelines.

International AIDS Vaccine Initiative

Table of Required SUB-AWARD DATA ELEMENTS

IAVI Agreement Number A08723 (YR 4 Award)

Required Information per 2 CFR 200.331(a)

1.	**Federal Award Identification:**	HIV Vaccine and Biomedical Prevention Research Project – Objectives 1 and 2
2.	**Sub-recipient Name:**	**KRISHNA INSTITUTE OF MEDICAL SCIENCES DEEMED TO BE UNIVERSITY (KIMSDU)**
3.	**Sub-recipient DUNS Number:**	859167931
4.	**Federal Award Identification Number:**	USAID Cooperative Agreement AID-OAA-A-16-00032
5.	**Federal Award Date:**	**11/13/2019**
6.	**Sub-award Period of Performance:**	**11/13/2019 - 6/30/2020**
7.	**Amount of Federal Funds Obligated by this Annual SOW/MOD:**	$97,745
8.	**Total Federal Amount Obligated including this Annual SOW/MOD:**	$97,745
9.	**Total Amount of the Federal Award Committed to the Sub-award Organization:**	$97,745
10.	**Total Sub-award Amount (including other donor funding)**	$97,745
11.	**Federal Award Project Description (FFATA):**	ADVANCE: Sub Result 2.3b:South-South collaboration work to create a cohesive regional network for conducting work on community preparedness, immuno-biology, product development and increase opportunities for training and collaboration between East and Southern Africa and India, by sharing samples, expertise, data, and capacity, while focusing on common health and scientific goals including HIV prevention.
12.	**Name of Federal Awarding Agency**	U.S. Agency for International Development (USAID)
13.	**Pass-through Entity Name and Contact Information**	International AIDS Vaccine Initiative (IAVI) 125 Broad Street, 9th Floor, New York, NY 10004 Lola Sunmonu: lsunmonu@iavi.org.
14.	**CFDA Number and Name**	98.001, USAID Foreign Assistance for Programs Overseas

International AIDS Vaccine Initiative

15.	**R&D Funding**	Yes ☒No ☐
16.	**Sub-award Organization Indirect Rate**	8%
17	**Approved federally recognized, negotiated, or de Minimis KIMSDU (10% of MTDCR)**	N/A
18	**Additional requirements imposed on pass-through entity i.e. environmental compliance requirements (22CFR 216).**	
19	**Type of Award**	Cost Reimbursement ☒ Fixed Cost ☐ Other ☐

Study Title

Assessment of Experiential learning-based Community Engagement Tools to Enhance Research Literacy and Participation in HIV Biomedical Research in Rural Maharashtra

Protocol No: _203/2019-2020

Study Investigators, Implementation team and Institutional Affiliations

KIMSDU	
Asha Jadhav ***Principal Investigator*** Director Extension Activities Krishna Institute of Medical Sciences, deemed to be University, Pune Bangalore Highway, Malkapur, Karad Dist .Satara 415110 Email: kimsdea@gmail.com Phone:9421576382	**Signature:** DocuSigned by: Dr. Asha Jadhav 337CA0A9F1E84EE... **Date:** 10/16/2020
• Suhas Shewale - Program Manager • Ganesh Shinde - Project Assistant • Manoj Kumbhar - Project Assistant • Ravindra Kurade - Project Assistant • Nayana Yenbhar - Project Assistant • Sachin Sakate - Interventionist • Asmita Deshpande - Interventionist • Satish Kamble - Field worker • Vaibhav Patil - Counsellor • Anisa Mulla – Field worker/Technician • Shruti Kulkarni - Data Entry Operator and Accountant • Rais Patel - Study Co-ordinator • In working with partner CBOs (e.g. SANGRAM- VAMP, Muskaan)	
NARI	
Seema Sahay ***Study Advisor*** Scientist-G, ICMR-National AIDS Research Institute, Pune-411026 Email: ssahay@nariindia.org Phone: 020-27331200	**Signature:** DocuSigned by: Dr. Seema Sahay 10A4CA6C6FD3466... **Date:** 10/21/2020
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This study is made possible by the support of the American People through the United States Agency for International Development (USAID) and the US President's Emergency Plan for AIDS Relief (PEPFAR) through IAVI.

Contents

1. Summary of the Study

India stands at a crucial crossroad where in spite of structured programmatic efforts resulting in steady decline in national prevalence, HIV/AIDS continues to be significant public health issue with considerable inter-state variations in prevalence among high risk populations like, Men who have Sex with Men (MSM), Female Sex Workers (FSW), People Who Inject Drugs (PWID), Transgender Women (TGW), adolescents, migrants and truckers among others. With rapidly evolving global HIV disease management landscape and focused efforts towards innovative biomedical tools including pre-exposure prophylaxis (PrEP), microbicides, long-acting implantable anti-retrovirals, therapeutic and preventative broadly neutralizing antibodies etc., it will be imperative to conduct appropriate long-term population-based cohort studies to develop scientifically proven, cost-effective and scalable intervention strategies in alignment with regional and population needs for maximal impact on the HIV epidemic.

Success of the above efforts also critically depend on strong and equitable community engagement efforts at all stages of research to enhance community understanding, appreciation and participation in biomedical research, as proposed by the Good Participatory Practice (GPP) guidelines. Towards this, experiential learning tools, based on participatory research paradigm help democratize, contextualize and humanize the complex data and scientific concepts that often cloak conversations around HIV research and hence help create a 'HIV competent community' that would enable community members to support each other in achieving positive behavior change. In accordance with this, the current study is focused on understanding factors influencing community participation in research as well as roll out and assess an experiential learning-based intervention towards enhancing community understanding and appreciation of HIV science and research to encourage informed and voluntary engagement, promoting health seeking behavior and community collectivization.

The study will be conducted using a mixed methods approach including quantitative surveys as well as qualitative interviews and discussions focused on FSW, MSM and TG populations across Satara, Sangli and Kolhapur districts in rural Maharashtra. Baseline quantitative survey to capture community perspectives about their willingness to participate in BMR will be conducted with 600 participants, among which 400 participants will be exposed to the experiential learning-based intervention session (40 intervention session with 10 participants each). Each intervention session will include interactive games and participatory theatre to trigger open dialogues which will be navigated through semi structured community conversations and a post-intervention feedback survey. These 400 participants and another intervention naïve 200 participants will be subjected to an end-line quantitative survey to assess any change in knowledge about HIV science and attitude towards HIV BMR. A separate set of 20 Key Informant Interviews (KII) will be conducted with relevant information rich stakeholders across the study sites to help understand the structural factors influencing service uptake, the existing needs and the implementation challenges in the current context. Data from above activities along with structured diary entries by the facilitators will help evaluate process parameters that will inform and improve further implementation of the intervention as well as help validate the success of the intervention rolled out as a part the current study.

The data collected and analyzed from the activities mentioned above will enable understanding the following:

- ***Key drivers of community participation in BMR*** – An insight into the facilitators and barriers for community participation with in-depth understanding of the individual, interpersonal, social and structural drivers of decision-making as well as external influencers like current COVID pandemic across key populations (FSWs and MSMs) and sites within rural Maharashtra. This will also help identify areas where the experiential learning tools can be utilized to bring about a change in the community behavior.
- ***Influence of the EL tools on research literacy and willingness for BMR participation –*** It will be possible to capture the immediate and retained change in the community understanding of HIV science and research, variation in their willingness to engage in research and also provide some insights into their perceptions about the need and science behind better health seeking behavior like regular testing and drug adherence.
- ***Factors influencing implementation of the EL tools –***The study will aid in elaborating the fidelity, track the reception, active participation and engagement of the participants, quality of the conduct, how satisfied the end users were with the tools in terms of their ease of understanding and simplicity of the messages. It will also pave the way towards assessing the potential uptake of these tools by the community and understanding the practical challenges that may be posed in the context of other external factors.

All of the above taken together will contribute towards influencing the network of behaviors including health seeking practices, community collectivization, research literacy and hence positively impacting the core desired change in the willingness to participate in biomedical research. The core essence of the study lies in the fact that it will be a step forward in strengthening the participatory mechanisms of GPP to make research “equitable, reciprocal and relatable” towards building a research enabling ecosystem.

2. Background and Rationale

2.1. HIV in India

India stands at the intersection in the response to its HIV epidemic and has made significant steps in controlling the same. New HIV infections and AIDS-related deaths have dropped by 46% and 22%, respectively, since 2010 (NACO Technical Report 2017). The adult HIV prevalence at national level has continued its steady decline from an estimated peak of 0.38% in 2001-03 through 0.34% in 2007, 0.28% in 2012 and 0.26% in 2015 to 0.22% in 2017 (NACO Technical Report 2017). However, despite strong programmatic efforts resulting in overall decline in HIV prevalence, HIV continues to be a public health issue with considerable inter-state variations in prevalence among certain populations at higher risk of HIV infection like, Men who have Sex with Men (MSM), Female Sex Workers (FSW), People Who Inject Drugs (PWID), Transgender (TG), adolescents, migrants and truckers among others (Joshi and Mehendale 2019; NACO HSS Technical Report 2017; NACO Technical Report 2017; NACO NSP 2017-2014). Therefore, it is imperative to understand community needs and perspectives towards HIV prevention and care to develop improved disease management strategies which are region and population specific.

The HIV disease management landscape has also been evolving and newer advancements in the prevention and treatment methodologies have brought about a paradigm shift in approaches to address the global HIV disease burden. Ongoing biomedical research focused on complex interplay between host, virus and the environment are informing towards enabling development and implementation of new tools for HIV prevention and treatment, for example, for pre-exposure prophylaxis (PrEP), microbicides, long-acting implantable anti-retrovirals, therapeutic and preventative broadly neutralizing antibodies etc. It will be imperative to identify scientifically proven, cost-effective and scalable intervention and prevention strategies in alignment with regional and population needs for maximal impact on the HIV epidemic. Towards this, long-term cohort studies across the globe have been instrumental in focusing on different aspects of the HIV-disease and in working towards a better disease management tool.

2.2. Community Engagement

Given the above, for success of any efforts towards HIV prevention and care among the at-risk populations, it will be critical to design and implement regionally effective outreach activities to understand community needs, improve community awareness and attitude towards HIV research and enhance service uptake. Strong and equitable community engagement should focus on involving communities at all stages of research including the conceptualization, protocol, recruitment and enrollment, follow up, results and final dissemination (Day et al 2018; Forsythe et al 2016, Concannon et al 2014). HIV research field has championed innovative community/ stakeholder engagement for decades now resulting in development of the Good Participatory Practice (GPP) guidelines which proposes equitable, reciprocal and relatable engagement strategies to enhance community understanding, appreciation and participation in biomedical research. Parallel entities such as Nuffield Council of Bioethics also recommends rigorous engagement with public, professional, political and policy stakeholders to inform ethical conduct of research such that the benefits to society are realized in a way that is consistent with public values.

Existing data reveals that while many methods are used (Mack et al 2013; Ditmore et al 2011; Ramjee et al 2008; NIMH Collaborative HIV/STD Prevention Trial Group 2007; McQueen et al 2007; Morin et al 2003), most community engagement is conducted using researcher-driven, top-down methods (Day et al 2018) driven by deep rooted social dynamics and structural inequalities, and therefore, it is unclear how effective these are for fostering meaningful and equitable partnerships and continuous dialogue as the GPP guidelines recommend (UNAIDS GPP guidelines 2011). Engagement methods which are based on participatory model can help achieve more meaningful inclusion of communities and provide a greater opportunity for community- researcher dialogues by breaking the social-structural boundaries and allowing marginalized voices to be heard (Raynolds and Sariola 2018). It is also reported that the extent to which the vulnerable communities engage in research is also driven by societal and structural contexts within which the research is embedded and hence it is very critical to engage the community beyond as 'participants' but as providers of social and technical knowledge that researchers should learn to ensure that interventions are effective and responsive to community needs and interests (Raynolds and Sariola 2018).

Beginning with the fundamental premise that end-user communities constitute the most important stakeholder group in the research enterprise, and they deserve to know not just the 'how' but more importantly the 'why' behind the research they contribute towards, experiential learning tools, based on participatory research paradigm help democratize, contextualize and humanize the complex data and scientific concepts that often cloak conversations around HIV research. Formative research through multiple conversations with various national and regional stakeholders helped in understanding the following key challenges with regard to engaging communities in research:

- Communications are often complex, prescriptive and jargon-laden resulting in limited explanation of what exactly is happening in our bodies and how science can help;
- Communities often do not own the research since they are not consulted or engaged early enough in the research process; and not always informed of research outcomes;
- Lack of understanding of HIV research and absence of safe spaces to openly discuss about research leads to lack of trust between researchers and community members.

Towards this, tools based on experiential learning (including participatory games and theatre) have been co-designed and co-developed in working with the target communities. These tools have brought together ideas from the behavioral sciences, social psychology, gamification, participatory theatre and the creative arts and to help demystify the interaction of HIV within the human body and resulting challenges including viral diversity, latency, drug resistance, etc. The current intervention based on these experiential learning tools is aimed at bridging some of the above-mentioned gaps towards the following:

- Informed and active participation of end-user communities;
- Enhanced sense of engagement and ownership and equity in community stakeholders;
- Enhance community understanding, appreciation and engagement among public health research;
- Creation of safe space for co-learning and open exchange.

