

## REGIONAL OFFICE FOR South-East Asia

OFFICE ADDRESS:

PERMANENT: WORLD HEALTH HOUSE, INDRAPRASTHA ESTATE, MAHATMA GANDHI ROAD, NEW DELHI-110 002, INDIA, WWW.SEARO.WHO.INT TEMPORARY: METROPOLITAN HOTEL OFFICE BLOCK, BANGLA SAHIB ROAD, GOLE MARKET, SECTOR 4, NEW DELHI-110 001, INDIA ANNEX – RED FORT CAPITAL PARSVNATH TOWER 1, BHAI VIR SINGH MARG, GOLE MARKET, SECTOR 4, NEW DELHI-110 001, INDIA TEL: 91-11-4304 0200 /0161, FAX: 91-11-2336 8355

In reply please refer to: M3/15/1

Dr Niranana Mahantashetti Director Women's and Children's Health Research Unit Jawaharlal Nehru Medical Collage, KLE Academy of Higher Education and Research, Belagavi (JNMC Research Unit) Karnataka 590010, India

16 September 2019

Dear Dr Mahantashetti

### Subject: Designation of Women's and Children's Health Research Unit, Jawaharlal Nehru Medical College, KLE Academy of Higher Education and Research, Belagavi (JNMC Research Unit) as a WHO Collaborating Centre for Research in Maternal and Perinatal Health (WHO-CC IND 156)

I am pleased to inform you that the World Health Organization has designated the Women's and Children's Health Research Unit, Jawaharlal Nehru Medical College, KLE Academy of Higher Education and Research, Belagavi (JNMC Research Unit) as a WHO Collaborating Centre for Research in Maternal and Perinatal Health (WHO-CC IND 156).

As previously agreed, Dr Shivaprasad Goudar will act as Head of the Centre. Should there be any change in the future, I would be grateful if you would inform WHO without delay.

The agreed terms of reference and workplan of the Centre are attached. We wish to emphasize that institutions designated as WHO Collaborating Centres are expected to implement the agreed workplan in a timely manner and to the highest possible standard of quality. Any issue that may affect the implementation of the agreed workplan should be brought to the attention of the WHO responsible officer, Dr Mariana Widmer, Technical Officer, HQ/MPA Maternal Perinatal Health, Prevent Unsafe Abortion Tel:+41 22 791 4323,Email: widmerm@who.int

For information on administrative matters, please visit the WHO website http://www.who.int/collaboratingcentres/information/en/.

We wish to also emphasize that institutions designated as WHO Collaborating Centres must also comply with the attached terms and conditions for WHO collaborating centres. We wish to draw your particular attention to the fact that the WHO name and emblem may only be used by a WHO Collaborating Centre as described in those terms and conditions.

Cont'd...2/-

cc: The Secretary, Ministry of Health and Family Welfare, Government of India, Nirman Bhawan, New Delhi

cc: The Joint Secretary (IH Division), Ministry of Health and Family Welfare, Government of India, Nirman Bhawan, New Delhi

cc and through: The WHO Representative to India, Nirman Bhawan, New Delhi

Page 2/-

Dr Niranana Mahantashetti Director Women's and Children's Health Research Unit Jawaharlal Nehru Medical Collage, KLE Academy of Higher Education and Research, Belagavi (JNMC Research Unit) Karnataka 590010

M3/15/1

16 September 2019

Finally, please note that institutions designated as WHO Collaborating Centres must complete a short online progress report form once a year. On the anniversary of the designation date, details will be sent to the email address of the Head of the Centre specified in the designation form.

The designation of your institution as a WHO Collaborating Centre will be effective for a period of 4 years from **17 September 2019**, and will automatically end on **17 September 2023**, unless redesignation has been approved by WHO before that date. During the period of designation, either party may revoke the designation at any time by giving three months advance notice in writing.

I look forward to our successful collaboration.

Yours sincerely,

Dr Poonam Khetrapal Singh Regional Director

Encl: As stated



Offica of the J. N. MEDICAL COLLEGE LAGA 2019 Dr. Bouda 101 **NCT** 

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Dr Niranana Mahantashetti Director Women's and Children's Health Research Unit Jawaharlal Nehru Medical Collage, KLE Academy of Higher Education and Research, Belagavi (JNMC Research Unit) Karnataka 590010, India

16 September 2019

Dear Dr Mahantashetti

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Page 2/-

Dr Niranana Mahantashetti Director Women's and Children's Health Research Unit Jawaharlal Nehru Medical Collage, KLE Academy of Higher Education and Research, Belagavi (JNMC Research Unit) Karnataka 590010

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### 16 September 2019

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I look forward to our successful collaboration.

Yours sincerely,

Dr Poonam Khetrapal Singh **Regional Director** 

Encl: As stated



The designation form consists of three parts:

Part I -	Institutiona	<b>I</b> Profile
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Part II - Terms of Reference (TOR)

Part III – Workplan

This designation form below, together with the Terms and conditions for WHO collaborating centres will serve as the agreement between the proposed institution and WHO if the designation as WHO collaborating centre is approved by WHO. Completion and submission of the designation form, however, does not guarantee that the designation will be approved.

Folder eCC\_00018907 is in stage Notification Letter

Name of the University, Hospita	al, Research Institute, Academy or Ministry
Jawaharlal Nehru Medical Colleg Research Unit)	e, KLE Academy of Higher Education and Research, Belagavi (JNMC
Name of the Division, Departme	ent, Unit, Section or Area
Women's and Children's Health F	Research Unit
City	CC Reference Number
Belagavi	IND-156
Title	
WHO collaborating centre for rese	earch in maternal and perinatal health

### Part I - Institutional Profile

The status of WHO CC is granted to an administrative unit of an institution (i.e. department, division or unit) and not to the institution as a whole in the vast majority of cases. For example, WHO CC status is granted to the Department of Microbiology of the University of ABC and not to the university itself. A WHO CC is not a legal entity. The legal entity is the proposed institution, i.e. the ministry, academy, university, established research institute or hospital, of a part thereof.

In the section entitled "sources of funding" some questions refer to the proposed terms of reference and activities included in the workplan of this proposal. Therefore please limit your responses to what is relevant in relation to the proposed terms of reference and activities included in the workplan.

However, when a question refers to the "proposed institution", please provide information on the legal entity as a whole (for example the University of ABC).

Address of the proposed institution

1.1 Street and number	JNMC Campus, Nehru Nagar
1.2 City	Belagavi
1.3 State/Region/Canton/Province	Karnataka
1.4 Postal Code	590010
1.5 Country	IND
1.6 WHO Region	SEARO

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1.7 Phone

1.8 Fax

1.9 Web site

## Collaborating Centres DESIGNATION FORM

+91 831 247 4200

+918312472891

http://kledeemeduniversity.edu.in/

If you would like your institution to receive important news and other communications from WHO (unrelated to the work as a WHO CC) such as launching of new WHO campaigns, new WHO publications, etc, please indicate an email address.

Staff of the proposed institution

1.10 Name of the director of the institution as a whole

Dr Niranjana Mahantashetti

1.11 - Name and email of the proposed heads of the WHO collaborating centre (Please note this information will be listed in the public database)

Salutation	First Name	Last Name	Email Address
Dr	Shivaprasad	Goudar	sgoudar@jnmc.edu
Salutation	First Name	Last Name	Email Address

1.12 Please list the names of professional who will work on the proposed terms of reference or activities of the workplan together with their professional qualifications (e.g. Dr John Smith MPH). Please do not include full resumes or biographies.

Dr Avinash Kavi MD Dr Yogesh Kumar S MD Dr Sunil S Vernekar MD Dr Yeshita V Pujar MD Dr Manjunath S Somannavar MD Dr Sangappa M Dhaded MD DM Dr Shivaprasad S Goudar MD

### Sources of funding

NOTE: Private-sector entities in this form refer to three categories: (i) business associations representing commercial enterprises, (ii) entities that are not at "arms' length" from their commercial sponsors, and (iii) partially or fully state-owned commercial enterprises that act like private-sector entities.

An entity that is "at arms' length" from another entity should meet the following three conditions: (i) to be financially and organizationally independent from the other entity, (ii) not to take instructions from the other entity, and (iii) not to be influenced or not reasonably perceived to be influenced in its decisions, activities, mandate and work by the other entity.

1.13 During the last two years, what percentage of the funding of the proposed institution was core funding? Core funding refers to funding that is received regularly from secure sources, as opposed to ad-hoc contributions.

over 75% regular (core) funding

1.14 Please provide a complete list of donors that provide funding for the proposed institution, such as private-sector organizations, philanthropic foundations, nongovernmental organizations, governments, inter-governmental organizations and members of the public. Please include the full names of all donors, but not the amount donated.

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KLE Academy of Higher Education and Research- Not Applicable- >75% of the core funding is through tuition fees from students of the University.

JNMC Women's and Children's Health Research Unit- NICHD Eunice Shriver Kennedy Global Network for Women's and Children's Health Research (currently in the fourth cycle of funding), World Health Organization, the National Institute of Child Health and Human Development, the American Academy of Pediatrics, the Thrasher Research Fund, UK Medical Research Council – Department of Bio-technology, Govt. of India Newton-Bhabha Fund, and the Bill & Melinda Gates Foundation.

With reference to the proposed terms of reference and activities included in the workplan of this proposal-Source of funding is included in the work plan document.

1.15 Tobacco/arms-related disclosure statement .

Under the WHO Framework of Engagement with non-State Actors, WHO does not engage with the tobacco industry or non-State actors that work to further the interests of the tobacco industry. Moreover, WHO does not engage with the arms industry.

For the purposes of this statement: tobacco industry refers to any entity involved in the manufacture, sale or distribution of tobacco and related products, and any affiliate of such an entity; and arms industry refers to any entity involved in the manufacture, sale or distribution of arms, and any affiliate of such an entity.

To determine whether the proposed institution conforms to this rule, please answer the following questions:

• Is the proposed institution, or was the proposed institution over the last four years, part of the tobacco or arms industries (as defined above)?

• Is the proposed institution, or has the proposed institution over the last four years, engaged in activities that support the interests of the tobacco industry? This includes, but is not limited to, supply contracts, contract work, services and lobbying.

• Does the proposed institution currently, or did the proposed institution over the last four years, have any other association or relationship with the tobacco industry (as defined above)? This includes in particular investment interests (other than general mutual funds or similar arrangements whereby the institution has no control over the selection of the investments), commercial business interests, the provision or receipt of financial and/or other support.

• Does the proposed institution have any formal association, affiliation or links with private-sector entities and other non-State actors whose policies or activities negatively affect human health and are not in line with WHO's policies, norms and standards, in particular those related to noncommunicable diseases and their determinants?

The answer is yes to at least one of the questions above. Please provide details

By selecting this choice I confirm that the answer to all the questions above is no

[If yes] Please provide details (i.e. the names of entities, their activities, level of funding).

1.16 Is there any prospect that the proposed terms of reference or activities of the workplan will be funded by one or more private-sector entities that have, or may be perceived as having, a direct or indirect commercial interest in those proposed terms of reference or activities of the workplan?

Yes 🔽 No 🔽

[If yes] Please provide the names of these entities, their business activities and the level of funding.

1.17 Is any of the proposed terms of reference or activities of the workplan, or is there a prospect that any of the proposed terms of reference or activities of the workplan will be, performed as part of or related to work (research or other) commissioned by private-sector entities?

Yes 🔽 No 🔽

[If yes] Please provide the names of these entities, their business activities and the level of funding.

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1.18 Is any of the proposed terms of reference or activities of the workplan, or is there a prospect that any of the proposed terms of reference or activities of the workplan will be, funded directly or indirectly by unspecified funds from one or more private-sector entities?

Yes 🔽 No 🔽

[If yes] Please provide the names of these entities, their business activities, level of funding, for what such funding is being, or will be, used and whether the implementation of the proposed terms of reference and activities of the workplan is dependent on the support of one or more of these private sector entities.

1.19 Are the salaries of staff who will work on the proposed terms of reference or activities of the workplan or their posts funded by one or more private sector entities, were they ever funded in this way in the past or could they receive such funding in future?

Yes 🔽 No 🔽

[if yes] Please provide the names of these entities, their business activities, level of funding, for which staff or what posts such funding is being, or will be, used, and the functions of such staff and/or posts.

1.20 Did over the last three years, does currently, or is there a prospect that, any specific staff who will work on the proposed terms of reference or activities of the workplan (including the proposed head(s) of the WHO collaborating centre), have any other interactions, affiliations or relations with, or any other personal, professional, financial or business interests in, one or more private sector entities that could give rise to a real or perceived conflict of interest or reputational risk?

### Such risks may exist

(i) if the private sector entity has a direct or indirect commercial interest in all or part of the proposed terms of reference or activities of the workplan, or may be perceived as having such interest;
(ii) if the business activities of the entity engage with the tobacco industry and /or arms industry; or non-State actors that work to further the interests of the tobacco industry ; or
(iii) if the private sector entity has a vested interest in exerting influence on the proposed terms of reference or activities of the workplan and/or their outcome or may be seen as having such interest.

Interactions, affiliations, relations with, or other personal, professional, financial or business interests include, but are not necessarily limited to, collaborative projects or initiatives, employment, consultancy, investment interests (e.g. stocks, bonds, stock options, other securities, but not mutual funds, pension funds or similar investments that are broadly diversified), commercial business interests (e.g., proprietorships, partnerships, joint ventures), patents, trademarks, or copyrights (including pending applications), proprietary know-how in a substance, technology or process.

Yes 🔽 No 🔽

[if yes] Please provide details.

### Institutional characteristics

1.21 What type of entity is the proposed institution? Private Please provide details

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The K.L.E. Academy of Higher Education & Research was established on 13th April, 2006 as per the Ministry of Human Resource Development, Government of India, Notification No.F.9-19/2000-U-R(A) dated 13th April, 2006, under the recommendation of University Grants Commission.

Vision: "To be an outstanding university of excellence ever in pursuit of newer horizons- To build self reliant global citizens through assured quality educational Programmes". Mission

• To promote sustainable development of Higher Education consistent with statutory and regulatory requirements.

• To plan and continuously provide necessary infrastructure, learning resources required for Quality education and innovations.

• To stimulate, to extend the frontiers of knowledge, through Faculty Development and Continuing Education Programmes.

• To make research a significant activity involving Staff, Students and Society.

• To promote Industry / Organization, Interaction/Collaborations with Regional National / International bodies.

• To establish healthy systems for communication among all stake holders for vision oriented growth.

• To fulfill the National Obligation through Rural Health Missions.

The KLE Society, Sponsoring society of KAHER a private trust was established in the year 1916 and has been serving thousands of people in the field of education for nearly 10 decades! Presently, KLE Society manages a staggering 250 institutions including schools, colleges, technical institutions, research centers and Business schools.

University

By ticking this box you confirm that the entity you represent is a nonprofit entity.

1.22 Please attach a current organizational chart (1 page) of the institution, including its administrative units such as divisions, departments, sections or areas (whichever structure applies), indicating the one proposed as WHO collaborating centre.

Organisation Chart\_KAHER.pdf

1.23 Please attach the constitutive documents of the institution you represent e.g. constitution, registration document, by-laws or similar.

MOA and Other Documents\_KAHER.pdf

1.24 Number of years the institution is in operation.

more than 10 years

1.25 Please list major facilities and any specialized equipment available to the proposed institution (e.g. laboratories, training facilities, documentation centre), if applicable. Please do not list general office space or standard office equipment.

Clinical Skill laboratory (with Simulation, Mannequins and models) Meeting rooms and Conference halls (40 and 100 seating capacity) in a dedicated building of about 9000 square feet

25 MPBS Internet leased line with fibre optic backbone and WIFI network Server for data storage with and Data Management System facilities. Facilities for scanning, photocopy, cold storage, Data Archival, Dining area Basic Science Research Centre (Laboratory)

1.26 Does the proposed institution currently establish a smoke-free environment across its premises, which can be illustrated either through a documented institutional/departmental policy or through the existence of national/local smoke-free legislation? The smoke-free environment must apply to all indoor workplaces and public places of the institution's premises, and must entail a complete ban of smoking indoors and no areas designated for smoking.

Yes

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I understand that information on my entity and its engagements with WHO that are categorized as public domain will be published in the WHO Register.

The proposed institution agrees with the following Terms and conditions for WHO collaborating centres.

## Part II - Terms of Reference (TOR)

V

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World Health Organization

Please include the proposed terms of reference for the future collaboration between the proposed institution and WHO, as discussed prior to completing this form. In most cases, 1-3 TOR will be sufficient to provide a high-level framework of the future collaboration. For redesignations, the current terms of reference is automatically prefilled but can be revised as appropriate.

For detailed instructions on how to fill in this section please click on the link provided at the top of the form.

- **TOR 1** In alignment with WHO goals, to provide capacity building through Research Methodology Workshops at country level.
- **TOR 2** To participate in collaborative research in the area of Maternal and Newborn Health developed under WHO's leadership.
- **TOR 3** As agreed with WHO, disseminate and scale up evidence based interventions in the area of Maternal and Newborn Health.