These tools will thus help create an 'HIV competent Community' that would enable community members to support each other in achieving positive behavior change. Rooted in various theories of Social and Behavior Change Communication, the intervention aims to create strategies that would help support inclusive and meaningful community engagement. This study will aim to assess the utility of these tools

in achieving the intended outcomes and will also set the base for implementation and roll-out of these tools as a part of a broader community engagement plan that can be used for ongoing/upcoming biomedical research/clinical trials.

2.3. The National HIV Cohort Study (CoHRPICA) – Community engagement needs

The National HIV Cohort Program (**Co**horts for HIV **R**esistance and **P**rogression in **I**ndian **C**hildren and **A**dults – CoHRPICA), supported by the Department of Biotechnology (DBT), Indian Council of Medical Research (ICMR) and IAVI, is focused on creating specific cohorts, biorepository and database to enable understanding of the disease and aid in development of new tools for disease management. Towards this, the Program aims to bring together multiple institutes with interdisciplinary expertise (clinical, socio-behavioral and biomedical) across India to establish a consortium that leverages on individual strengths to accelerate population-based studies in HIV/AIDS. As a part of this, NARI (in working with KIMSDU) is responsible for establishing HIV uninfected cohorts from high risk populations (including exposed seronegative cohorts), Early HIV infected individuals and also HIV infected cohorts with and without co-morbidities. This initiative also provides platform for and leverages on successful long-term access to the relevant communities through meaningful engagement activities. In this context, the current set of experiential learning tools could prove to be an effective way of community inclusion and involvement in the proposed cohorts and future HIV research.

2.4. Rationale of the current study

As discussed above, involvement of community is a key element of HIV biomedical research including large-scale cohort studies and clinical trials which ensure ethical and scientific quality of research, its relevance to the affected community, rapid dissemination of the results and finally implementation of action based on the results (ICASO 2006). Therefore, it becomes extremely pertinent to extend the knowledge of these developments to the relevant community, understand their perspectives and the community needs, and their social and behavioral practices.

According to the National HIV Estimation data (NACO Technical Report 2017), although adult HIV prevalence among 15-49-year-old people has been declining in India, Maharashtra continues to be one of the high burden states with consistently high HIV prevalence among the FSW population. Also, Maharashtra turns out to be one of the high-risk pockets for MSMs/TGs with HIV prevalence greater than the national average (HSS Technical Report 2017). Therefore, representation of these communities in upcoming biomedical research and product trials will be indispensable for improved disease management. Thus, the current study would focus on FSW, MSM and TG population in rural Maharashtra.

Moreover, given the COVID-19 pandemic, it is important to understand the impact of the pandemic on the above-mentioned at-risk populations as the altered socio-economic condition, disrupted health services and increased stigma and discrimination are likely to affect their decision-making towards participation in biomedical research.

Given the above, the current study will focus towards understanding the factors influencing community participation in research and a set of experiential learning-based community engagement tools (including interactive games and participatory theatre) will be rolled out and assessed towards enhancing community understanding and appreciation of HIV science and research to encourage

informed and voluntary engagement, promoting health seeking behavior and community collectivization.

3. Study Aim and Objectives

3.1. Aim:

The aim of the study is:
Assessment of Experiential learning-based Community Engagement Tools to Enhance Research Literacy and Participation in HIV Biomedical Research in rural Maharashtra

3.2. Objectives:

The objectives of the current study are:
Objective 1: To understand the facilitators and barriers towards participation of HIV at-risk community (FSW, MSM and TG) in HIV biomedical research (BMR) studies
Sub-objectives:
1.1. To understand community willingness to participate in BMR & drivers of the decision-making;
1.2. To outline the influence of external factors (including COVID-19 pandemic) on the informed and voluntary BMR participation.

Objective 2: To assess the utility and implementation features of experiential learning-based (EL) tools towards advancing research literacy and community engagement in BMR
Sub-objectives:
2.1. To assess the overall change in knowledge, perception & willingness to participate in BMR brought about by the experiential learning tools;
2.2. To assess the role of experiential learning tools in enhancing community engagement in BMR;
2.3. To understand the salient factors that influence implementation of the intervention including in the context of the current COVID-19 pandemic.

4. Methodology

4.1. Study Population

The current study will focus on FSW, MSM and TG populations (18 years and above) across rural Maharashtra. As mentioned above, given the consistent high HIV prevalence among key populations in Maharashtra, it will be imperative to understand the social, economic, behavioral and structural drivers that influence overall health seeking behavior and service uptake and hence also play a role in influencing community willingness to participate in BMR. Moreover, given the vulnerability and disproportionate impact of COVID-19 pandemic on HIV at-risk communities, it is important to understand the influence of COVID-19 on the community response to inform ongoing/ upcoming BMR initiatives.

4.2. Study Sites

The study will be conducted by accessing FSWs, MSM and TG population across Sangli & Miraj (Sangli district); Karad (Satara Dist), Ichalkaranji & Kolhapur (Kolhapur Dist) in Maharashtra.

4.3. Conceptual Framework and Data Collection

4.3.1. COM -B Behavior Change framework

Behavior change interventions are fundamental components of effective public health management. These interventions are defined as coordinated set of activities designed to change specific behavioral pattern in target population. The COM-B model provides a comprehensive conceptual framework for designing and implementing behavior change interventions (Michie et al 2011). COM-B stands for Capability Opportunity Motivation – Behaviour. The model is constructed on the premises that any specific human behavior, chosen as target for intervention is a part of interactive network of behaviors. According to the COM-B model, for the target behavior (B) to occur there must be capability (C) in the concerned person/ community to perform the behavior utilizing the available opportunity (O) in terms of conducive physical and social environment, driven by sufficient strong motivation (M).

Each of these components can be divided heuristically into two types. Capability can be either 'physical' (having the physical skills, strength or stamina) or 'psychological' (having the knowledge and cognitive capabilities for memory and decision making) to perform the behaviour. Only psychological capability will be relevant for the current study (discussed below in sec). Opportunity can be 'physical' (environmental facilitators like time, location, resources) or 'social'
(including interpersonal influences, social cues and cultural norms). Motivation may be 'automatic' (processes involving emotion, impulses, desires and inhibitions) or 'reflective' (beliefs about self and the outcomes).

For the current study, the COM-B framework has been adapted to design, develop and analyze the experiential learning tool-based intervention targeted towards the ecosystem of behaviors that drive community willingness to participate in HIV BMR.

4.3.2. Data Collection parameters – Lines of enquiry

Based on the overarching conceptual framework of COM-B, the data collection efforts will be directed towards the following:

- Identifying key drivers (both enablers and barriers) of community participation in BMR;
- Analyzing influence of the EL tools on research preparedness and willingness to participate in BMR;
- Assessing shift in the level of engagement of the community in research due to intervention.

Towards the above, broad line of enquiry under each relevant component of COM-B are provided below:

Psychological capability

The indicators of change at individual and community level include:

- Knowledge about HIV science, before and after the intervention;
- Understanding of rationale behind and process involved in HIV research;
- Understanding scientific rationale behind health seeking practices such as regular testing and drug adherence.

Physical opportunity

The indicators that might influence research participation include:

- Burden of engagement – competing responsibilities including job, home and child care; availability of resource for mobility and travel; time and cost of travel;
- COVID induced social situation – Impact of mobility restriction, social distancing and additional COVID related stigma on participation.

Social opportunity

Interpersonal and social factors that might influence community involvement in research include:

- Moral values, stigma and discriminatory practices associated with HIV/AIDS;
- Gender norms and power dynamics in intimate relationships;
- Role model and positive deviance – exemplary participation of community representatives/ peers in HIV BMR;
- Access to appropriate information on HIV science/ research and opportunity for open conversations within community;
- Conducive environment that promote equity and inclusivity in research engagement.

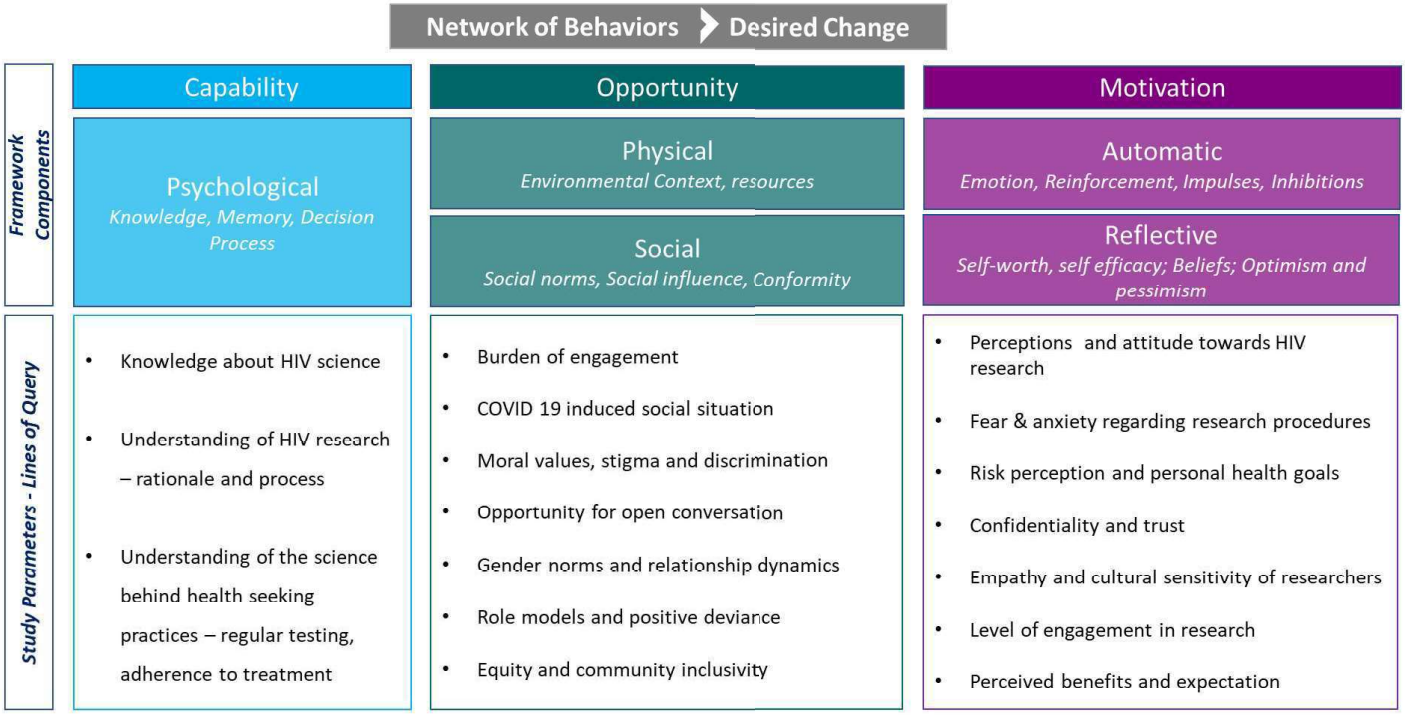

Figure 1: Overarching conceptual framework of the study

Automatic motivation

Emotional and impulsive factors that might drive willingness to participate in research include:

- Fear and anxiety regarding research procedures – fear of needle and blood collection; fear of side effects; anxiety about unintended disclosure of health condition (including HIV status);
- Tangible benefits such as regular health check-up, incentives and compensations.

Reflective motivation

Motivational indicators including belief and reasoning that might influence willingness to participate in research include:

- Perception attitude towards HIV research;
- Perception about HIV risk and personal relevance;
- Perceived benefits of research and expectation about outcome – altruism and community welfare;
- Confidentiality concerns and level of trust towards researchers;
- Experience regarding empathy and cultural sensitivity in researchers;
- Level of engagement that promote community-researcher dialogues and sense of shared ownerships.

Specific methodologies for collecting data in line with the above-mentioned parameters are described in the Section 5.

4.3.3. Process Evaluation Framework

Process evaluation is an essential component of this study aimed at understanding key factors that will inform and improve further implementation of the intervention as well as help validate the success of the intervention rolled out as a part the current study. Based on the available paradigm of process evaluation for public health interventions and research (Baranowski and Stables 2000; Steckler and Linnan 2002; Saunders et al 2005; Metzelthin et al 2010), a systematic approach has been adapted to include the following key parameters:

- *Fidelity:* It represents the quality and integrity of the intervention delivery in adherence to the original implementation plan. The indicators include frequency and duration, content, completeness and quality of delivery.
- *Reach:* The p*roportion and characteristic of the intended target population that participated in the intervention.* It is operationalized as the attendance and demographic characteristics of the participants.
- *Exposure:* It helps understand the extent to which participants are actively engaged, interact with and receptive to the modules and spontaneously initiated interactions.
- *Satisfaction:* It refers to the extent to which the intervention delivery was acceptable and agreeable to the participants as well as was likable and easy to understand. It also would help understand participant satisfaction from the interactions with facilitators and/or investigators.
- *Implementation:* it includes potential challenges that might affect effective intervention delivery, especially given the COVID-19 pandemic situation. It also includes perception of facilitators and peer educators regarding further adoption of the intervention tools for community engagement.