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# World Health Organization

# Collaborating Centres DESIGNATION FORM

Activity IDActivity titleCapacity building in alignment with WHO goals, TOR1ID27838Link to TORTOR1Name(s) of responsible staff at the institutionTor Avinash Kavi, Dr Yogesh Kumar S, Dr M S Somannavar, Dr S M Dhaded, Dr S S Goudar, Trype of activityTraining and educationWhy WHO is asking for this activity and how WHO will use the deliverables?As part of WHO and HRP mandate, research projects include capacity building activities activity and how WHO will use the through which investigators receive training on research methodology. By doing thisWhat concrete actions will be taken by the designated institution? Be specific.In collaboration with WHO, the designated institution will evaluate the possibility of replicating to the participants needs, and will conduct it among mid-level faculty staff from India. Upon successful implementation of the workshops, will and Bangladesh. Mid-level faculty staff fion India. Upon successful angladesh. Mid-level faculty staff includes Assistant and Associate Profesors of various specialities, as well as Research Scholars working in Medical Colleges and Research Institutions respectively in the North Kamataka region with special focus on reportable, proposals and scientific manuscripts. Workshops will be of 5 days to 2 weeks duration. Each activity will be of 5 days to 2 weeks duration. Each activity will be of the user will not be of a quality from Nomen's and Children's Health Research Intifutions respectively in the North Kamataka region with special focus on reportable. Schoars of various specialities, as on quality control procedures during the implementation of the research project. At the end of the workshops, participants will be able to with special	Part III – Workplan		
Name(s) of responsible staff at the institution       Dr Avinash Kavi, Dr Yogesh Kumar S, Dr M S Somannavar, Dr S M Dhaded, Dr S S Goudar.         Type of activity       Trainig and education         Why WHO is asking for this activity and how WHO will use the deliverables?       As part of WHO and HRP mandate, research projects include capacity building activities through which investigators receive training on research methodology. By doing this         What concrete actions will be taken by the designated institution? Be specific.       In collaboration with WHO, the designated institution will develop the training curriculum for the research methodology (qualitative and quanitative) and statistics workshops, will customize it according to the participants needs, and will conduct it among mid-level faculty staff fron India. Upon successful implementation of the workshops in India, the designated institution will evaluate the possibility of replaced institutions will evaluate the possibility of replaced institutions will evaluate the possibility of replaced institutions will evaluate and Bangladesh.         Mid-level faculty staff fron India. Upon successful implementation of the workshops in India, the designated role of sources in Nepal and Bangladesh.         Mid-level faculty staff includes Assistant and Associate Professors of various specialities, as well as Research Scholars working in Medical Colleges and Research network (arrous and newborn health.         Mid-level faculty staff includes for sample size calculation and for analysis of the research outcomes, and on quality control procedures during the implementation of the research project. At the end of the workshops, participants will be able to write full grant proposals and scientific manuscripts.	Activity	Activity title	Capacity building in alignment with WHO goals
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			Education and Research's J N Medical College will conduct these workshops. Additional
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World		rating Centres
Organization DESIGNATION FORM		
		Department of Medical Education J N Medical College Belagavi.
	What will be WHO's role in this activity?	WHO will collaborate with the designated institution in defining the training programme and in selecting the participants. WHO will confirm the selection of participants for the training and will approve the final programme. In addition, WHO staff will provide technical guidance for and during the workshops.
	Expected deliverables	Two workshops conducted. Capacity of participants on research methodology increased.
	Intellectual property rights	IP rights of ALL deliverables belong to WHO as per paragraphs 3.1.2 and/or 3.2.2 of the Terms and Conditions
	WHO Deliverable Code	14.1.1.H3
	Name(s) of funding sources	The cost of conducting these activities will be met from: 1. Indian Council of Medical Research, Fogarty International Centre and Bill & Melinda Gates Foundation 2. KLE Academy Higher Education and Research, Belagavi
	Activity timeframe	Every year one workshop on grant writing for duration of 2 weeks and one workshop on manuscript writing for 1 week duration will be conducted.
		developed for the workplan of the WHO constitute a standard activity of the ent.

## 9/16/2019 5:27:37 AM

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1 3		
Activity ID 27839	Activity title	With the guidance and leadership form WHO, to conduct secondary analysis for CHAMPION Trial
	Link to TOR	TOR2
		Dr S S Vernekar, Dr Yeshita Pujar,  Dr M S Somannavar, Dr S S Goudar,
	Type of activity	Research
	Why WHO is asking for this activity and how WHO will use the deliverables?	The CHAMPION trial database is a big and rich database which could answer lots of interesting questions related to the postpartum haemorrhage problematic. WHO/HRP does not have the capacity to run these analyses in a timely manner. Results of this analysis will help WHO understand the socio-economic aspects of the PPH problematic in one of the countries where the burden of this maternal complication is high.
	What concrete actions will be taken by the designated institution? Be specific.	With WHO guidance, the designated institution will develop the protocol for the analysis proposed, run the proposed statistical analyses and prepare a report with the results.
	What will be WHO's role in this activity?	WHO will guide the process for preparing the proposal, will guide the data analysis process, and will lead the discussion on the findings.
	Expected deliverables	Publication on the Effectiveness of Heat stable Carbetocin compared to Oxytocin in women delivering at public and private sector hospitals of India.
	Intellectual property rights	IP rights of ALL deliverables belong to WHO as per paragraphs 3.1.2 and/or 3.2.2 of the Terms and Conditions
	WHO Deliverable Code	3.1.5.H1
	Name(s) of funding sources	Jawaharlal Nehru Medical College Women's and Children's Health Research Unit , Belgaum
	Activity timeframe	December 2018: Secondary analyses to be completed. January 2019: Drafts of the publications for review. February 2019: Submission for publication
	This activity has been specifically of collaborating centre and does not of institution without WHO involveme	
Activity ID 27840	Activity title	Knowledge Translation on Maternal and Perinatal Health Research Projects
	Link to TOR	TOR3
		Dr Yogesh Kumar S, Dr M S Somannavar, Dr S S Goudar, Dr.Yeshita Pujar, Dr.Sunil
9/16/2019 5:27:37 AM		Page (9/11)

Page (9/11)



Name(s) of responsible staff at the Vernekar institution

Type of activity

World Health Organization

Information dissemination

Why WHO is asking for this activity and how WHO will use the deliverables?

The dissemination of the CHAMPION trial's results is very important for the uptake of the WHO postpartum haemorrhage recommendations by the country and it is part of the WHO/HRP agenda. India is one of the LMIC countries where the burden of postpartum haemorrhage is high and therefore, the need to implement the results of the CHAMPION trial is a priority for WHO. By requesting an Indian institute to disseminate the results in India, WHO is increasing the chances that the results of the research will be widely applied.

Following WHO guidance and to raise awareness on how to prevent postpartum haemorrhage, the institution will present the results of CHAMPION Trial at All India Congress of Obstetrics & Gynaecology (AICOG) and at the congress organized by the Federation of Obstetrics & Gynaecological Societies of India (FOGSI). The designated institution will also present the results of the trial in Nepal, at the Reproductive Health Supply Coalition Caucus. In addition, with WHO leadership, the institution will implement a demonstration project to identify barriers and facilitators for the eventual national roll-out of the heat-stable carbetocin use in the area of postpartum haemorrhage.

WHO will prepare the presentation that will be used by the institution at different conferences, and will discuss it with the institution to ensure alignment on the message that has to be given to the audience. In regard to the demonstration project, WHO will work jointly with the institution in defining the project and the process for a successful implementation.

1. 3 abstracts for dissemination meetings in India and in Nepal.

2. Use of heat-stable carbetocin for postpartum haemorrhage prevention implemented at district level of the 6 Indian provinces that participated in the CHAMPION trial.

IP rights of ALL deliverables belong to WHO as per paragraphs 3.1.2 and/or 3.2.2 of the Terms and Conditions

3.1.1.R4

Jawaharlal Nehru Medical College Women's and Children's Health Research Unit

Page (10/11)

What concrete actions will be taken by the designated institution? Be specific.

What will be WHO's role in this activity?

Expected deliverables

Intellectual property rights

WHO Deliverable Code Name(s) of funding sources

9/16/2019 5:27:37 AM

A		
World Health	<b>Collaborating Centres</b>	
Section Organization	DESIGNATION FORM	
Activity tin	eframe December 2018 -March 2019: Diss meetings April 2019: demonstration project p written June 2019: Stakeholder meetings August 2019: Training October 2019-February 2020: Sca	proposal
collaborati	y has been specifically developed for the workplan of the ng centre and does not constitute a standard activity of the without WHO involvement.	

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## REGIONAL OFFICE FOR South-East Asia

OFFICE ADDRESS:

PERMANENT: WORLD HEALTH HOUSE, INDRAPRASTHA ESTATE, MAHATMA GANDHI ROAD, NEW DELHI-110 002, INDIA, WWW.SEARO.WHO.INT TEMPORARY: METROPOLITAN HOTEL OFFICE BLOCK, BANGLA SAHIB ROAD, GOLE MARKET, SECTOR 4, NEW DELHI-110 001, INDIA ANNEX – RED FORT CAPITAL PARSVNATH TOWER 1, BHAI VIR SINGH MARG, GOLE MARKET, SECTOR 4, NEW DELHI-110 001, INDIA TEL: 91-11-4304 0200 /0161, FAX: 91-11-2336 8355

In reply please refer to: M3/15/1

Dr Niranana Mahantashetti Director Women's and Children's Health Research Unit Jawaharlal Nehru Medical Collage, KLE Academy of Higher Education and Research, Belagavi (JNMC Research Unit) Karnataka 590010, India

16 September 2019

Dear Dr Mahantashetti

### Subject: Designation of Women's and Children's Health Research Unit, Jawaharlal Nehru Medical College, KLE Academy of Higher Education and Research, Belagavi (JNMC Research Unit) as a WHO Collaborating Centre for Research in Maternal and Perinatal Health (WHO-CC IND 156)

I am pleased to inform you that the World Health Organization has designated the Women's and Children's Health Research Unit, Jawaharlal Nehru Medical College, KLE Academy of Higher Education and Research, Belagavi (JNMC Research Unit) as a WHO Collaborating Centre for Research in Maternal and Perinatal Health (WHO-CC IND 156).

As previously agreed, Dr Shivaprasad Goudar will act as Head of the Centre. Should there be any change in the future, I would be grateful if you would inform WHO without delay.

The agreed terms of reference and workplan of the Centre are attached. We wish to emphasize that institutions designated as WHO Collaborating Centres are expected to implement the agreed workplan in a timely manner and to the highest possible standard of quality. Any issue that may affect the implementation of the agreed workplan should be brought to the attention of the WHO responsible officer, Dr Mariana Widmer, Technical Officer, HQ/MPA Maternal Perinatal Health, Prevent Unsafe Abortion Tel:+41 22 791 4323,Email: widmerm@who.int

For information on administrative matters, please visit the WHO website http://www.who.int/collaboratingcentres/information/en/.

We wish to also emphasize that institutions designated as WHO Collaborating Centres must also comply with the attached terms and conditions for WHO collaborating centres. We wish to draw your particular attention to the fact that the WHO name and emblem may only be used by a WHO Collaborating Centre as described in those terms and conditions.