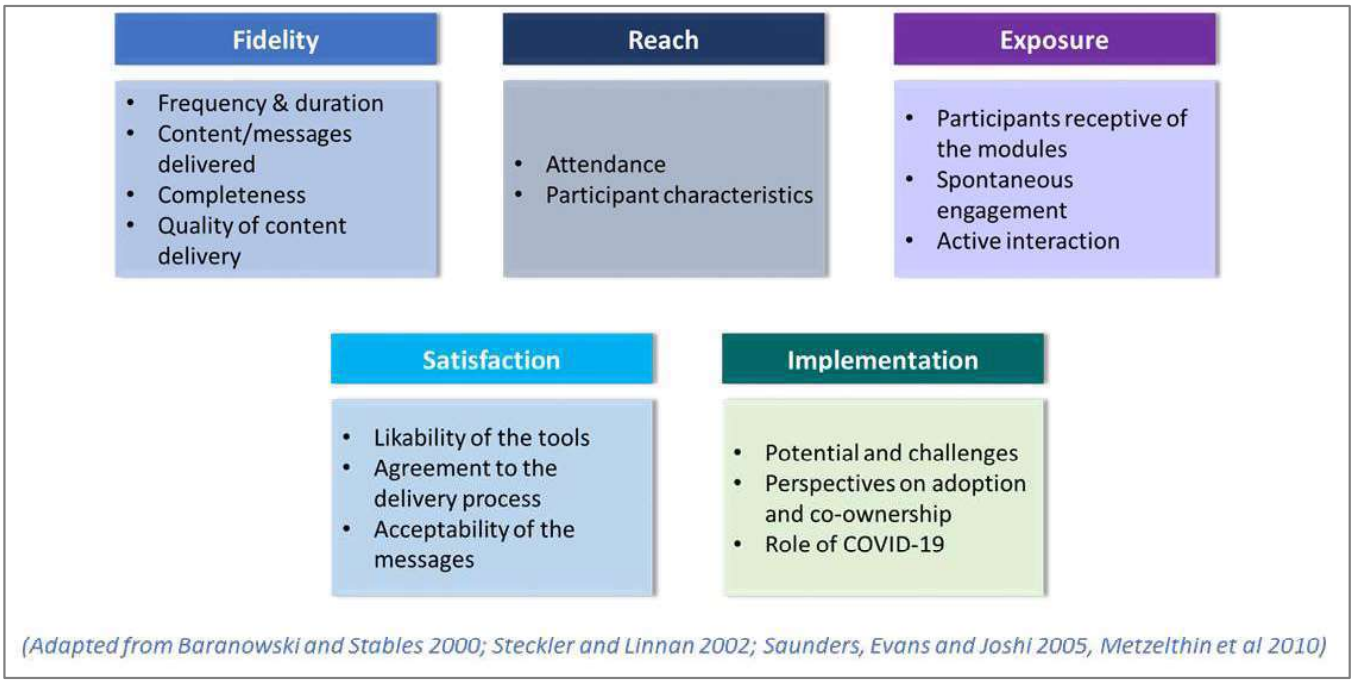

Figure 2: Process Evaluation Framework for current study.

Data regarding the above parameters will be collected through structured Diary records which will be provided to the field facilitators. The diaries will provide facilitators' account and interpretation of activities during intervention sessions. Facilitators need to maintain fill the templates provided in the diary after every session and these would be digitized once every month. Some aspects of satisfaction and implementation will also be captured from the post-intervention survey, community conversations and the key informant interviews.

4.4. Study Design

The study will be conducted using a mixed methods approach which will have quantitative surveys as well as qualitative interviews and discussions. The study activities are proposed over the period of 9 months. Details of the methodology across the study objectives are provided in Figure 1 below:

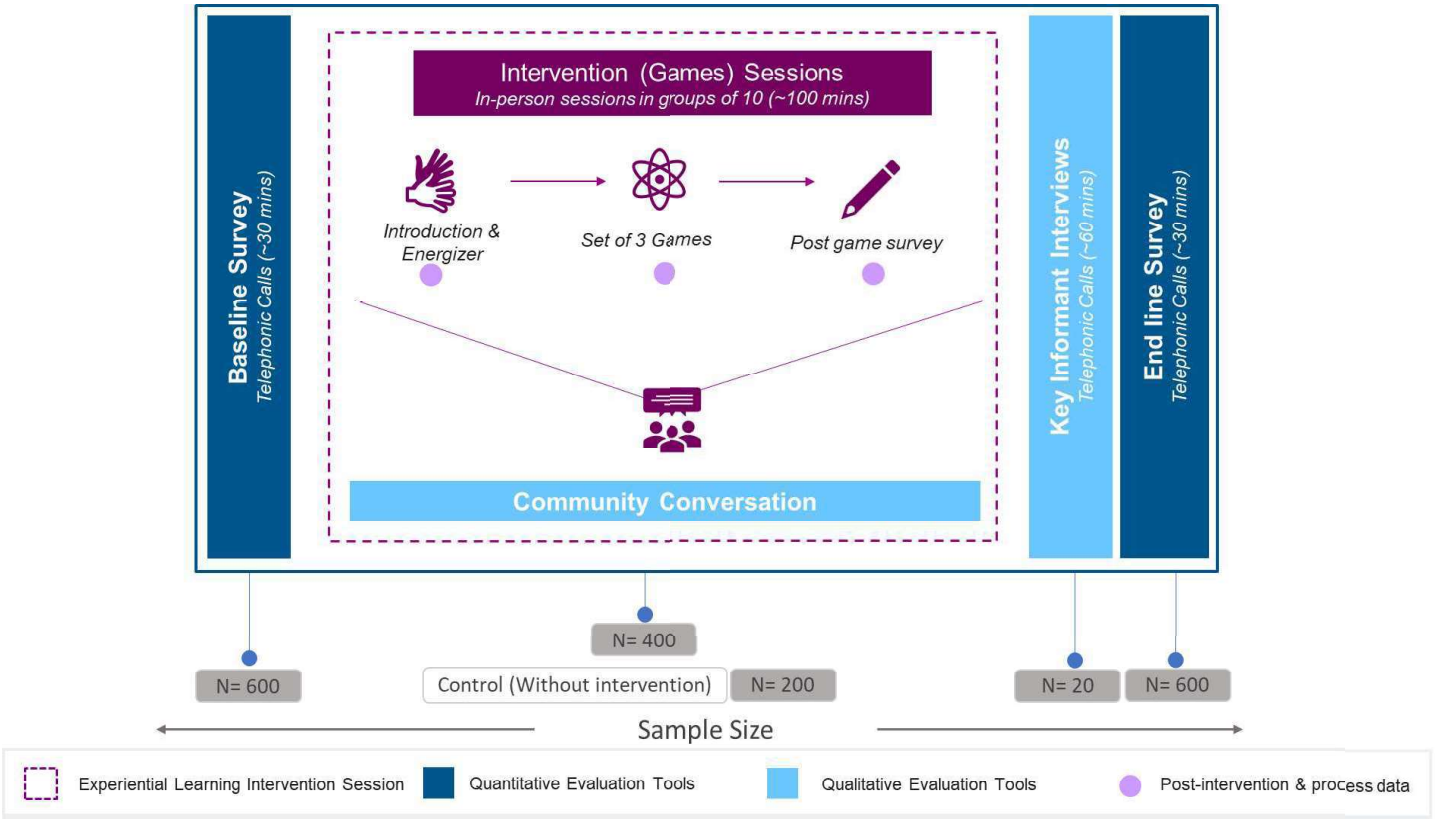

Figure 3: Overall study methodology

4.4.1. Methodology - Objective 1: To understand the facilitators and barriers towards participation of HIV at-risk community (FSW, MSM and TG) in HIV biomedical research (BMR) studies

Towards the above, data will be collected through:

- Baseline quantitative survey to capture community perspectives about their willingness to participate in BMR and also identify key drivers of their decision-making;
- Qualitative interviews with key informants (key informant interviews- KIIs) to help understand the social, behavioral and structural factors influencing service uptake; the existing needs (including of any new community engagement interventions) and the implementation challenges in the current context; and KI perspectives of community willingness to participate in BMR.

4.4.1.1. Baseline Surveys

- Target population:
  In order to capture diverse perspectives and build a comprehensive data set, the baseline survey will span across diverse subgroups of respondents among FSW (e.g. brothel based, street based,

internet/ social-media based, etc.) and MSM/TG (engage in sex work; are from lower/ middle class; single/ living with male/female partner/ heterosexually married, etc.) populations.

- Sampling:
  - A total of 600 baseline surveys will be conducted across all study sites to capture the diverse perspectives among FSW, MSM and TG population. This will include surveys with participants across Sangli/Miraj, Karad and Ichalkaranji/Kolhapur;
  - A purposive sampling will be done to achieve the above sample size;
- Access to target community:
  The above-mentioned populations will be accessed through extensive linkages with relevant CBOs working across Sangli, Satara and Kolhapur districts. Appropriate outreach mechanisms including stakeholder engagement for community sensitization and participant recruitment for data collection will be outlined in working with the CBOs.
- Method:
  The survey (Annexure 1) will be conducted through telephone calls. The responses will be captured on the paper Case Report Forms. However, the phone calls will also be audio recorded for necessary cross verification. In case of refusal for recording, no recordings will be done.

4.4.1.2. Key Informant Interviews (KIIs)

- Target population:
  KIIs will involve information-rich participants who have worked with the relevant populations and/ or in the field of HIV including health-care providers (e.g. clinicians, medical officer, staff nurse), researchers, bioethicists, other stakeholders (e.g. representatives from CBOs/ DAPCU), ASHA workers, community gatekeepers (e.g. brothel owners, Panch and Gramsevaks), HIV/human rights activists and also the study intervention facilitators/interventionists among others.
- Sampling:
  - A total of 20 KIIs will be conducted across all study sites to capture perspectives from various key informants as mentioned above;
  - A purposive sampling will be done to achieve data saturation with the indicative sample size representing relevant key informants across the study geography;
- Method:
  The qualitative semi-structured interviews (Annexure 2) will be conducted through telephonic conversations based on specific probes and topic guides. The audio recorded data from phone calls will be transcribed and translated for further analysis.

4.4.2. Methodology - Objective 2: To assess the utility and implementation features of experiential learning-based (EL) tools towards advancing research literacy and community engagement in BMR

The proposed intervention in the current study focusses on using gamification and participatory theatre-based tools co-created by involving all the study partners and relevant stakeholders including the community to trigger community conversations and help communities have open discussions and dialogues about HIV research and need for participation.
Towards the above, activities included are the following:

- Intervention implementation - Roll out of the tools among the FSW, MSM and TG population;

- Intervention Assessment- Assessment of the utility of the community engagement tools in advancing research literacy and participation in research.

4.4.2.1. Implementation of the intervention

- The intervention will be rolled out among 400 key populations in selected localities across Sangli/Miraj; Karad and Ichalkaranji/Kolhapur in Maharashtra.
- The intervention sessions will be implemented with a limited number of individuals (~10 participants per session) with appropriate measures of safety in alignment with national and regional guidelines available in the context of COVID-19 pandemic. Thus, to cover the proposed sample size, there will be 40 intervention sessions among FSW, MSM and TG populations across all study sites. Participation of a subset of individuals who participated in the quantitative baseline survey (400 out of the 600) will be essential for assessing the utility of the intervention.
- Each intervention session would include an introduction/icebreaker/energizer followed by one or a combination of the experiential learning module (set of 3-4 games) followed by an open community discussion to provide a safe space to the community members to raise their concerns and better understand the scope and purpose of biomedical research. The session will end with a brief post intervention survey to capture insights and feedback from the session.
- Towards the above, local level publicity and advertisements focused on the target populations will be adopted leveraging on extensive CBO linkages for increasing awareness and participation from the community. Community sensitization will be undertaken by developing appropriate outreach mechanisms in working with relevant CBOs. The community will be oriented about the project, activities, and ongoing and upcoming programs including National HIV Cohort Program. Different methods will be applied for community sensitization such as one to one session with community gatekeepers and opinion leaders, group sessions with limited number of individuals, dissemination of information through audio-visual modes and others based on feasibility and community needs. Also, peer volunteer will be identified for supporting the community sensitization work as well as their active engagement during the intervention sessions.

4.4.2.2. Assessment of EL-based community engagement Tools

The primary assessment of the intervention will be conducted through the following tools:

<u>During the Intervention Session</u>

- **Post- intervention surveys** (Annexure 3) will be associated with each individual intervention session. These would be conducted after each intervention session to aid in providing a statistical quantitative understanding of the immediate change brought about by the intervention.
- **Community Conversation** (Annexure 4) with the participants will be conducted after the EL based tools are played in each intervention session to help better assess changes in perceptions around HIV research, changes in willingness to participate in research, satisfaction & barriers to adoption and feedback about the gamified tools.
- **Process Data** (Annexure 5) will be captured by the intervention facilitators as a part of their field notes to enable assessment of process parameters like fidelity, reach, satisfaction, reception and participation.

In addition to the above, significant change stories captured through diary entries and community discussions will help understand changes in perceptions around HIV research, changes in willingness to participate in research and satisfaction & barriers to adoption. In addition, this tool will help

identify non-linear changes triggered through the intervention including capacity building of the team and changes in the relationship between researchers and community members.

<u>After the Intervention</u>

End line Survey

- To understand utility of the intervention in influencing broader perspectives at community level and capture retained change brought about by the intervention, an end line quantitative survey will be conducted among 600 key populations across all study sites. This will include the 400 participants who took part in the intervention sessions and remaining 200 would be those who did not participate in the intervention sessions and will serve as the control group. These 200 participants who serve as the control group need not be the same as those who had participated in the baseline survey mentioned above and could be different individuals.