Cont'd...2/-

cc: The Secretary, Ministry of Health and Family Welfare, Government of India, Nirman Bhawan, New Delhi

cc: The Joint Secretary (IH Division), Ministry of Health and Family Welfare, Government of India, Nirman Bhawan, New Delhi

cc and through: The WHO Representative to India, Nirman Bhawan, New Delhi

Page 2/-

Dr Niranana Mahantashetti Director Women's and Children's Health Research Unit Jawaharlal Nehru Medical Collage, KLE Academy of Higher Education and Research, Belagavi (JNMC Research Unit) Karnataka 590010

M3/15/1

16 September 2019

Finally, please note that institutions designated as WHO Collaborating Centres must complete a short online progress report form once a year. On the anniversary of the designation date, details will be sent to the email address of the Head of the Centre specified in the designation form.

The designation of your institution as a WHO Collaborating Centre will be effective for a period of 4 years from **17 September 2019**, and will automatically end on **17 September 2023**, unless redesignation has been approved by WHO before that date. During the period of designation, either party may revoke the designation at any time by giving three months advance notice in writing.

I look forward to our successful collaboration.

Yours sincerely,

Dr Poonam Khetrapal Singh Regional Director

Encl: As stated



## REGIONAL OFFICE FOR South-East Asia

PERMANENT: WORLD HEALTH HOUSE, INDRAPRASTHA ESTATE, MAHATMA GANDHI ROAD, NEW DELHI-110 002, INDIA, WWW.SEARO.WHO.INT TEMPORARY: METROPOLITAN HOTEL OFFICE BLOCK, BANGLA SAHIB ROAD, GOLE MARKET, SECTOR 4, NEW DELHI-110 001, INDIA ANNEX – RED FORT CAPITAL PARSVNATH TOWER 1, BHAI VIR SINGH MARG, GOLE MARKET, SECTOR 4, NEW DELHI-110 001, INDIA TEL: 91-11-4304 0200 /0161, FAX: 91-11-2336 8355

In reply please refer to:

Dr Niranjana Mahantashetti Director Women's and Children's Health Research Unit, Jawaharlal Nehru College KLE Academy of Higher Education and Research JNMC Campus, Nehru Nagar Belagavi, Karnataka

25 October 2023

Dear Dr Mahantashetti,

### Subject: Redesignation of Women's and Children's Health Research Unit, Jawahar Lal Nehru Medical College as a WHO Collaborating Centre for Research in Maternal and Perinatal Health (WHO-CC IND 156)

I am pleased to inform you that the World Health Organization has designated the Women's and Children's Health Research Unit, Jawaharlal Nehru Medical College, KLE Academy of Higher Education and Research, Belagavi (JNMC Research Unit) as a WHO Collaborating Centre for Research in Maternal and Perinatal Health (WHO-CC IND 156).

As previously agreed, Dr Shivaprasad Goudar will act as Head of the Centre. Should there be any change in the future, I would be grateful if you would inform WHO without delay.

The agreed terms of reference and workplan of the Centre are attached. We wish to emphasize that institutions designated as WHO Collaborating Centres are expected to implement the agreed workplan in a timely manner and to the highest possible standard of quality. Any issue that may affect the implementation of the agreed workplan should be brought to the attention of the WHO responsible officer Dr Mariana Widmer at <u>widerm@who.int</u>

For information on administrative matters, please visit the WHO website https://www.who.int/southeastasia/about/partnerships/collaborating-centres.

Cont'd...2/-

cc: The Secretary, Ministry of Health and Family Welfare, Government of India, Nirman Bhawan, New Delhi

The Joint Secretary (IH Division), Ministry of Health and Family Welfare, Government of India, Nirman Bhawan, New Delhi

The WHO Representative to India, Nirman Bhawan, New Delhi

OFFICE ADDRESS:

Page 2/-

Dr Niranjana Mahantashetti Director Women's and Children's Health Research Unit, Jawaharlal Nehru College KLE Academy of Higher Education and Research JNMC Campus, Nehru Nagar Belagavi, Karnataka

25 October 2023

Finally, please note that institutions designated as WHO Collaborating Centres must complete a short online progress report form once a year. On the anniversary of the designation date, details will be sent to the email address of the Head of the Centre specified in the designation form.

The designation as a WHO Collaborating Centre will be effective for a period of 4 years of redesignation, as from **14 September 2023**, and will automatically end on **14 September 2027**, unless redesignation has been approved by WHO before that date. During the period of designation, either party may revoke the designation at any time by giving three months advance notice in writing.

I look forward to our successful collaboration.

Yours sincerely,

Dr Poonam Khetrapal Singh **Regional Director** 

Encl: As stated



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

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

Dated: 28.12.2021

## Notification

With reference to call for Expression of Interest for participation in the Indian Clinical Trial & Education Network (INTENT) dated 22.09.2021, the applications received were reviewed by a screening committee, consisting of external experts. The institutes were selected under the following subheads:

- 1. Advanced Centre for Clinical Trial (ACCT)
- 2. Regional Clinical Trial Unit (RCTU)
- 3. ICMR-Centre for Clinical Trial (ICCT)
- 4. Specialty Centre for Clinical Trial (SCCT)
- 5. Knowledge Partner for Clinical Trial (KPCT)

The Institutes/Centres selected to be a part of the INTENT are tabulated below. The details of the network, along with the Terms of Reference (ToR) will be shared with the centres individually.

**Dr. Aparna Mukherjee** (on behalf of Indian Clinical Trial & Education Network)

Scientist-E & In charge Clinical Studies, Trials & Projection Unit Epidemiology and Communicable Division Indian Council of Medical Research, New Delhi



## 1. Advanced centers for clinical trials (ACTT)

Zone	Institute	Lead Applicant
	All India Institute of Medical Sciences, New Delhi	Dr. Rakesh Lodha
North	Post Graduate Institute of Medical Sciences and	Dr. Samir Malhotra
	Education, Chandigarh	
	S.M.S. Medical College and Attached Hospitals,	Dr. Sudhir Bhandari
	Jaipur, Rajasthan	
West	Mahatma Gandhi Institute of Medical Sciences,	Dr. Abhishek V. Raut
	Sevagram, Maharashtra	
	ICMR- National AIDS Research Institute (NARI),	Dr. Abhijit Vasantrao Kadam
	Pune, Maharashtra	
	All India Institute of Medical Sciences,	Dr. Sujit Kumar Tripathy
East	Bhubaneswar, Odisha	
	ICMR- National Institute of Cholera and Enteric	Dr. Suman Kanungo
	Diseases (NICED), Kolkata, West Bengal	
North-	North Eastern Indira Gandhi Regional Institute of	Dr. Chayna Sarkar
East	Health and Medical Sciences (NEIGRIHMS),	
	Shillong, Meghalaya	
Central	King George Medical University, Lucknow, Uttar	Dr. Himanshu D Reddy
	Pradesh	
	Jawaharlal Institute of Medical Education &	Dr. Sandhiya Selvarajan
	research (JIPMER), Puducherry	
South	St Johns Medical College, Bengaluru, Karnataka	Dr. Denis Xavier
	Amrita Institute of Medical Sciences, Kochi,	Dr. Jaideep Menon
	Kerala	

## 2. Regional Clinical Trial Unit (RCTU) (MRU/ MRHRU Network)

Zone	Institute	
North	All India Institute of Medical Sciences, Rishikesh, Uttarakhand	
West	ICMR-National Institute For Research In Reproductive and Child Health	
	Mumbai (Dahanu), Maharashtra	
East	ICMR-Regional Medical Research Centre, Bhubaneswar (Tigria), Odisha	
Rajendra Institute of Medical Sciences, Ranchi, Jharkhand		
North-East	t Silchar Medical College & Hospital, Silchar, Assam	
South	Gandhi Medical College, Secunderabad, Telangana	



## 3. ICMR Centers for Clinical Trials (ICCT)

Zone	Institute	Lead Applicant
	Pandit Bhagwat Dayal Sharma Post Graduate Institute of Medical Sciences (PGIMS) Rohtak, Haryana	Dr. Savita Verma
North	Government Medical College and Hospital, Chandigarh	Dr. Deepak Chawla
	Dayanand Medical College and Hospital, Ludhiana, Punjab	Dr. Sandeep Kaushal
	Christian Medical College, Ludhiana, Punjab	Dr. M Joseph John
	All India Institute of Medical Sciences, Jodhpur, Rajasthan	Dr. Pankaj Bhardwaj
West	KEM Hospital & Research Centre, Pune, Maharashtra	Dr. Anand Kawade
vvest	Dr. D. Y. Patil Medical College, Hospital and Research Centre, Pune, Maharashtra	Dr. Srikanth Tripathy
	Datta Megha Medical College, Wardha, Maharashtra	Dr. Zahiruddin Quazi Syed
	SCB Medical College and Hospital, Cuttack, Odisha	Dr. Samita Mahapatra
East	IMS & SUM Hospital, Bhubaneswar, Odisha	Dr. Soumya Surath Panda
	ICMR- Rajendra Memorial Research Institute of Medical Sciences, Patna, Bihar	Dr Krishna Pandey
North-East	JN Medical College, Imphal, Manipur	Dr. H. Nirendrakumar Singh
Central	All India Institute of Medical Sciences, Bhopal, Madhya Pradesh	Dr. Rajnish Joshi
	Tirunelveli Medical College, Tirunelveli, Tamil Nadu	Dr. Shantararaman.K.
	Karnataka Institute of Medical Sciences, Hubli, Karnataka	Dr. Ram S. Kaulgud
	Pondicherry Institute of Medical Sciences, Puducherry	Dr. Anil J Purty
South	DM Wayanad Medical College, Wayanad, Kerala	Dr. Aneesh Basheer
	Narayana Medical College & Hospital, Nellore	Dr. Surya Prakash Rao
	Jawaharlal Nehru Medical College, KLE Academy of Higher Education and Research Belagavi, Karnataka	Dr Shivaprasad S Goudar
	SRM Medical College Hospital & Research Centre, Chennai, Tamil Nadu	Dr. Melvin George



## 4. Specialty Center for Clinical Trial (SCCT)

Specialty	Institute	Lead Applicant
Tuberculosis	ICMR-National Institute for Research in Tuberculosis (NIRT), Chennai, Tamil Nadu	Dr. C. Padmapriyadarsini
Cancer	Tata Memorial Centre, Mumbai, Maharashtra	Dr.Rajendra A Badwe
Neurology	National Institute of Mental Health and Neurosciences (NIMHANS), Bengaluru, Karnataka	Dr Sriganesh K
	Sree Chitra Tirunal Institute for Medical Sciences & Technology, Trivandrum	Dr. Jeemon Panniyammakal
Endocrinology	Diabetes Foundation, New Delhi	Dr. Anoop Misra
Laboratory	ICMR-National Institute of Virology, Pune, Maharashtra	Dr. Pragya D. Yadav

## 5. Knowledge Partners for Clinical Trials (KPCT)

Institute	Lead Applicant
The George Institute of Public Health, Hyderabad,	Prof. Vivekanand Jha
Telangana	
Centre for Chronic Disease Control (CCDC), New Delhi	Dr. Kavita Singh
Centre for Public Health Kinetics, New Delhi	Dr. Sunil Sazawal



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Carly Simon Singer, Author Dr Rajesh Powar Dept of Plastic Surgery K.L.E.S Hospital & Medical Research Centre Nehru Nagar <u>Belgaum 590 010</u> Karnataka

March 10, 2004

Dear Dr Powar

I refer to the Agreement No IN-S-5-1 signed between our two organizations for the extension of free cleft lip and palate surgeries to poor children.

As provided in Clause IV of the said Agreement, I am pleased to extend the validity of the same up to 31<sup>st</sup> December 2005 on the same terms.

Please sign the duplicate copy of this letter confirming your acceptance and return the same to me for our records.

I'd like to take this opportunity of placing on record our sincere appreciation of the good work done by you, your team and the management of KLES Hospital providing cleft reconstructive surgeries to poor children since the start of our 'partnership'. 'We regard it a privilege to be associated with a team like yours and look forward to working together with all of you – putting smiles on desperate faces and giving those unfortunate children a second chance at life.

Best regards

Yours sincerely,

Ahala Satish Kalra Regional Director – South Asia

The Smile Train - Headquarters 245 Fifth A enue, Suite 2201 New York, NY 10016 Tel: 212.689,9190 Fax: 212.649,9299 www.smiletrain.org

Smile Train China Building 15, Room 302 51 Shuicheng Nan Road Shanghai 201103 PRC Tel: 86.21.6219.6750 Fax: 86.21.6219.2642

Dr. RAJESH S. POWAR M.S., M.Ch., D.N.B, PROJECT DIRECTOR KLES SMILE TRAIN PROJECT K.L E.S. HOSPITAL & MRC, BELGAUM

> Smile Train India S 240 Panchsheel Park New Delhi 110 017 INDIA Tel: 91.11.2601.36.48 Fax: 91.11.2601.36.49



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Bette Midler Sinor Actor

Carly Simon Singer, Author Dr Rajesh Powar Project Director – Smile Train Cleft Project Dept of Plastic Surgery K.L.E.S Hospital & Medical Research Centre Nehru Nagar <u>Belgaum 590 010</u> Karnataka

December 5, 2005

Dear Dr Powar

I refer to the subsisting Agreement and the subsequent amendments thereto between our two organizations for the provision of free cleft lip and palate surgeries to poor children at your hospital.

As provided in Clause V of the original Agreement, we are pleased to extend the validity of the same up to 31<sup>st</sup> December 2007 on the terms as presently applicable.

This letter is being sent in triplicate; please sign all three copies confirming your acceptance and return *two* copies to me for our records.

I'd like to take this opportunity of placing on record our sincere appreciation of the good work done by you, your team and the management of K.L.E.S Hospital providing cleft reconstructive surgeries to poor children since the start of our 'partnership'.

We deem it a privilege to be associated with a team like yours and look forward to working together with all of you – putting smiles on desperate faces and giving those kids a second chance at life.

With all good wishes to you, your colleagues and your loved ones for the coming holiday season.

Best regards

Yours sincerely,

Satish Kalra Regional Director – South Asia

cc: Hana Fuchs

The Smile Train - Headquarters 245 Fifth Avenue, Suite 2201 New York, NY 10016 Tel: 212.689.9199 Fax: 212.689.9299 www.SmileTrain.org Smile Train China Building 2, Room 2C 889 Wuzhong Road Shanghai 201103 PRC Tel: 86.21.6401.8985 Fax: 86.21.6401.8984

Dr. RAJESH SPOWAR M.S., M.Ch., D.N.B., PROJECT DIRECTOR KLES SMILE TRAIN PROJECT K.L E.S. HOSPITAL & MRC, BELGAUM

> Smile Train India S 240 Panchsheel Park New Delhi 110 017 INDIA Tel: 91.11.2601.36.48 Fax: 91.11.2601.36.49

> > .



March 28, 2007

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Lily Tomlin Actor, Comedian

Alex Trebek Host of Jeopardy!

Donald Trump Entrepreneur

Bradley Whitford

The Smile Train Headquarters 245 Fith Avenue, Suite 2201 New York, NY 10016 Tel: 212.689,9199 Fax: 212.689,9299 www.smiletrain.org Dr. Rajesh Powar Project Director K.L.E.S. Hospital & Medical Research Centre Dept. of Plastic Surgery Nehru Nagar Belguam 590 010 Karnataka India

Dear Dr. Powar,

We refer to the existing Agreement and the subsequent amendments thereto between our two organizations for the provision of free cleft lip and palate surgeries to poor children at your hospital.

We wish to make the following additions to Clause II that spells out the 'Obligations of the Parties':

- 1. All cleft lip and palate surgeries and other related treatments provided to patients covered under this program shall be <u>totally</u> free, with no hidden costs.
- 2. Paying patients treated for cleft lip and palate surgeries and other related treatments will not be eligible for Smile Train support and records pertaining to those shall not be submitted.
- 3. No donation shall be solicited or accepted from or behalf of any patient treated under this program.

These additions shall form an integral part of the Agreement.

This letter is being sent in triplicate; please sign all three copies confirming your acceptance and return two copies to Satish Kalra, Regional Director-South Asia, for our records.

We greatly value our 'partnership', deem it a privilege to be associated with a team like yours, and look forward to working together with all of you – putting smiles on desperate children's faces and giving them a second chance at life.

Kind regards.

Yours sincerely,

DeLois H. Greenwood Vice President

Shanghai 201103 PRC

Tel: 86.21.6401.8985

Fax: 86.21.6401.8984

, The Smile Train China Building 2, Room 2C 889 Wuzhong Road The Smile Train India S 240 Panchsheel Park New Delhi 110017

New Delhi 110017 INDIA Tel: 91.11.2601.36.48 Fax: 91.11.2601.36.49 The Smile Train Africa P.O. Box 2168 Maragoli Avenue Central Nakuru KENYA Tel: 254.726260405

Dr. Rajesh Powar **Project Director** K.L.E.S. Hospital & Medical **Research** Centre

The Smile Train Brazil Rua Dr. Luis Capriglione 200 Ithanhangá 22641-050 Rio de Janeiro, RJ, BRAZIL Tel: 55.21.2492.3509 Fax: 55.21.24948472

The Smile Train Mexico Privada San Dieguito Nr. 8 Acapantzingo, Cuernavaca Morelos 62440 MEXICO Tel: 52.777.3141038

Satish Kalra Regional Director - South Asia



DIRECTORS

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PRESIDENT

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SUPPORTERS

Dr Rajesh Powar Dept of Plastic Surgery K.L.E.S Hospital & Medical Research Centre Nehru Nagar Belgaum 590 010 Karnataka, INDIA

December 27, 2008

### Dear Dr. Powar,

I refer to the subsisting Agreement and the subsequent amendments thereto between our two organizations for the provision of free cleft lip and palate surgeries to poor children at your hospital.

As provided in Clause IV of the original Agreement, we are pleased to extend the validity of the same up to 31<sup>st</sup> December 2010 on the terms as presently applicable.

This letter is being sent in triplicate; please sign all three copies confirming your acceptance and return two copies to me for our records.

I'd like to take this opportunity of placing on record our sincere appreciation of the good work done by you, your team and the management of K.L.E.S Hospital & Medical Research Centre for providing cleft reconstructive surgeries to poor children since the start of our 'partnership'.

We deem it a privilege to be associated with a team like yours and look forward to working together with all of you – putting smiles on desperate faces and giving those kids a second chance at life.

With all good wishes to you, your colleagues and your loved ones for the coming New Year.

Best regards

Yours sincerely,

Satish Kalra Regional Director – South Asia

cc: Hana Fuchs

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The Smile Train World Headquarters, 41 Madison Avenue, 28th Floor, New York, NY 10010 Tel: 1.212.689.9199 Fax: 1.212.689.9299 www.smiletrain.org The Smile Train UK, PO Box 583, Northampton, NN3 6UH Tel: 0870 127 6269 www.smiletrain.org.uk Registered Charity No. 1114748 Smile Train offices are also located in Brazil China India Indonesia Kenya Meyico Nigeria Philippines Thailand and Vietnam



Dr. Rajesh Powar KLES Dr.Prabhakar Kore Hospital & MRC Dept. of Plastic Surgery Nehru Nagar Belgaum 590010 Karnataka

December 17, 2012

Dear Dr Powar

I refer to the subsisting Agreement and the subsequent amendments thereto between our two organizations for the provision of free cleft lip and palate surgeries to poor children at your hospital.