In addition to these, as a part of the KIIs as mentioned in section 5.3.1.2., insights on the utility of the intervention and implementation challenges will also be covered which will contribute towards assessment of the intervention tools.

As mentioned earlier, all these methodologies will facilitate addressing the line of enquiry under the over-arching framework of COM-B. Towards that, the methodological mapping is provided below:

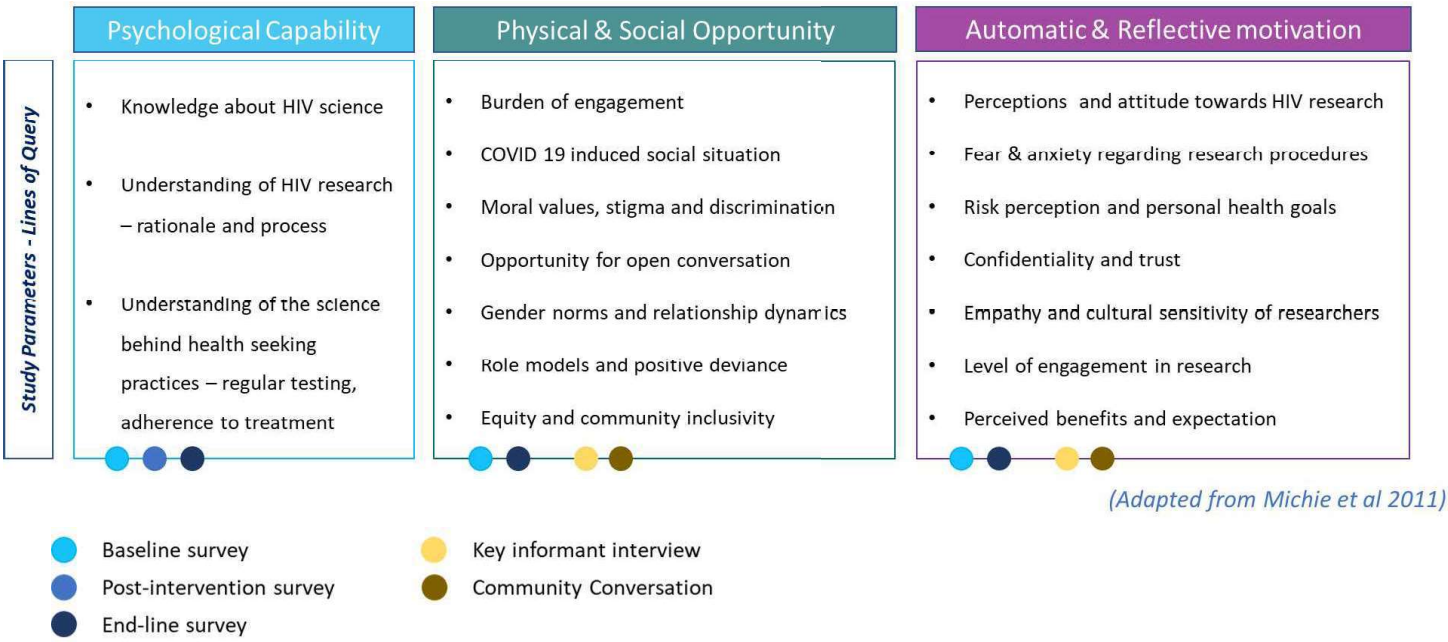

Figure 4: Mapping of specific methods on line of enquiry.

5. Data Analysis

5.1. Data Compiling

Quantitative data compiling

A digital data entry platform (MS-Access based forms) will be developed to transcribe and enter the quantitative data collected through baseline, end line and post-intervention survey. The transcribed data will be cleaned, coded as per the conceptual framework and curated site-wise and population-wise to facilitate statistical analysis. Basic descriptive analysis will be conducted using standard statistical programs such as Stata or R. Any change in response to the survey questions capturing knowledge of HIV science, attitude towards HIV BMR and factors driving willingness to participate in HIV BMR from baseline to end-line across populations and geography will be detected using paired t-test. Appropriate correlation matrices will be developed to analyze the interplay between key drivers of community participation in BMR.

Qualitative data compiling

A draft code book of first level codes ('*a priori*' codes) will be developed based on the conceptual framework and topic guides. To begin with, the interview responses will be deductively coded based on the initial code book. After conducting analyses of a few transcripts based on the code book, the emerging codes will be added to the code book. Additional inductive coding will also be conducted to account for new context emerging from the transcripts. All the transcribed and translated transcripts will be redacted (to remove any personally identifying information that might inadvertently have been recorded) and uploaded into NVivo qualitative data analysis software. All codes will be then entered into NVivo and tagged to associated chunks of text. Texts corresponding to each of the first-level codes will be reviewed by the study investigators.

5.2. Data Analysis

The purpose of this study is to understand the drivers of community willingness to participate in BMR and to assess the utility of the EL-based tools to enhance research literacy and hence affect a change in the willingness of the community to participate in BMR. The mixed methods approach, which uses triangulation to strengthen and ensure accuracy of data (Lincoln & Guba, 1978) was applied. According to Denzin and Lincoln (2015), triangulation is a process in which several methods are used in the study and might be used in four basic ways (1) data triangulation, (2) methods triangulation, (3) theory triangulation and (4) researcher triangulation. In this study, data triangulation, methods triangulation and researcher triangulation will be used.

Data source triangulation refers to arriving at an inference based on two or more different data sources (e.g., data from KPs and key informants). Similarly, methods triangulation refers to arriving at tentative inferences using two different methods (e.g., quantitative surveys and conversations among KPs). Researcher triangulation is applied when different data analysts will compare and contrast the codes and inferences they derived from different data sources and methods of data collection ('constant comparison method'). Also, the draft summary from each data analyst will be read by the investigators and any differences in interpretation will be discussed with those data analysts and a consensus will be arrived at, if possible. Otherwise, the rival explanations will be presented. These kinds of data source triangulation, methods triangulation and researcher triangulation enhance the reliability of the findings [Pope, Ziebland & Mays, 2000; Strauss & Corbin, 1998]. Triangulation does not refer to mere

'cross checking' but it focuses on how the different data sources and researchers' perspectives shape the inferences. A comprehensive study analytical framework is provided in Figure 5 below.

5.3. Data Validation

Data validation could be operationally defined as a process which ensures the correspondence of the final data with a number of quality characteristics (Zio et al 2016) like accuracy, relevance, completeness, comparability and coherence. Researcher checking will be conducted among 5% of the quantitative surveys, 10% of the intervention sessions and 1-2 additional key informant interviews to gain feedback and assess data and interpretations. Study implementation and data analysis also will incorporate researcher reflexivity and researcher triangulation [Lincoln and Guba, 1985]. Diaries will be written, field notes will be maintained, and peer debriefing will be done to maintain ongoing awareness of the social location and how it may influence the research process and interpretation.

5.4. Data Security for storage and transmission

Names or other personal identifiers will not be used in any study related documents of the participants. Unique identification codes (participant ID – PID) will be assigned to all individual records, including case report forms, digital recordings and transcripts. A link book will be maintained to store the personal information and the coded PID and this will be maintained in a secured location at KIMSDU and will only be accessed by the staff responsible for this study. Only the investigators and key research staff at the participating research institutes (KIMSDU, Karad and NARI, Pune) will have access to the case report forms, transcripts/translated text and digital recordings. As soon as an interview is completed, the audio file will be downloaded from the digital recorder to password-protected computers and deleted from the digital recorder. The transcriptionist and translator will sign a confidentiality pledge that they will not reveal any information from the interviews to anyone else. The digital copies of transcripts and translated text will also be stored on password-protected computers. During the intervention sessions, long shot photographs will be captured which will not reveal personal identity of any participants.
All digital recordings will be redacted, and any personal identifying information will be removed. Only this study's research staff at the participating research institute and the study sponsors will have access to the de-identified transcripts and translated text which will be assigned unique PIDs. Digital recordings will be deleted two years after the completion of the study (the two-year delay is to ensure there are no gaps in the transcripts/translated text till the time of manuscript writing). Redacted transcripts/translated text will be kept for three years and then destroyed.

Informed consent forms will be separately stored, and will include signs, initials or 'x' marks rather than names. Hard copies of the data and related documents will be stored in a secure location in locked cabinets in the offices of KIMSDU and will be accessed only by the research staff.

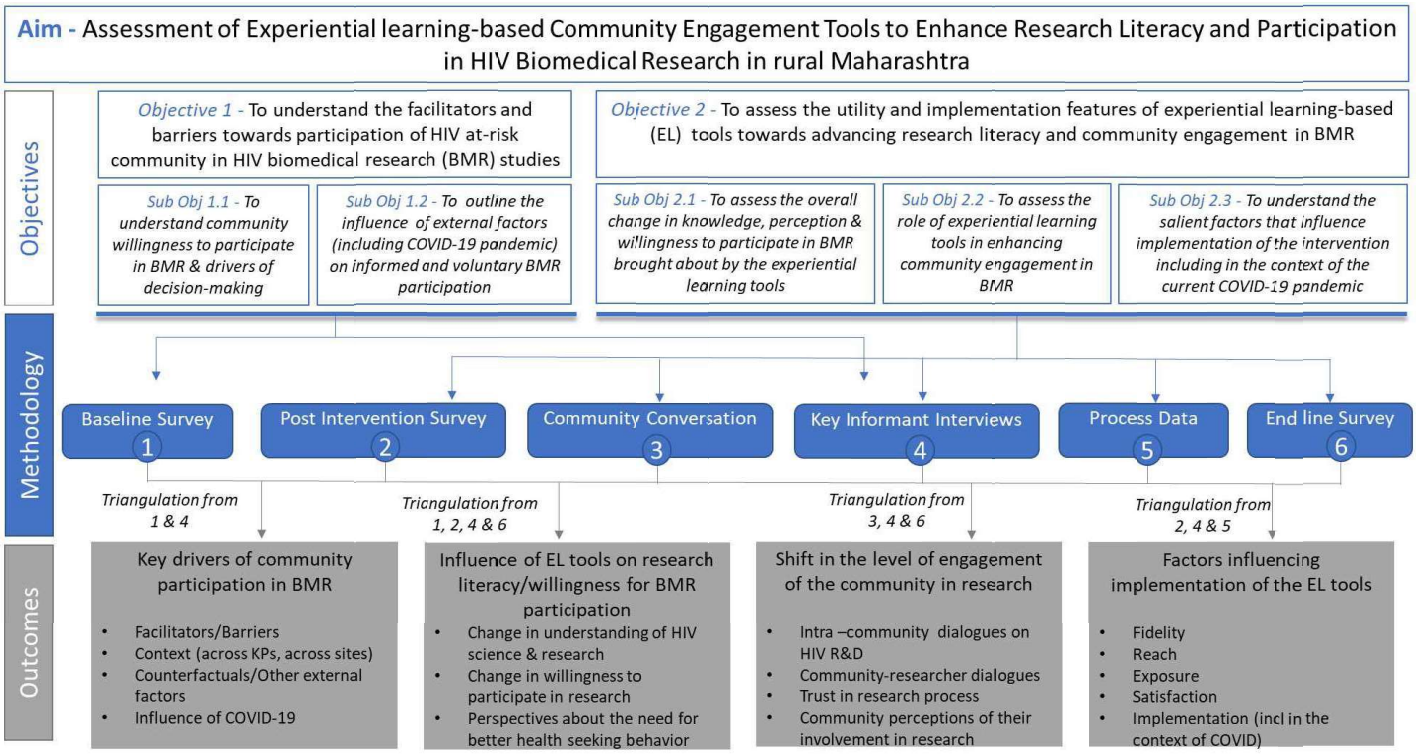

Figure 5: Study Analytical framework

6. Study Outcomes

Data collected and analyzed through the various sources and methods will eventually enable understanding of the aspects as mentioned in the Figure 6 below.