As provided in Clause IV of the original Agreement, we are pleased to extend the validity of the same up to 31st December 2014 on the terms as presently applicable.

This letter is being sent in triplicate; please sign all three copies confirming your acceptance and return two copies to your region Program Director for records.

I'd like to take this opportunity of placing on record our sincere appreciation of the good work done by you, your team and the management of KLES Dr.Prabhakar Kore Hospital & MRC for providing cleft reconstructive surgeries to poor children since the start of our 'partnership'.

We deem it a privilege to be associated with a team like yours and look forward to working together with all of you – putting smiles on desperate faces and giving those kids a second chance at life.

With all good wishes to you, your colleagues and your loved ones for the coming New Year.

**Best regards** 

Yours sincerely,

Satish Kalra Regional Director – South Asia

cc: Robert Toth

. 11.01.2013

Dr. Rajesh S. Powar - Project Director KLES Smile Train Project KLES Dr. Prabhakar Kore Hospitar& MRC- Selgaum.

The Smile Train World Headquarters, 41 Madison Avenue, 28th Floor, New York, NY 10010 Tel: 1.212.689.9199 Fax: 1.212.689.9299 www.smiletrain.org The Smile Train UK, PO Box 583, Northampton, NN3 6UH Tel: 0870 127 6269 www.smiletrain.org.uk Registered Charity No. 1114748 Smile Train offices are also located in Brazil, China, India, Indonesia, Kenya, Mexico, Nigeria, Philippines, Thailand, and Vietnam.

### PRESIDENT

**Brian F. Mullaney** Co-Founder, President & Board Member

DIRECTORS

Charles B. Wang Co-Founder & Chairman The Smile Train

Mark E. Atkinson Creative Director Otto Studios

Robert T. Bell Executive Director Charles B. Wang Foundation

**Donald B. Murphy** Partner Brown Brothers Harriman & Company

Richard Price Managing Director\_ ING Clarion Partners

Susannah Schaefer New York Islanders

Robert K. Smits, Esq. Salans

Tamsen Ann Ziff Honorary Board Member The Smile Train SUPPORTERS

Candice Bergen

**Tom Brokaw** Former Anchor & Managing Editor, NBC Nightly News

Warren Buffett CEO Berkshire Hathaway

Walter Cronkite Former Managing Editor & Anchor CBS Evening News

**Dr. h.c. Walter Haefner** Chairman Careal Holding AG

Jane Kaczmarek Actor

Bette Midler Singer, Actor

Colin Powell Former U.S. Secretary of State

Carly Simon Singer, Author

Lily Tomlin Actor, Comedian

Alex Trebek Host of Jeopardy!

Donald Trump Entrepreneur

Bradley Whitford Actor Representative Office Smile Train Inc. S 240 Panchsheel Park New Delhi 110 017, India



".... one of the most productive charities -dollar for deed ---in the world." --- The New York Times

Dr. Rajesh Powar KLES Dr.Prabhakar Kore Hospital & MRC Dept. of Plastic Surgery Nehru Nagar Belgaum 590010 Karnataka

December 15, 2014

### Dear Dr Powar

I refer to the subsisting Agreement and the subsequent amendments thereto between our two organizations for the provision of free cleft lip and palate surgeries to poor children at your hospital.

As provided in Clause IV of the original Agreement, we are pleased to extend the validity of the same up to 31st December 2016 on the terms as presently applicable.

This letter is being sent in triplicate; please sign all three copies confirming your acceptance and return two copies to your region Program Director for records.

I'd like to take this opportunity of placing on record our sincere appreciation of the good work done by you, your team and the management of KLES Dr.Prabhakar Kore Hospital & MRC for providing cleft reconstructive surgeries to poor children since the start of our 'partnership'.

We deem it a privilege to be associated with a team like yours and look forward to working together with all of you – putting smiles on desperate faces and giving those kids a second chance at life.

With all good wishes to you, your colleagues and your loved ones for the coming New Year.

**Best regards** 

Yours sincerely,

Mamtaa Carrol Regional Director – South Asia

cc: Leela Imam cc: Mackinnon Engen



Certificate No. Certificate Issued Date Account Reference Unique Doc. Reference Purchased by Description of Document **Property Description** Consideration Price (Rs.)

### First Party

Dr.

Statutory Alert.

Second Party Stamp Duty Paid By Stamp Duty Amount(Rs.)



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  - (One Hundred And Fifty only)

# Please write or type below this line.

### Agreement

e Poust Di Pai This agreement ("Agreement") is made between Smile Train India, a not-for-profit company incorporated Frosunder Section 25 of the Companies Act, 1956, registered under Section 11(1) of the Foreign Contribution Regulation) Act, 2010 having its registered office at - Plot No.3, LSC Sector-C, Pocket 6/7, Vasant - Kunj New Delhi - 110070, hereinafter referred to as "Smile Train".

### and

Karnataka Lingayat Education Society, which owns and operates a Hospital in the name and style of KLES Prabhakar Kore Hospital & Medical Research Centre, Nehru Nagar, Pelagavi 590010, Karnataka, hereinafter referred to as "the Hospital ".





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Page 1 of 7

iamo Certificate should be verified at "www.shorestamp.com". Any discrepancy in the details on this Certificate and as

### RECITALS

- Smile Train is promoted by a global charity whose mission is to provide assistance and support for A required treatments for poor children born with cleft lip and palate around the world.
- The Hospital has the requisite equipment, infrastructure and suitably qualified and trained medical B staff capable and willing to provide, inter alia, free or subsidized medical treatment to poor and needy patients.
- While the Hospital is desirous of extending totally free cleft lip and palate surgeries to patients and C offer other related rehabilitative services free of cost, it does not have the financial resources to do SO.
- D The parties now desire to enter into a cooperative, joint effort (the "Program") through which the Hospital will extend totally free cleft reconstructive surgeries to poor patients who would not otherwise have been able to afford those and significantly expand its continuing educational programs in the field of reconstructive surgery for medical specialists through financial, technical and other support from Smile Train.

#### TERM AND EFFECTIVE DATE I.

- A Funding of the partnership shall begin on January 1, 2018 (the "Effective Date") and continue until December 31, 2019, unless expressly terminated as provided in the Termination Clause VII of this Agreement.
- Upon expiration of such period, this Agreement shall stand terminated unless Smile Train in its B sole discretion renews this Agreement.

#### **OBLIGATIONS OF THE PARTIES** II.

## A. THE HOSPITAL

The Hospital shall ensure that only qualified medical personnel perform or assist in Program 1. surgeries, all of whom shall be duly certified and in good standing with appropriate medical oversight authorities. Program surgeries and treatments shall be performed only in hospitals that have been explicitly approved by Smile Train, and that are permitted to operate in accordance with and in full compliance with the governing laws, rules and standards in India, and the terms of this Agreement.

In addition to meeting the requirements of Section II.A.1., prior to commencement of this Agreement, the Hospital will carry out a thorough internal medical audit of participating Hospital(s) to ensure compliance with Smile Train's Safety and Quality Protocol, as described C. Belonisa. at Attachment B (the "Protocol") and shall comply with the Protocol throughout the term of the Program. The Hospital acknowledges that (i) Smile Train has developed the Protocol for the express purpose of ensuring and maintaining high safety standards, quality improvement and quality control and (ii) the adoption and continued implementation of the Protocol by the Hospital is a condition to Smile Train's obligations hereunder. In the event of any conflict between the Protocol and applicable laws or medical standards in the Hospital's territory, the Hospital shall inform Smile Train and Smile Train shall have the right, in its sole discretion, to Medical Director & Chief terminate this Agreement and withdraw funding or to waive such conditions of the Protocol Medical Director & Onton as manife freessary to permit compliance with such applicable laws and/or medical standards KLES Dr. Prabhakar Koreas in the centre in the centre in the centre in the centre of the centre in the centre of the centre

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3. In the event of serious complications leading to irreversible, grievous harm or patient death (a "Sentinel Event" as defined in the Protocol), the Hospital will (i) immediately notify Smile Train of such Sentinel Event, and (ii) implement the review process set forth by Smile Train for Sentinel Event protocol. As part of the Protocol, the Hospital specifically undertakes to report all Sentinel Events within 24 hours of the event's occurrence, using Smile Train's "Sentinel Event Report Form" (Attachment C to this Agreement). The Hospital will report Board of Management any Sentinel Event to Smile Train, in the manner provided under the Protocol.

K.L.E. Society, BELAGAVI

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Page 2 of 7

- 4. The Hospital shall participate in Smile Train Express ("STX"), a free, global, cleft care database, by submitting the completed patient record information (Attachment D "Patient Medical Record"), and gathering patient consent forms, subject to restrictions imposed by and compliance with all applicable laws in the Hospital's territory regarding the treatment of medical information, including but not limited to, the Information Technology Act, 2000 Information Technology (Reasonable Security Practices and Procedures and Sensitive Personal Data or Information) Rules, 2011. Further, the Hospital hereby grants consent to Smile Train to use, disclose and transfer any information (including the Patient Medical Records and Sentinel Event Report Forms) submitted by the Hospital, to third parties, Smile Train affiliates, in accordance with the Agreement and the Protocol.
- 5. The Hospital shall upload only such Smile Train sponsored surgeries to STX as have been performed at its own hospital(s) or those that have been explicitly approved by Smile Train in writing as affiliates to the Hospital's hospital(s). The Hospital shall list the affiliated hospital(s) on the initial Smile Train application for approval. Any subsequent affiliated hospital(s) must be approved by Smile Train in writing before the surgery takes place. In the event that the affiliated Hospital is a separate legal entity, a separate agreement will be executed between such affiliated Hospital and Smile Train.
- 6. The Hospital shall extend totally free cleft lip and palate surgeries to all poor patients covered under this Program *with no hidden costs.* The Hospital also accepts that patients paying for cleft lip and palate surgeries will not be eligible for Smile Train support under this Program and records pertaining to those paying patients shall not be submitted to STX.
- 7. The Hospital shall not solicit or accept any payment or donation from or on behalf of any patient treated as part of the Program.
- 8. The Hospital shall not claim nor accept any support, partial or complete, from any source other than Smile Train for surgeries sponsored and paid for by Smile Train under this Agreement.
- 9. The Hospital shall maintain a separate account of all funds received from Smile Train under this Agreement and all uses of such funds.
- 10. Smile Train shall have the right to have the separate account and all of Hospital's accounts periodically audited by independent external auditors chosen by Smile Train and the Hospital grees to extend all cooperation for such audits.

KLES Smile Train policy on Smile Train Funded Multiple Interventions during one surgery is KLES Smile Train attached to this Agreement as Attachment E, and the Hospital shall abide by this policy.

- 12. The Hospital shall submit an online Payment Verification Form in the format provided from to time by Smile Train prior to the remittance of any financial support by Smile Train.
  - 13. The Hospital shall also comply with Smile Train's Child Protection Policy ("Policy"), by submitting the duly signed Child Protection Policy Declaration ("Declaration") at the time of execution of this Agreement. Both the Policy and Declaration are attached to this Agreement as Attachment F.

Aedical Director & Chief Executive & LES Dr. Prabhakar Kold. HPfie Hospital will not assign any part or all of this Agreement without Smile Train's prior LES Dr. Prabhakar Centre, Bwritten consent. Any attempt to assign in violation of this Section is void in each instance. Smile Train reserves the right to assign this Agreement or any of its rights or obligations under this Agreement without the Hospital's consent.

15. The Hospital understands and acknowledges that Smile Train in performing its obligations under this Agreement will partner with, employ or engage third parties or any entity from Smile Train's affiliates.

Board of Management K.L.E. Society, BELAGAVI

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Page 3 of 7

### B. SMILE TRAIN

- 1. Smile Train will contribute a mutually agreed amount as contribution (to be separately communicated) for each primary cleft lip repair, primary cleft palate repair and a few specified secondary surgical interventions ("Contribution") carried out by the Hospital. For the purpose of receiving this Contribution, the surgeries will be limited to:
  - i. patients over the age of 3 months for cleft lips and 6 months for cleft palates; and
  - ii. those within ASA Classes 1 and 2 only.
    - (for clarifications please refer Attachment B, the Protocol)
- 2. Smile Train reserves the right to amend the above criteria at any time at its sole discretion, without any notice and without assigning any reasons.
- 3. The Contribution per surgery envisaged above is neither a reimbursement nor a service fee. It is a donation intended to *partially* defray the costs of treatment, with the remainder borne by the Hospital. The amounts paid by Smile Train will be all-inclusive, and there shall be no additional reimbursement of any expenses unless agreed by Smile Train in advance, in writing.
- 4. Smile Train will remit the agreed funding on a monthly basis as set forth in the Program Summary attached hereto as Attachment A, based on the number of Patient Medical Records uploaded to the STX server in the prior month, subject to such Patient Medical Records being verified and found correct by Smile Train.
- 5. The Contribution by Smile Train under this Agreement shall be used solely for the purposes specified. Diversion of these funds for any other purpose without the prior written approval of Smile Train is expressly forbidden and shall be grounds for immediate termination of this Agreement. The Hospital shall indemnify Smile Train, its directors and officers with respect to any misuse of funds. Smile Train shall also have the right to stop the funding forthwith if directed by a lawfully established authority.

## III. REPRESENTATIONS OF THE PARTIES

- A. THE Hospital
  - 1. The Hospital is a running, well established medical facility, validly existing and in good standing under the laws of India and in the state where it operates and has the requisite rights and authority to carry on its activities as now being conducted and to execute, deliver and perform its obligations under this Agreement, and will ensure that the hospital(s) where surgeries take place under this Agreement have the licenses and meet the qualifications required by law in India for providing the medical services described herein and have licensed medical professionals with the skill, experience and appropriate medical facilities to provide safe and quality care. Hospital shall report any change to this status immediately to Smile Train.
  - 2. The execution, delivery and performance by the Hospital of this Agreement has been duly authorized by all required corporate action on the part of the Hospital. The obligations of the Hospital under this Agreement are valid, legal and binding obligations of the Hospital, enforceable against it in accordance with its terms.

Medical Director & Chief Stigation of the Hospital under this Agreement will violate, conflict with, result in KLES Dr. Prabhakar Kore bereach of, constitute a default under the governing documents of the Hospital, any material contract by which the Hospital is bound, or any statute, ordinance, judgment, order, decree, regulation or rule of any court, governmental or medical body affecting or relating to the Hospital.

4.

4. Except as otherwise provided in or contemplated by this Agreement, no consent of, waiver from, application or notice to any party is required in order for the Hospital to execute, deliver and perform this Agreement or to consummate the transactions contemplated hereby.

Board of Management K.L.E. Society, BELAGAVI

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5. Notwithstanding the generality of the foregoing, the Hospital represents that it is authorized to receive foreign contribution in accordance with applicable Indian laws and will ensure that the Contribution is utilized only for the purposes as provided under this Agreement and in accordance with applicable Indian laws.

### B. SMILE TRAIN

- 1. Smile Train is a not-for-profit company incorporated under Section 25 of the Companies Act, 1956, registered under Section 11(1) of the Foreign Contribution (Regulation) Act, 2010 vide Registration Number 231661597 having its registered office at Plot No.3, LSC Sector-C, Pocket 6/7, Vasant - Kunj New Delhi - 110070.
- Smile Train Inc., is a promoter and amongst the highest contributors of Smile Train, located 2. at 41 Madison Avenue, 28th floor, New York, NY 10010, USA and is set up and registered as a Section 501(c)(3) public charity as defined by Section 501(c)(3) of the Internal Revenue Code under Federal tax law of the United States of America.
- 3. All signatories to this Agreement confirm they have the necessary and valid authorities delegated to them to sign this Agreement.
- The execution, delivery and performance by Smile Train of this Agreement has been duly authorized by all required corporate action on the part of Smile Train. The obligations of Smile Train under this Agreement are valid, legal and binding obligations of Smile Train, enforceable against it in accordance with its terms, except as such enforceability may be subject to or limited by bankruptcy, insolvency, reorganization, moratorium, receivership and similar laws affecting creditors' rights generally and general principles of equity.
- Neither the execution and delivery by Smile Train of this Agreement, nor the performance of 5. any other obligation of Smile Train under this Agreement will violate, conflict with, result in the breach of, constitute a default under the governing documents of Smile Train, any material contract by which Smile Train is bound, or any statute, ordinance, judgment, order, decree, regulation or rule of any court or governmental body affecting or relating to Smile Train.
- 6. Except as otherwise provided in or contemplated by this Agreement, no consent of, waiver from, application or notice to any party is required in order for Smile Train to execute, deliver and perform this Agreement or to consummate the transactions contemplated hereby.

#### IV. **REPORTING, RENEWAL AND SUSPENSION**

AS At least 30 days prior to the end of the funding period (which would be the period between January To December 31 each year) ("Funding Period") the Hermitian in the period between January (annexed hereto as Attachment G or as may be updated from time to time and shared with the Hospital) highlighting the achievements of the achievem KLES Dr. Hospital) highlighting the achievements of the goals of this Program as set forth in Attachment A the progress of funding efforts.

At that time, Smile Train will determine whether funding will be renewed/extended. The decision B to renew funding will be at the sole discretion of Smile Train, and Smile Train will not be obliged Medical Director & Chief Exercitate conclusion of the Funding Period. to give any reasons should it decide not to renew the same. If Smile Train does not renew, funding

KLES Dr. Prabhakar-Kore Hospital & mile Train reserves the right to suspend this Agreement, wholly or in part, for any reason at any Medical Research Cent time during the subsistence of this Agreement, by providing written notice to the Hospital.

#### V. **PUBLIC RELATIONS**

Smile Train reserves the right to publicize the cooperative efforts between the parties hereto through the use of literature, photographs, video film production and other media. The Hospital permits and allows Smile Train to use any and all of its materials including its trademarks and any literature in relation to the matters that it works on with Smile Train under this Agreement. Smile Train will also issue press releases

SECRETARY **Board of Management** K.L.E. Society, BELAGAVI

Manch Page 5 of 7

and have the option to hold press conferences to announce the Program and its progress over the duration of the Funding Period. The Hospital agrees to be receptive in assisting Smile Train's efforts for publicity and/or additional fundraising. The Hospital acknowledges that the words "Smile Train", "Changing the World One Smile at a Time" and the logo of the smiling train are the exclusive intellectual property of Smile Train's affiliates. The Hospital shall immediately cease use if so instructed by Smile Train or its affiliates. In any and all publications and other public relations vehicles describing the Program, the parties hereto agree to receive prior approval from the other before using the other's name or intellectual property.

#### INDEMNIFICATION; LIABILITY VI.

The Hospital shall be solely responsible for any losses arising out of the Hospital's performance of this Agreement. The Hospital agrees to indemnify and hold harmless Smile Train, its affiliates, members, officers, directors, employees, agents and representatives (each such person, an "Indemnified Party") from and against any and all losses, claims, damages and liabilities, whether joint or several (the "Indemnifiable Losses"), related to, or arising out of, or in connection with, Hospital's actions in performing this Agreement, including but not limited to the performance of Program surgeries and related services and any advice, course of treatment, diagnosis or any other information, services or products that the Hospital or any director, officer, member, manager, employee, affiliate or associate of the Hospital provides to any patient.