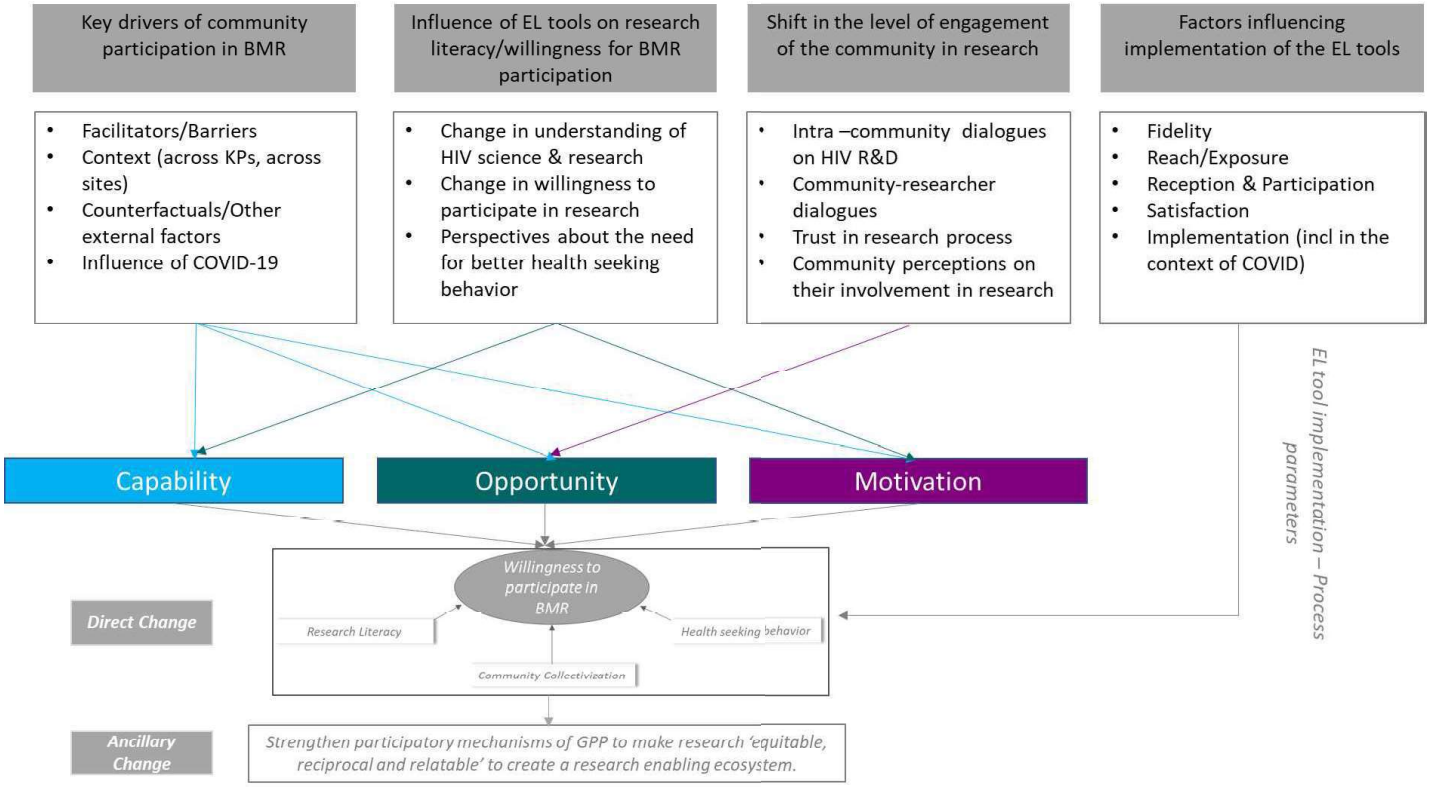

Figure 6: Study Outcomes

Key drivers of community participation in BMR – An insight into the facilitators and barriers for community participation in research will enable deeper understanding of the individual, interpersonal, social and structural drivers of decision-making and how this varies within the different key populations (FSWs, MSM, TG) and also capture nuanced variation across sites within rural Maharashtra. This will also elaborate the influence that other external factors like the current COVID-19 pandemic has on the community responses. This would form a basis for identifying areas where the experiential learning tools can be utilized to bring about a change in the community behavior.

Influence of the EL tools on research literacy and willingness for BMR participation – The design of the tools is based on the theory of change and has been informed by social science and behavioral psychology. Through the study, it will be possible to capture the immediate and retained change in the community understanding of HIV science and research, variation in their willingness to engage in research and also provide some insights into their perceptions about the need and science behind better health seeking behavior like regular testing and drug adherence.

Shift in the level of engagement of the community in research **–** As literature reveals that majority of the community engagement in research is focused on informing the community without expectation of a two-way dialogue or consulting them for feedback on a proposed research. However, greater levels of engagement to involve them in conceptualization and design, collaborate to have shared decision-making and work together towards a shared goal is often times lacking. Through this study, it is intended to assess community perceptions about their level of engagement in the process of this participatory mechanism and also understand if the tools have changed intra-community and community-researcher dialogues about research and science.

Factors influencing implementation of the EL tools **–** For the successful implementation of the EL tools it is critical to understand the salient factors which impact their effectivity. The study will aid in elaborating the fidelity, track the reception, active participation and engagement of the participants, quality of the conduct, how satisfied the end users were with the tools in terms of their ease of understanding and simplicity of the messages. It will also pave the way towards assessing the potential uptake of these tools by the community and understanding the practical challenges that may be posed in the context of other external factors.

All of the above taken together will contribute towards influencing the network of behaviors including health seeking practices, community collectivization, research literacy and hence positively impacting the core desired change in the willingness to participate in biomedical research. The core essence of the study lies in the fact that it will be a step forward in strengthening the participatory mechanisms of GPP to make research "equitable, reciprocal and relatable" towards building a research enabling ecosystem.

7. Ethical Considerations

7.1. Informed consent process

Informed consent will be obtained prior to any data collection (Annexure 6). Participants in the telephonic interviews and surveys will be presented with brief background information that outlines the scope of the study and a verbal consent will be obtained. During this procedure, the participant will be allowed to ask questions that facilitate the participant's understanding about the study as well as aim of the interview/ survey.

As part of the informed consent process, all potential participants will be told that their participation or not in interviews will not affect the services they currently receive or may receive in the future from their respective community agencies.

During the intervention sessions, consent from all participants will be taken (Annexure 6). The participants will be presented a brief outline of the session and the points at which they will be required to be part of any data collection (survey/discussions/photographs) and a written consent of the participants will be taken. Participants can refuse to participate in any of the session components and the same will be respected at any point.

7.2. Possible risks and measures to minimize risks

There is no direct or indirect harm to any participant due to their participation in the interview/ survey/ intervention session under the study. There will be efforts directed towards appropriate

priming of the potential participants and the date and time of the interview will be selected considering individual convenience.

7.3. Compensation

All the participants who take part in the telephonic interview/ survey/ intervention session will be compensated, wherever applicable, for their time and engagement.

8. Study Management and Governance

8.1. Participating institutes and organizations

The participating institutes and organizations are KIMSDU, NARI in partnership with other CBOs like SANGRAM-VAMP and Muskaan.

8.2. Roles and responsibilities

Responsibilities	**KIMSDU**	**NARI**	**CBOs**	**IAVI**
Funding of the study				✔
Preparatory Activities				
Development of study protocol	✔	✔		✔
Development of conceptual/theoretical/analytical framework	✔	✔		✔
Design and co-creation of community engagement tools (games and theatre) for intervention	✔	✔	✔	✔
Development of data collection tools • Topic guides for qualitative data collection • Study questionnaire • Gamified data collection tools for intervention	✔	✔	✔	✔
Study implementation				
Training of study team and peer educators	✔	✔	✔	✔
Stakeholder engagement	✔	✔	✔	
Qualitative data collection	✔			
Quantitative data collection	✔			
Roll out of intervention	✔		✔	
Data Analysis				
Analysis of study data	✔	✔		✔
Dissemination of study findings				
Report writing (monthly reports and final report)	✔	✔		
Manuscripts/ publications (population wise as well as overall results)	✔	✔		✔
Study oversight				
Study team coordination	✔			

Study conduct according to recommended best practices and ethical standard	✔	✔	✔	
Protocol adherence and technical appropriateness	✔	✔	✔	✔
Study Monitoring				✔

8.3. Study Implementation and Oversight

8.3.1. Study Implementation Team

The study implementation team will consist of study staff at KIMSDU including the Program Manager, Project Assistants, Interventionists, Field workers, Data entry operator and peer educators from the partner CBOs. This team will be responsible for on-ground implementation of the study.

8.3.2. Study Work Group (SWG)

Principal Investigator from KIMSDU, Study Advisor from NARI and relevant CBO representatives constitute the Study Work Group who will be responsible for study oversight on a regular basis. The SWG will be ensuring technical appropriateness of the study conduct in adherence with the study protocol as well as will account for all the ethical and practical considerations while engaging with the community.

8.3.3. Community Advisory Board (CAB)

Community Advisory Board will be the liaison between the community and the SWG. This entity including community representatives will be responsible for facilitating dialogues on community perspective about the study conduct and provide directions/ suggestions for effective implementation.

8.3.4. Study Monitoring

Sponsor (IAVI) initiated on-site monitoring will be conducted to ensure that the study is conducted according to the protocol and is in compliance with applicable regulations and guidelines, recorded and reported in accordance with the protocol, is consistent with locally-accepted practices and standard operating procedures.

The Investigators and participants, by giving consent, agree that the monitor may inspect study facilities and source records (e.g., informed consent documents, other source documents) as well as observe the performance of study procedures. Such information will be treated as strictly confidential and will under no circumstances be made publicly available. The Principal Investigator will permit inspection of the facilities and all study-related documentation by authorized representatives of IAVI and Government and Regulatory Authorities relevant to this study.

Given the travel restrictions and other logistic issues due to COVID-19 pandemic, remote monitoring will be conducted as necessary. Remote monitoring may reduce the need for onsite visits, however, it is recognized that remote monitoring will not replace on-site monitoring completely. If remote monitoring identifies issues that cannot be resolved with the site by email or phone, or if significant issues are identified, an on-site monitoring visit may be conducted, if feasible. Participants confidentiality will be strictly maintained during sharing participant's information remotely.

8.3.5. Advisory Group

The Advisory Group consisting of domain experts will be responsible for reviewing the study progress viz a viz proposed objective and provide necessary guidance for effective roll out and assessment of the experiential learning tools as well as ensure technical appropriateness as per the global standard.

8.4. Study Deliverables

The key deliverables would include submission of (a) monthly progress and site-specific performance reports including field events, photos from sites etc; (b) SOPs, intervention strategy and training resources developed including guidelines and manuals; (c) original raw data (including field notes, transcriptions) and compiled data with analysis (including computer programmes, source codes, and any written documentation) (d) power point presentation including top line findings and final report upon completion of the study (e) Budget utilization certificate to IAVI. In addition, any publication/ submission of abstract/summary or presentations in national and international conferences/peer reviewed journals must have prior approval from IAVI.

8.5. Investigator's Records

The Investigator will maintain and store in a secure manner complete, accurate, and current study records throughout the study. Study records include administrative documentation, including reports and correspondence relating to the study, as well as documentation related to each participant and should be kept in a secure location.

8.6. Data Ownership

The data resulting from the study will be jointly shared by the partner organizations and funders (KIMSDU, NARI, CBOs and IAVI). Any use of the data from the study during and beyond the study will be in consensus with the partner organizations and the funders. The authorship of the resultant scientific publications, report or white paper will be also shared between the partners.

8.7. Dissemination of study results and Publications

The knowledge synthesized through the study and the study outcomes would be disseminated to the larger community across the study sites through dissemination workshops and relevant study generated reports after the completion of the study in alignment with the ethical compliances of extending the beneficial outcomes to the community.

Manuscripts will be developed from the study reports. All manuscripts, abstracts, reports will be reviewed and approved by the study PI, study advisor and in working with the CBOs and study sponsors. The researchers along with other contributors from partner agencies (including CBOs and sponsor), where appropriate, who have substantially contributed to the manuscript will be given a co-authorship in accordance with the standard publication ethics guidelines.

9. References

Baranowski T, Stables G. (2000) Process evaluations of the 5-a-day projects. *Health Educ Behav.* 27(2):157-166.

Concannon TW, Fuster M, Saunders T, Patel K, Wong JB, Leslie LK, et al. (2014) A systematic review of stakeholder engagement in comparative effectiveness and patient-centered outcomes research. *J Gen Intern Med.* 29(12):1692–701.

Day S, Blumberg M, Vu T, Zhao Y, Rennie S, Tucker J.D. (2018) Stakeholder engagement to inform HIV clinical trials: a systematic review of the evidence, *J Int AIDS Soc.*, 21(S7): e25174

Denzin NK, Lincoln YS (2015) The Sage handbook of qualitative research. Los Angeles: SAGE.

Ditmore MH, Allman D. (2011) 'Who is Helsinki?' Sex workers advise improving communication for good participatory practice in clinical trials. *Health Educ Res.* 26(3):466–75.

Forsythe LP, Ellis LE, Edmundson L, Sabharwal R, Rein A, Konopka K, et al. (2016) Patient and stakeholder engagement in the PCORI pilot projects: description and lessons learned. *J Gen Intern Med.* 31(1):13–21.

Joshi RK, Mehendale SM. (2019) Determinants of consistently high HIV prevalence in Indian Districts: A multi-level analysis. *PLoS ONE* 14(5): e0216321.

Lincoln YS, Guba EG (1985) Naturalistic Inquiry, SAGE Publications, 1985.

Mack N, Kirkendale S, Omullo P, Odhiambo J, Ratlhagana M, Masaki M, et al. (2013) Implementing good participatory practice guidelines in the FEM-PrEP Preexposure Prophylaxis Trial for HIV Prevention among African Women: a focus on local stakeholder involvement. Open *Access J Clin Trials*. 5:127–35.

MacQueen K, Namey E, Chilongozi D, Mtweve S, Mlingo M, Morar N, et al. (2007) Community perspectives on care options for HIV prevention trial participants. *AIDS Care*. 19(4):554–60.

Metzelthin, S.F., van Rossum, E., de Witte, L.P. et al. (2010) The reduction of disability in community-dwelling frail older people: design of a two-arm cluster randomized controlled trial. *BMC Public Health* 10, 511.

Michie, S., van Stralen, M.M. & West, R. (2011) The behaviour change wheel: A new method for characterising and designing behaviour change interventions. *Implementation Sci* 6, 42.

Morin SF, Maiorana A, Koester KA, Sheon NM, Richards TA. (2003) Community consultation in HIV prevention research: a study of community advisory boards at 6 research sites. *J Acquir Immune Defic Syndr.* 33(4):513–20.

National AIDS Control Organization & ICMR-National Institute of Medical Statistics (2018). HIV Estimations 2017: Technical Report. New Delhi: NACO, Ministry of Health and Family Welfare, Government of India.

National AIDS Control Organization (2017). HIV Sentinel Surveillance: Technical Brief, India 2016-17. New Delhi: NACO, Ministry of Health and Family Welfare, Government of India.

National AIDS Control Organization (2017). National Strategic Plan for HIV/AIDS and STI 2017 – 24. New Delhi: NACO, Ministry of Health and Family Welfare, Government of India.

NIMH Collaborative HIV/STD Prevention Trial Group. (2007) Ethical issues in the NIMH Collaborative HIV/STD Prevention Trial. *Aids*.21 Suppl. 2: S69–80.

Pope, C., Ziebland, S., & Mays, N. (2000). Analysing qualitative data. *British Medical Journal*, 320(7227), 114-116.

Ramjee G, Kapiga S, Weiss S, Peterson L, Leburg C, Kelly C, et al. (2008) The value of site preparedness studies for future implementation of phase 2/IIb/III HIV prevention trials: experience from the HPTN 055 study. *J Acquir Immune Defic Syndr.* 47(1):93–100.

Reynolds L and Sariola S. (2018) The ethics and politics of community engagement in global health research. *Critical Public Health*. 28:3, 257-268.

Saunders RP, Evans MH, Joshi P. (2005) Developing a process-evaluation plan for assessing health promotion program implementation: a how-to guide. *Health Promot Pract.* 6(2):134-147.

Steckler, A., & Linnan, L. (Eds.). (2002). Process evaluation for public health interventions and research. Jossey-Bass/Wiley.

Strauss, A., & Corbin, J. (1998). Basics of Qualitative Research: Techniques and Procedures for Developing Grounded Theory.

The International Council of AIDS Service Organization. (2006) Community involvement in HIV vaccine research: making it work. https://www.avac.org/sites/default/files/resource-files/Community%20Involvement%20in%20HIV%20Vaccine.pdf

UNAIDS/AIDS Vaccine Advocacy Coalition (2011). Good participatory practice: guidelines for biomedical HIV prevention trials 2011. Geneva: UNAIDS.

Zio MD, Fursova N, Gelsema T, Gießing S, Guarnera U et al (2016) Methodology for data validation 1.0, revised edition (June 2016)

https://ec.europa.eu/eurostat/cros/system/files/methodology_for_data_validation_v1.0_rev-2016-06_final.pdf

10. Annexures

10.1. Data collection tools

10.1.1. Baseline survey (Annexure 1)

10.1.2. Key informant interview (Annexure 2)

10.1.3. Post intervention survey (Annexure 3)

10.1.4. Community Conversation (Annexure 4)

10.1.5. Process data collection (Annexure 5)

10.2. Informed Consent Form (Annexure 6)

Sub-award/Contract Budget Narrative

The budget narrative provides a detailed description of all costs included in the budget.

PERSONNEL – Total INR 38,34,000

The Contract staff will be hired for the study and their salary structure is at par with what is decided by Govt of India for Project Staff of different cadres. This also includes the fringe benefits and these details are provided in the sections below.

The personnel details are as follows:

1. ***Principle investigator (PI) - Dr.Asha Jadhav [Institutional support]***
   The PI will have the responsibility of overall co-ordination and supervision of work done under this project. She will ensure technical appropriateness of the study design and study conduct and also guide the study staff in their day to day activities, data collection and data analysis. ***The PI will be supported by KIMSDU and will not draw any salary from this project***.

2. ***Co-Principle investigator (Co-PI)- Dr.S.K.Danga [Institutional support]***
   He will have a managerial role and will report to the PI. He would be both scientific and administrative-in-charge of the overall project. He will also lead planning and coordination of activities to train the research staff and implement the surveys and qualitative studies at the study sites. ***He will be supported by KIMSDU and will not draw any salary from this project.***

3. ***Program Manager - INR 8,40,000***
   The Programme Manager (Non medical) will have a managerial and social scientist'role and s/he will report to the PI/ NARI. He/ she will be responsible for planning and implementation of the study. He/ she will generate weekly reports based on the program indicator rubric. Programme Manager will be responsible for forming linkages with various stakeholders and organizations at study sites to ensure smooth conduct of the research studies. He/ she would be responsible for recruitment of key population for the studies as the ultimate aim of the study is to create interest in biomedical research participation. His/her role will require extensive travel to visit the study sites and he/she will be responsible for Community Advisory Board meetings and Community Monitoring Board meetings, overall functioning and supervision of team. S/he will assess the needs of the local communities, identify gaps in knowledge, plan and coordinate trainings of the research staff and implement surveys, qualitative studies, socio behavioral and cultural determinant studies, bringing the community and the centers together. S/he will generate and disseminate reports and raise relevant issues to senior program officials and local stakeholders. S/he will work in and ensure compliance with procedures and SOPs, and other regulatory compliances. S/he will work closely with senior officers and supporting staffs of KIMSDU & NARI and facilitate project related activities. S/he will devote 100% effort to implement every activity of the project in community and his/her time has been budgeted at INR 8,40,000 @ INR 70,000 per month.

4. ***Project Assistant (Two) - INR 7,44,000***
   Two project assistants (one male and one female) will be engaged in pre- and post test counseling and data collection for health camps in clusters in Karad and Patan including HIV testing and other health service-related activities. The counseling activity will also be pursued at field unit/ clinic for biomedical research. The male person will be required for counseling, interviewing and interacting with male participants, support in networking with other NGOs/

CBOs/ health centers. Similarly, the female person will be responsible for similar activities with the female participants. They will be paid an annual salary of INR 3,72,000 each @ INR 31,000 per month for 12 months.

5. ***Project Assistant (Two) - INR 4,96,000***
   The two Project Assistants (one male and one female; non medical) will be junior social scientists responsible for conducting sensitization meetings, counselling, conducting in depth interview, focused group discussions, key informant interviews, data collection for field-based socio-behavioral studies, conducting outreach programs, data transcription and management from qualitative studies. They will be paid a total salary of INR 2,48,000 each @ INR 31,000 per month for 08 months.

6. ***Project Assistant cum interventionist (Two)- INR 2,88,000***
   The two Project Assistants cum Interventionists (one male and one female; non medical) will be a field worker who will be engaged in conducting baseline and end line surveys and interviews in Karad, Patan and Sangli. They will also be responsible for intervention dissemination and support with design and data management from the quantitative surveys. They will be paid a total salary of INR 1,44,000 each @ INR 18,000 per month for 08 months.

7. ***Project Technician (Field Worker, One)- INR 2,16,000***
   The Project Technician will be primarily responsible for field work, community engagement, various other project specific activities and data collection. S/he will be paid a total salary of INR 2,16,000 @ INR 18,000 per month for 12 months.

8. ***Staff Nurse – INR 3,78,000***
   She will assist in community engagement as well as health screening. She will be paid a total of INR 3,78,000 @ INR 31,500 per month for 12 months.

9. ***Laboratory technician – INR 2,16,000***
   S/he will perform HIV testing in community and compliance with biosafety measures. S/he will be paid a total of INR 2,16,000 @ INR 18,000 per month for 12 months.

10. ***Accountant cum Data Entry Operator - INR 3,72,000***
    Data entry operator will be required to enter data related to the Karad/Patan/Sangli unit activities, responsible for maintaining all financial details, procurement records, Data management and cleaning. S/he will devote 100% effort to for various procurement and other financial activities , financial reports,as well as he /she will be responsible for data entry. S/he will be paid a total of INR 3,72,000 @ INR 31,000 per month for 12 months.

11. ***Co-ordinator – Mr Rais Patel [Institutional Support]***
    He will be responsible for conducting the research studies, will ensure compliance with study procedures and will assist in arranging health camps. ***He will be supported by KIMSU and will not draw any salary from this project.***

12. ***Health assistant– Ms Rajashri Yadav [Institutional Support]***
    She will assist in community engagement as well as health screening. ***He will be supported by KIMSDU and will not draw any salary from this project.***

Fringe Benefits- INR 2,84,000

Fringe benefits for all budgeted staff are calculated at a rate of 8% of the annual base salary as per KIMSDU guidelines. The fringe benefits rate break-up is calculated as follows:

Fringe Benefits	**%**	**INR**
Health Insurance	4	1,42,000
Communication Charges	2	71,000
Petrol Expenses	2	71,000
Total	**8**	**2,84,000**

SUPPLIES – Total INR 8,58,188

The following supplies will be needed:

1. ***Laboratory Consumables: INR 3,00,000***

S.N.	Consumable	Cost/Unit INR	No of Units	Cost
1	HIV kits (Two types of kits)	150	1500	2,25,000
2	Plastic ware (pricker , gloves etc.) & Misc.	50	1500	75,000
Total Cost				**3,00,000**

2. ***Headphone & Recorder, Battery: INR 80,000***
   Headphone, recorder will be required for qualitative component.i.e for recording interview of participants. Total 4 sets of data recorders costing INR 20,000 each will be needed. Thus, this material has been budgeted at a total cost of INR 80,000.

3. ***Computer, Computer Accessories and Software: INR 3,28,188***
   (1-time purchase)

Product	Cost (INR)	No of Units	Total Cost
Computer	45,000	2 Unit	90,000
Laptop (8th Generation Intel® Core™ i5-8250U Processor)	67,989	1 Unit	67,989
Printer	18,999	1 Unit	18,999
NVIVO Software	1,51,200 (Current rate USD 2100 for 3-user license)	1 Unit (3 user)	1,51,200

   2 PC will be used by two Project Assistants for developing research surveys and other community engagement materials like posters, presentations, flyers. They will also conduct data transcription and management and daily record maintenance of various activities. Either of the PCs will also be shared by the data entry operator for entering study data on a daily basis. 1 Laptop will be needed and used by Project Manager for overall data overview and management, data analysis and report generation. A laptop will enable efficient working during monitoring and supervision ary travel and real time data verification as s/he will be on field and at the various sites like KIMSDU and NARI as per requirements. 1 printer will be required for various printing needs during the study. A Licensed software multi-user - NVIVO, will be purchased for qualitative and mixed method research to analyze unstructured or qualitative data like interviews, open-ended survey responses etc and it will be shared with NARI.

4. ***Printing and Stationery: INR 1,50,000***
   Towards the creation of questionnaires, consent forms and related formats, project reports, training materials, SOPs, guidelines etc., the cost for printing and stationery materials has been budgeted at INR 1,50,000 (INR 15 per page for approximately 10,000 pages).

TRAVEL – Total INR 4,90,000

International Travel: **Not Applicable**

Domestic Travel - INR 4,90,000

Sr.No.	Particulars	No.of Vehicles	Cost of Petrol, Lubricants & maintenance	Per month cost	No.of Months	Total cost
1	Community Mobilization, Survey, Testing & Intervention related travel	2	15,000	30,000	12	3,60,000
2	Oversight and monitoring related travel (incl by NARI)	1 (one trip per month)	5,000	5,000	12	60,000
3	Miscelleneous travel	2 trips for 2 days (Airfare @ INR 20,000 per trip and lodging @ INR 7000 per day)				70,000
					Total	4,90,000

The study staff and field workers will require to travel to Karad, Patan & Sangli for various activities including community outreach and health camps. 2 vehicles per month will be dedicated for this travel across the various sites (multiple trips will be made) and a consolidated cost of INR 15,000 per vehicle will be paid for this purpose towards cost of petrol, lubricants and maintainence. This will amount to a total of INR 3,60,000 for 12 months.
In addition, the PI/Co-PI will need to travel to conduct supervisory visits to the study sites estimated at 1 trip per month. A vehicle will be hired for to and fro travel @ INR 5,000 per trip amounting to a total of INR 60,000.
The PI/co-PI/study staff will also be attending relevant technical consultation meetings and conferences within India to enable incorporation of technical insights into the study and also enable greater visibility of the study to relevant national stakeholders. This has been estimated at 2 trips for 2 days with Airfare @ INR 20,000 per trip and lodging @ INR 7000 per day amounting to a total of INR 70,000.

OTHER DIRECT COSTS – Total INR 11,46,790

1. ***Community Advisory Board (CAB) Meetings (Two) - INR 1,50,000***

Sr.No.	Particulars	Units	Rate	Per meeting cost	Cost for 2 meetings
1	Honorarium to CAB member	15	1,000	15,000	30,000
2	Venue charges	01	27,500	27,500	55,000
3	Refreshments	50	650	32,500	65,000

			Total	**75,000**	**1,50,000**

Two CAB meetings at the cost of INR 75,000 per meeting will be arranged (once in six months) to review community research preparedness work and guide project efforts to ensure alignment with community interests, needs and expectations. The average member size of such meetings ranges from 45-50 (15 CAB members and others from peers and study staff) and the cost of the meeting will be incurred towards making necessary logistical arrangements including venue charges, refreshment, travel charges and stationery. An honorarium will also be paid only to each CAB member.

2. Capacity Building Training Program (Four) - INR 1,00,000

Sr.No.	Particulars	Units	Rate	Per meeting cost	Cost for 4 meetings
1	Honorarium to Resource person	05	2,000	10,000	40,000
2	Venue charges	01	5,000	5,000	20,000
3	Refreshments	01	5,000	5,000	20,000
4	IT and other support	01	5,000	5,000	20,000
			Total	**25,000**	**1,00,000**

A total four trainings (at the cost of INR 25,000 per training) of direct and indirect stakeholders including key population representatives will be carried out to ensure effective community outreach and engagement and research preparedness towards the ultimate objective of conducting cohort studies. The cost of the training will include expenses incurred towards making necessary logistical arrangements like venue bookings, refreshments, IT support etc.

3. Compensation for participants – INR 2,63,040

Sr.No.	Particulars	Units	Rate	Cost
1	Travel allowance to IDI participant from general & high-risk populations	12+24=36	300	10,800
	Refreshment	36	60	2,160
	Travel allowance to Key informants (KII) 3 (each from 4 categories- 1. Medical officer, 2. Staff nurse & other health care staffs, 3.CBO representative, 4. DAPCU officials)	3*4 =12	300	3,600
	Refreshment	12	60	720
2	Travel allowance of FGD	16	300	4,800

	participants Refreshment	16	60	960
3	Baseline & end line survey participants	800	300	2,40,000
			Total	**2,63,040**

Each participant attending in depth interviews (IDIs), key informant interviews (KIIs) and focused group discussions (FGDs) and those participants who are part of the baseline survey and end line survey will be eligible for compensation for travel . There will be about 64 participants in the IDIs, KIIs and FGDs; 400 participants in the baseline survey and 400 participants in the end line survey. The cost per participant will be approximately INR 300 and 60 INR will be expected for refreshment of 64 persons. Thus, a total cost of INR 2,63,040 will be incurred.

4. ***Peer fee – INR 3,750***
   Total fifteen peers will be identified and trained for disseminating and implementing various intervention models in the community and will be responsible for community mobilization. Peer will be given INR 250 for each session. There will be a total 5 sessions each month for 3 months leading to a total of 15 sessions. Thus a total of INR 3,750 is budgeted for this.

5. ***Translation fee – INR 1,50,000***
   Translation of data from Marathi/Hindi to English from the data collection of IDI, FGD, KII will be outsourced, this would cost tentatively around INR 30 per page and for all qualitative data translation of approximately ~5000 pages a total of INR 1,50,000 has been budgeted.

6. ***Community sensitization through promotional activities - INR 60,000***
   Total 4 Community Sensitization meetings will be held (one in each quarter) at the cost of INR15,000 per meeting, towards ensuring dissemination of IEC materials. This outreach would include both print and electronic media. Relevant IEC materials created and distributed will include pamphlets, brochures, posters etc. This is budgeted at a total cost of INR 60,000.

7. ***Tools development for Intervention – INR 50,000***
   For taking the various intervention modules to the community, different mechanisms such as - street plays, videos, experiential games, theatre activities, etc. will be carried out that would require creation/purchase of various materials and props. A total cost of INR 50,000 has been budgeted for the same.

8. ***Recruitment advertisement – INR 15,000***
   For recruiting various personnel under the project, advertisements will be taken out in all local newspapers; budgeted at INR 15,000.

9. ***Contingency Costs – INR 1,50,000***
   Expert consultations will be organized at regular intervals to ensure scientific appropriateness of study tools and data collection mechanisms. Also, there will be study initiation visit and

monitoring visits. Thus, a contingency cost of INR 1,50,000 has been budgeted to cover such ad hoc consultations and meetings.

10. Dissemination Workshop – INR 2,05,000

S.No.	Item	Rate	No.of persons	Total
1	Hospitality and refreshment (Tea, Snacks and Lunch)	650	40	26,000
2	Travelling allowance for resource person	15,000	10	1,50,000
3	Banner for hall & welcome counter	2,000		2,000
4	Communication charges	2,000		2,000
5	Other incidental expenses	25,000		25,000
			Total	**2,05,000**

Towards the end of the study, a workshop will be organized at KIMSDU on qualitative research methods and dissemination of the broad findings of the study. This workshop will also provide the opportunity for knowledge sharing and capacity building among the broader research fraternity in qualitative research methods, data management and data analysis. Expected participants will be researchers, anthropologists, social worker, study team and medical PG students form KIMSDU as well as NARI and IAVI. The expenses will include hospitality and refreshments, travel expenses (aprrox 10 resource personnel from outside), communication and other incidental charges budgeted @ INR 2,05,000.

INDIRECT COSTS: **INR 5,06,318**

Indirect costs are budgeted at a rate of 8% on modified total direct costs (MTDC) in accordance with 2 CFR 200.414.

Sub-award/Contract Budget Narrative

The budget narrative provides a detailed description of all costs included in the budget. The study is budgeted for a total amount of INR 44,64,313

PERSONNEL – Total INR 26,27,737

The Contract staff will be hired for the study and their salary structure is at par with what is decided by Govt of India for Project Staff of different cadres.

The personnel details are as follows:

1. ***Principle investigator (PI) - Dr.Asha Jadhav [Institutional support]***
   The PI will have the responsibility of overall co-ordination and supervision of work done under this project. She will ensure technical appropriateness of the study design and study conduct and also guide the study staff in their day to day activities, data collection and data analysis. ***The PI will be supported by KIMSDU and will not draw any salary from this project***.

2. ***Program Manager – Suhas Shewale - INR 5,59,944***
   The Programme Manager (Non medical) will have a managerial and social scientist'role and she will report to the PI/Study Advisor. She will be responsible for planning and implementation of the study. She will generate weekly reports based on the program indicator rubric. Programme Manager will be responsible for forming linkages with various stakeholders and organizations at study sites to ensure smooth conduct of the research studies. She would be responsible for recruitment of key population for the studies as the ultimate aim of the study is to create interest in biomedical research participation. Her role will require extensive travel to visit the study sites and he/she will be responsible for Community Advisory Board meetings and Community Monitoring Board meetings, overall functioning and supervision of team. She will assess the needs of the local communities, identify gaps in knowledge, plan and coordinate trainings of the research staff and implement surveys, qualitative studies, socio behavioral and cultural determinant studies, bringing the community and the centers together. She will generate and disseminate reports and raise relevant issues to senior program officials and local stakeholders. She will work in and ensure compliance with procedures and SOPs, and other regulatory compliances. She will work closely with senior officers and supporting staffs of KIMSDU & NARI and facilitate project related activities. The project manager, with an annual base salary of INR 8,40,000 will devote 66.7 % of her annual time on this project as she will be working on this project for 8 months. For the 8 months, she will be devoting 100% time on this project. We have budgeted this post at INR 70000/month for 8 months

3. ***Project Assistant (Two)*** **– Ganesh Shinde, Manoj Kumbhar -** ***INR 4,95,950***
   Two project assistants will be engaged in data collection for the baseline and endline survey. They will be required for interacting with the study partitipants, fixing appointments, support in networking with other NGOs/ CBOs/ health centers. They will also be involved in data transcription of the qualitative component of the study and coding of the data. The Research assistants (Two), with an annual base salary of INR 3,72,000 will devote 66.7 % of their annual time on this project as they will be working on this project for 8 months. For the 8 months, they

will be devoting 100% time on this project. We have budgeted this post at INR 31000/month for 8 months.

4. ***Project Assistant (Two) -Nayana Yenbhar, Ravindra Kurhade*** **- INR 4,95,950**
   The two Project Assistants will be junior social scientists responsible for conducting sensitization meetings, counselling, conducting in depth interview, focused group discussions, key informant interviews, data collection for field-based socio-behavioral studies, conducting outreach programs, data transcription for Key informant interviews and Focus Group discussions and assist in management from qualitative studies.
   The project assistants, with an annual base salary of INR 372000 will devote 66.7% of their annual time on this project as they will be working on this project for 8 months. For the 8 months, they will be devoting 100% time on this project. We have budgeted this post at INR 31000/month for 8 months

5. ***Project Assistant cum interventionist (Two)- Asmita Deshpande, Sachin Sakate - INR*** **2,87,971**
   The two Project Assistants cum Interventionists (one male and one female; non medical) will be a field worker who will be engaged in conducting baseline and end line surveys.
   They will also be responsible for intervention dissemination and support with design and data management from the quantitative surveys.
   They will also be engaged in transcription of the Group discussions and Key informant interviews.
   The project assistants, with an annual base salary of INR 2,16,000 will devote 50% of their annual time on this project as they will be working on this project for 6 months. For the 8 months, they will be devoting 100% time on this project. We have budgeted this post at INR 18000/month for 8 months

6. ***Project Technician (Field Worker, One)- Satish Kamble*** **- INR 1,43,986**
   The Project Technician will be primarily responsible for field work, community engagement, seeking appointments for the survey and interviews, support logistics, organizing venues, dates, place for the intervention and Focus Group discussions, coordinate with the Key persons of the CBO.
   The project technician, with an annual base salary of INR 2,16,000 will devote 66.7% of their annual time on this project as they will be working on this project for 8 months. For the 8 months, they will be devoting 100% time on this project. We have budgeted this post at INR 18000/month for 8 months.

7. ***Counsellor – Vaibhav Patil*** **-** INR 2,51,975
   He will assist in community engagement. He will be involved in providing counselling services, linking the participants to the local government health care facilities for the services that they may need, and assist in general health check up for the participants who request for these.
   He assist in note taking for the Key informant Interviews and Focus Group discussions and transcription and coding of this data.
   The counsellor, with an annual base salary of INR 3,78,000 will devote 66.7% of his annual time on this project as he will be working on this project for 8 months. For the 8 months, he will be devoting 100% time on this project. We have budgeted this post at INR 31500/month for 8 months.

8. ***Field Worker/ Technician– Anisa Mulla -*** INR 1,43,986
   She will assist in counseling services to participants and support them seek health care at the nearest government facilities. S/he will support the transcription activities. The field worker/technician, with an annual base salary of INR 2,16,000 will devote 66.7% of her annual time on this project as she will be working on this project for 8 months. For the 8 months, she will be devoting 100% time on this project. We have budgeted this post at INR 18000/month for 8 months

9. ***Accountant cum Data Entry Operator – Shruti Kulkarni -*** INR 2,47,975
   Data entry operator will be required to enter data related to the Karad, Sangli, Ichalkaranji unit activities, responsible for maintaining all financial details, procurement records, Data management and cleaning. She will devote 100% effort to for various procurement and other financial activities , financial reports,as well as she will be responsible for data QC and data entry. The Accountant cum Data Entry Operator, with an annual base salary of INR 3,72,000 will devote 66.7 % of her annual time on this project as she will be working on this project for 8 months. For the 8 months, she will be devoting 100% time on this project. We have budgeted this post at INR 31000/month for 8 months

10. ***Co-ordinator – Mr Rais Patel [Institutional Support]***
    He will be responsible for conducting the research studies, will ensure compliance with study procedures and will assist in arranging data collection activities. ***He will be supported by KIMSU and will not draw any salary from this project.***

SUPPLIES – Total INR 2,05,000

The following supplies will be needed:

1. ***Printing and Stationery: INR 2,05,000***
   Towards the creation of questionnaires, consent forms and related formats, project reports, training materials, SOPs, guidelines, intervention documentation, paper reams, box files for storage etc., The cost for printing and stationery materials has been budgeted at INR 2,05,000

TRAVEL – Total INR 2,82,008

International Travel: **Not Applicable**

Domestic Travel - INR 2,82,008

Sr.No.	Particulars	No.of Vehicles	Cost of Petrol, Lubricants & maintenance	Per month cost	No.of Months	Total cost
1	Community Mobilization,	2	12,000	24,000	8	1,92,000

	Intervention related travel					
2	Oversight and monitoring related travel (incl by NARI)	1 (one trip per month)	7,000	7,000	8	56,000
3	Miscelleneous travel	Miscellaneous travel (1 trip for 2 days (Airfare @ INR 20,000 per trip and lodging @ INR 7000 per day)/Miscellaneous travel				34,000
					Total	2,82,000

The study staff and field workers will require to travel to Karad, Sangli, Kolhapur for various activities including community sensitization, preparatory meetings with NGOs, providing logistics support, delivering reimbursement vouchers, collecting study reimbursement receipts from participants etc.
2 vehicles per month will be dedicated for this travel across the various sites (multiple trips will be made) and a cost of 12000 per vehicle will be paid for this purpose towards cost of petrol, lubricants and maintainence. This will amount to a total of INR 2,82,000 for 8 months
In addition, the PI/Study Advisor/Program Manager will need to travel the study sites/ NARI estimated at 1 trip per month. A vehicle will be hired for to and fro travel @ INR 7,000 per trip amounting to a total of INR 56000.
The PI /study staff will also be attending relevant technical consultation meetings and conferences within India to enable incorporation of technical insights into the study and also enable greater visibility of the study to relevant national stakeholders. They would also travel for conducting Key Informant interviews with identified stakeholders. This has been estimated at 1 trip for 2 days with Airfare @ INR 20,000 per trip and lodging @ INR 7000 per day amounting to a total of INR 34,000.

OTHER DIRECT COSTS – Total INR 10,18,886

1. ***2 Virtual Community Advisory Board (CAB) Meetings- INR 30,000***

Sr.No.	Particulars	Units	Rate	Per meeting cost	Cost for 2 meetings
1	Honorarium to CAB member	15	1,000	15,000	30,000

Two CAB meetings at the cost of approximately INR 15000 per meeting will be arranged (once in six months) to review community research preparedness work and guide project efforts to ensure alignment with community interests, needs and expectations. The average member size of such meetings ranges from 45-50 (15 CAB members and others from peers and study staff) and the cost of the meeting will be incurred towards paying honorarium to CAB members.

2. ***Capacity Building Virtual Training Program - INR 50,000***

Sr.No.	Particulars	Units	Rate	Per meeting cost	Cost for 3 meetings

1	Honorarium to Resource person	05	2,000	10,000	30,000
2	IT and other support				20,000
			Total		**50,000**

A total three trainings of direct and indirect stakeholders including key population representatives will be carried out to ensure effective community outreach and engagement and research preparedness towards the ultimate objective of conducting cohort studies.

The cost of the training will include expenses incurred towards honorarium of resource persons IT support (purchasing portable internet connection, web camera, speakers for computers) etc.

3. ***Reimbursement for participants – INR* 4,89,000**

Sr.No.	Particulars	Units	Rate	Cost
1	Reimbursement for study participants KII participants participants	30	300	9000
2	Reimbursement for study participants Intervention	400	300	120000
3	Reimbursement for Survey participants baseline and endline	1200	300	360000
			Total	**4,89,000**

Each participant attending key informant interviews (KIIs), intervention sessions and those participants who are part of the baseline survey and end line survey will be eligible for reimbursement for the time spent for participating in the study. The cost per participant will be approximately INR 300. Thus, a total cost of INR **4,89,000** will be incurred.

4. ***Peer fee – INR 1,00,000***

Total ten peers will be identified and trained for disseminating and implementing various intervention models in the community and will be responsible for community mobilization. Peer will be given INR 250 for each session, for 40 such sessions (approximately 10 participants in each session)
Thus a total of INR 1,00,000 is budgeted for this.

5. ***Translation fee – INR 1,82,886***

Translation of data from Marathi/Hindi to English from the data collection of , KII and community conversations will be outsourced, this would cost tentatively around INR 6000 per hour and for all qualitative data translation of approximately 30 hours (20 KII for around 60 minutes each , 10 community conversation audio files of approximately 30 minutes each) total of INR 1,82,886 has been budgeted.

6. ***Community sensitization through promotional activities - INR 45,000***

Total 3 Community Sensitization meetings will be held (one in each quarter) at the cost of INR15,000 per meeting, towards ensuring dissemination of IEC materials. This outreach would

include both print and electronic media. Relevant IEC materials created and distributed will include pamphlets, brochures, posters etc. This is budgeted at a total cost of INR 45,000.

7. ***Contingency Costs – INR 90,000***

Expert consultations will be organized at regular intervals to ensure scientific appropriateness of study tools and data collection mechanisms. Also, there will be study monitoring visits.
This is also budgeted towards miscellaneous expenses, personal protection eqipments, mobile recharge for research team to conduct telephonic interviews etc.
Thus, a contingency cost of INR 90,000 has been budgeted to cover such ad hoc consultations and meetings.

8. ***Engagement with Community Based Organization (CBO) partners – INR 3,42,330***

Local CBOs/NGO partners will be engaged to enable on-ground implementation of the study by facilitating access/interactions with relevant communities and providing space and facilities for the community meetings. Towards this, a cost of INR 48,904 per month for a period of 7 months has been been budgeted.

9. ***Dissemination Workshop – INR 32,000***

S.No.	Item	Rate	No.of persons	Total
1	Communication charges	2,000		2,000
2	Other incidental expenses	30,000		30,000
			Total	**32,000**

Towards the end of the study, a workshop will be organized at KIMSDU on qualitative research methods and dissemination of the broad findings of the study. This workshop will also provide the opportunity for knowledge sharing and capacity building among the broader research fraternity in qualitative research methods, data management and data analysis. Expected participants will be researchers, anthropologists, social worker, study team and medical PG students form KIMSDU as well as NARI and IAVI. This would be conducted online.

INDIRECT COSTS: **INR 3,30,690**

Indirect costs are budgeted at a rate of 8% on modified total direct costs (MTDC) in accordance with 2 CFR 200.414.

KRISHNA INSTITUTE OF MEDICAL SCIENCES
"DEEMED TO BE UNIVERSITY", KARAD

Accredited by NAAC with 'A' Grade (CGPA: 3.20 on 4 Point Scale)
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Declared U/s 3 of UGC ACT, 1956 vide Notification no.F.9-15/2001-U.3 of the Ministry of Human Resource Development, Govt. of India
Karad, Dist. : Satara (Maharashtra State) Pin : 415539 Tel : 02164-241555-8 Fax: 02164-243272/242170
Website : www.kimskarad.in E-mail: registrar@kimskarad.in

KIMSDU/G-3/4403/2019

Date : 04/12/2019

To
International AIDS Vaccine Initiative,
4, Factory Road, Ansari Nagar West,
New Delhi.

Invoice No. KIMS/RE/001/19-20		Dated: 04/12/2019
Sr. No.	Description	INR
1.	Release of advance under the project entitled: "Implementation and Evaluation of Community Based Intervention for Upliftment and Voluntary Participation in Biomedical Research Studies" Installment 1: 30,000 USD @ 1 USD =69.85 Grant No: A08723	2,095,500.00
	Total	2,095,500.00

- PAN No : AAATK1255H
- Bank Account No. : 14980200004429
- Bank Name : FEDERAL BANK
- Branch Address : Karad Branch, Plot No. 469/B, Ground Floor Ganesh Apartment, Shaniwar Peth Karad, MAHARASHTRA STATE, INDIA. 415110
- IFSC Code : FDRL0001498

Registrar
KIMSDU, Karad.

Krishna Institute of Medical Sciences "Deemed to be University", Karad

Dr. Asha Jadhav
Site Principle Investigator

KRISHNA INSTITUTE OF MEDICAL SCIENCES "DEEMED TO BE UNIVERSITY",
KARAD.

(Declared U/s 3 of UGC Act, 1956 vide Notification No. F.9-15/2001-U.3 of the Ministry of Human Resource Development, Govt. of India.)

Karad, Dist. Satara (Maharashtra State) Pin: 415 110 Tel: 02164-241555-58 Fax: 02164 243272/242170
Website: www.kimsuniversity.in E-mail: contact@kimsuniversity.in

Date: 10 June 2020

To
International AIDS Vaccine Initiatives
4, Factory Road, Ansari Road West
New Delhi

Invoice no.:
Date: 10 June 2020

Sr No	Description	INR
1	Release of advance under the project entitled 'Implementation and evaluation of community based intervention for upliftment and voluntary participation in biomedical research studies' Instalment no. 2: 30,000 USD @ 1 USD = 69.85 Grant number A08723	2,095500.00
	Total	**2,095500.00**

PAN No	AAATK1255H
Bank Account No:	14980200004429
Bank Name	Federal Bank
Branch Address	Karad Branch, Plot No. 469/B, Ground Floor Ganesh Apartment, Shanivar Peth, Karad, Maharashtra, India 415110
IFSC Code	FDRL0001498

Registrar, KIMSDU, Karad

Dr Asha Jadhav, Site Principal Investigator

Krishna Institute of Medical Sciences "Deemed To Be University" KARAD

International AIDS Vaccine Initiative
Subaward / Contract Budget

General Information	
Project Manager	Dr.Asha Jadhav
Organization	Krishna Institute of Medical Science "Deemed to be University" (KIMSDU), Karad
Project Title	Implementation and Evaluation of Community Based Intervention for Upliftment and Voluntary Participation in Biomedical Research Studies
Project Duration	One year
Project Manager Contact Information	
Title	
Address 1	
Address 2	
City	
State/Province	
Country	
Zip Code	
Phone	
Email	
Contract Administrator Contact Information	
Name	Dr.S.K.Danga
Title	Medical Officer
Phone	9372045685
Email	sunder147@gmail.com

n: Krishna Institute of Medica	Project Manager: Dr.Asha Jadhav	Project: Implementation and Evaluation of Community Based Intervention	Project Duration: One year

	NAME	DATE
y:	Dr Asha Jadhav	8/30/2019
st Rate: [1]	8%	
et Currency:	USD (@0.0143)	

PERSONNEL

	Title	Annual Base Salary	% Effort	Fringe Benefits %	Salary Request	Fringe Amount	Total Sala
dhav	Principle Investigator		75.0%		--	--	
ga	Co-Principle Investigator		50.0%		--	--	
	Program Manager Non medical (12 m	12,012	100.0%	8.0%	12,012	961	
	Project Assistant (12 months)-Two	10,639	100.0%	8.0%	10,639	851	
	Project Assistant (8 months)-Two	7,093	100.0%	8.0%	7,093	567	
	Project Assistant cum Interventionist (8	4,118	100.0%	8.0%	4,118	329	
	Project technician (Field worker)-(12 m	3,089	100.0%	8.0%	3,089	247	
	Staff Nurse -12 months-One	5,405	100.0%	8.0%	5,405	432	
	Lab technitian	3,089	100.0%	8.0%	3,089	247	
	Accountant cum Data Entry Operator 1	5,320	100.0%	8.0%	5,320	426	
tel	Co-ordinator		50.0%		--	--	
ri Yadav	Health Assistnt		50.0%		--	--	
					--	--	
					--	--	
					--	--	
L - TOTAL							

SUPPLIES *(Please itemize supplies below)*

	Unit	Unit Cost	Number of Units	
Consumables	HIV test kits and Plasticware	3	1,500	
e & Recorder ,Battery		286	4	
Computer Accessories		644	2	
		972	1	
tware		2,162	1	
		272	1	
nd Stationery	Pages	0	10,000	

n: Krishna Institute of Medica	Project Manager: Dr.Asha Jadhav	Project: Implementation and Evaluation of Community Based Intervention	Project Duration: One year	
TOTAL				

n: Krishna Institute of Medica	Project Manager: Dr.Asha Jadhav	Project: Implementation and Evaluation of Community Based Intervention	Project Duration: One year

INTERNATIONAL TRAVEL

Title	From / To	Transportation	Lodging	Meals	
ONAL TRAVE - TOTAL					

DOMESTIC TRAVEL [2]

Title	From / To	Transportation	Lodging	Meals	
y Mobilization related travel	Karad to Sangli,Patan	5,148			
versight related travel	Karad/Pune to Sangli,Patan, Karad	858			
eous travel		1,001			
TRAVEL - TOTAL					

CONSULTANTS

Title	Unit (Hour, Day)	Unit Rate	Number of Units	

n: Krishna Institute of Medica	Project Manager: Dr.Asha Jadhav	Project: Implementation and Evaluation of Community Based Intervention		Project Duration: One year

NTS - TOTAL

OTHER DIRECT COSTS [3]

escription	
y Advisory Board (CAB) Meetings (two meeting in a year)	
uilding training Program (4 capacity building program in a year)	
tion for participants with refreshment for total 864 (64+400+400) particicpants at 300 INR rate and 60 INR per person refreshment cost for 64 participants	
er session ,Total 15 peers for 15 sessions in Karad,Patan & Sangli (5 session at ecah place monthly)	
n fee (Translation form Hindi/Marathi to English & Typing) tentative pages ~ 5000 per page 30 INR	
y sensitization throug promotional activities & media sensitazation (4 meeting will be organised)	
elopment for Intervention	
nt advertisement	
ons & Meetings	
tion workshop	

ECT COSTS - TOTAL

SUMMARY

t Costs *(Total of all budgeted costs)*	
dified Direct Costs (Total Direct Costs less Capital Equipment)	
ct Costs (@8%)	

ARD [1]

CAPITAL EQUIPMENT > USD$5,000 [1,4]

	Description	

n: Krishna Institute of Medica	Project Manager: Dr.Asha Jadhav	Project: Implementation and Evaluation of Community Based Intervention	Project Duration: One year

QUIPMENT > USD$5,000 - TOTAL

charges should be based on an organization's existing NICRA with the US Government. Organizations that do not have a NICRA letter with the US Government may elect to either (a) charge all costs as direct costs in the b
a de minimis rate of 10 percent of modified total direct costs (MTDC). This 10% de minimis rate may be used indefinitely (2 CFR 200.414). Costs must be consistently charged as either indirect or direct costs, but may not
arged or inconsistently charged as both. MTDC means all direct salaries and wages, applicable fringe benefits, materials and supplies, services, travel, and up to the first $25,000 of each subaward (regardless of the perio
nce of the subawards under the award). MTDC excludes equipment, capital expenditures, charges for patient care, rental costs, tuition remission, scholarships and fellowships, participant support costs and the portion of
in excess of $25,000. Other items may only be excluded when necessary to avoid a serious inequity in the distribution of indirect costs, and with the approval of the cognizant agency for indirect costs.

ust comply with the Fly America Act

euticals are defined as restricted goods and must be purchased in accordance with USAID guidelines (ADS Chapter 312 - https://www.usaid.gov/sites/default/files/documents/1876/312.pdf)

ent means tangible personal property (including information technology systems) having a useful life of more than one year and a per-unit acquisition cost which equals or exceeds the lesser of the capitalization level esta
n-Federal entity for financial statement purposes, or $5,000. See also §§200.12 Capital assets, 200.20 Computing devices, 200.48 General purpose equipment, 200.58 Information technology systems, 200.89 Special purp
t, and 200.94 Supplies

geted costs must be allowable in accordance with 2 CFR 200 Subpart E, Cost Principles: http://www.ecfr.gov/cgi-bin/text-idx?SID=68d04dd5b9d6af9eee19903dd4173199&mc=true&node=sp2.1.200.e&rgn=div6