#### TERMINATION VII.

- A. This Agreement may be terminated by either party without assigning any reasons, by giving 30 days' notice of its intention to do so, in writing to the other.
- B. Notwithstanding the above, Smile Train reserves the right to terminate this Agreement immediately at any time, at its sole discretion, in the event of fraud, violation of medical standards, misuse of funding of any kind, or misrepresentation, without any further liability under this Agreement.
- C. The Agreement shall stand terminated immediately if so directed by any statutory body or government department acting within the framework of the law.
- D. On the termination or expiry of the term of this Agreement, the Hospital shall return all records, publicity material, brochures, etc. pertaining to the Program, and furnish to Smile Train a full accounting of the disbursement of funds and expenditures incurred under the Program up to the effective date of termination within 30 days. As of the effective date of termination of the Agreement, for any reason whatsoever, Smile Train will not be required to provide any Contribution to the Hospital except for payments required to be made prior to the date of Rejest S. Remination, in accordance with the terms of this Agreement and the payment process prescribed

## Project Diredierein. S Smile Train Pro KLES STVILL MAMENDMENT Dr. Prat

- Belgui This Agreement may not be amended or modified except by an instrument in writing signed by, or on behalf of, each of the parties hereto.

#### NONDISCLOSURE IX.

The specific terms of this Agreement are privileged and confidential, and the parties hereto undertake not to divulge the same to any third party without the prior, express written permission of the other. The only exceptions to this will be their duly appointed legal attorneys and advisors, or duly empowered statutory Medical Direbodies and government agencies acting within the requirements of the law. The parties hereto also KLES Dr. Prachaertake to institute all reasonable steps to ensure that the confidentiality is maintained within their Medical Researchective organizations.

#### PRIOR AGREEMENT X.

This Agreement supersedes and replaces any and all previous agreements between the parties.

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**Board of Management** K.L.E. Society, BELAGAVI

## XI. OTHERS

- A. This Agreement is on a 'principal-to-principal' basis and it does not confer any right to either party to represent the other, act on its behalf as its agent or authorized representative, issue public statements, make commitments of any kind or claim any relationship beyond the one provided in the Agreement. The duties and responsibilities of the Hospital shall be rendered solely by the Hospital and not as an agent, representative, or employee of Smile Train. The Hospital shall have full control of all its acts, doings, and proceedings relating to or requisite in connection with the discharge of its duties and responsibilities under this Agreement.
- B. The Hospital warrants that funds will be used in compliance with all applicable Indian laws and United States anti-terrorist financing and sanction laws and regulations. In this regard, the Hospital agrees to take all reasonable steps to ensure that no person or entity expected to receive funds in connection with this agreement is named on the either List of Specially Designated Nationals and Blocked persons and entities maintained by the Office of Foreign Assets Control of the U.S. Department of the Treasury or list of banned terrorist organisations under Section 35 of Unlawful Activities (Prevention) Act, 1967, maintained by the Ministry of Home Affairs, Government of India or any such equivalent list.
- C. The Hospital shall ensure that it is at all times in compliance with all relevant laws of the land affecting the implementation of the terms of this Agreement.
- D. In the event of any litigation arising out of this Agreement, both parties accept and acknowledge that the laws of India shall apply, and the courts in New Delhi shall have exclusive jurisdiction.

**IN WITNESS WHEREOF**, the parties hereto have caused this Agreement to be executed by their duly authorized representatives as of the dates written below:

For and o Education S	on behalf of Karnataka Lingayat ociety	For and on behalf of Smile Train
	Signature	Manit' Cauch
Place	Name of Officer Board of Management K.L.E. Society, BELAGAVI	New Delhi L Mamta Carroll Director
Date	Title of Officer	Date
	behalf of KLES Prabhakar Kore Medical Research Centre	
Place	Signature Director & Chief Execu Medical Director & Chief Execu KLES Dr. Prabhakar Kore Hospi Messinal Research Centre, BELA Medical Director/Superintendent	
Date For and on	Title of Officer behalf of KLES Prabhakar Kore	
Hospital & Director	Medical Research Centre - Project	
Place	Dignature Ch S. Powar L Project Director Name of Officer Kore Hospital & MRC- Belgadan. Title of Officer	



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Chief Executive

Rajesh S. Power

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# Government of National Capital Territory of Delhi

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IN-DL73527689604590Q 08-Jan-2018 07:45 PM IMPACC (IV)/ dl959203/ DELHI/ DL-DLH SUBIN-DLDL95920350104161138842Q SMILE TRAIN INDIA Article 5 General Agreement Not Applicable 0 (Zero) SMILE TRAIN INDIA Not Applicable SMILE TRAIN INDIA 150 (One Hundred And Fifty only)

Board of Management K.L.E. Society, BELAGAVI

Please write or type below this line.....

# LICENCE AGREEMENT

This Licence Agreement (the "Agreement") is executed at New Delhi and is entered into as of the 1st day of January, 2018

K.L.E. Society, BEDAGAV Board of Management

KLES Dr. Prabhakar Kore Hospital & Medical Research Centre, BELAGAVI.

# BETWEEN

KAIN INC., having its registered office at 41 Madison Avenue, 28th Floor, New York, New York 10010, USA (hereinafter referred to as "Licensor") which expression shall, unless repugnant to the context or meaning thereof, include its successors and permitted assigns of the First Part;

AND

Hory Atert: KLES Dr Prabhakar Kore Hospital & Knj disarspaciety ut BELAGAMil Certificate and as reliable on the website to the definition of the certificate and as reliable on the website to the definition of the certificate and as reliable on the website to the definition of the certificate.

com Medical Director & Chief Executive 1/ cent

Board of Management

Karnataka Lingayat Education Society, having its registered office at Nehru Nagar, Belagavi 590010, Karnataka which owns and operates a Hospital in the name and style of KLES Prabhakar Kore Hospital & Medical Research Centre located at Nehru Nagar, Belagavi 590010, Karnataka (hereinafter referred to as "Licensee") of the Second Part;

### AND

Smile Train India, a company incorporated under the laws of India having its registered office at Plot No.3, LSC Sector-C, Pocket 6/7, Vasant - Kunj New Delhi - 110070 (hereinafter referred to as "Smile Train India") which expression shall, unless repugnant to the context or meaning thereof, include its successors and permitted assigns of the Third Part.

### **RECITALS:**

WHEREAS, Smile Train India, an affiliate of the Licensor, incorporated under Section 25 of the Companies Act, 1956, having its registered office at - Plot No.3, LSC Sector-C, Pocket 6/7, Vasant -Kunj New Delhi - 110070, has entered into an Agreement dated 1st January 2018 with the Licensee, whereby the Licensee is to extend totally free cleft reconstructive surgeries to poor patients who would not otherwise have been able to afford them, and significantly expand its continuing educational programs in the field of reconstructive surgery for medical specialists through financial, technical and other support from Smile Train India ("Program Agreement");

WHEREAS, pursuant to the Program Agreement, the Licensee desires to obtain the license for use of the Materials (as defined below), to effectively participate and comply with its obligations under the Program Agreement ("Licensee Works");

WHEREAS, Licensor is the owner of, inter alia, all right, title and interest in and to those certain materials, a copy of which is attached hereto as "Exhibit A" and made part hereof, (the "Materials"); and

WHEREAS, Licensor is willing to grant to the Licensee a non-exclusive limited licence to use the Materials for the purpose(s) described herein.

Dr. Rajes Rejector projector WaTHEREFORE, in consideration of the foregoing and of the covenants and agreements contained MES Sherein, and for other good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, the parties hereto do hereby agree as follows:

> LICENSE OF RIGHTS 1.

Licensor hereby non-exclusively licenses to Licensee the right to include the Materials Medical Director & Chief Execcommercial purposes only, worldwide during the Term; in the Licensee Works and all related promotional materials for non-profit and non-

Medical Director & Chief Exceeded & Hospital & KLES Dr. Prabhakar Kore Hospital & Nedical Research Centre, BEL Arcensee may use the Materials only in strict adherence with this Agreement and may

#### 2. **APPROVALS**

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Prior approval of the Licensor shall be required for any and all uses of the Materials who shall have the right to approve, in its own discretion, any and all uses of the Materials. Wherever in SECRETAR Board of Management Licensor's approval or consent is required, Licensee will request Licensor for K.L.E. Society, BELL the information in respect of which such approval or consent is required and provide Licensor with the information in respect of which such approval or consent is sought. Approval or disapproval of the Licensor shall be communicated within five (5) business days of receipt of such request from Licensee. Failure to respond within the stipulated period provided herein shall be deemed as denial by the Licensor of the approval or consent request. Manihi Powar

Rajash S. REPRESENTATIONS AND WARRANTIES BY LICENSOR

Board of Management K.L.E. Society, BELAGAVI

Licensor represents and warrants that: Medical Director & Chief Executive In-284658 Dy Prabhakar Kore Hospital & Medical Research Centre BELAGAVI

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- Licensor has the full right, power, legal capacity and authority to enter into this (a) Agreement and to carry out the terms hereof and to grant to Licensee the rights and privileges granted hereunder;
- There are no liens, claims, encumbrances, legal proceedings, restrictions, agreements (b) or understandings which will or which may conflict or interfere with, limit, or are inconsistent with or otherwise affect any of the provisions of this Agreement or the enjoyment by Licensee of any right granted to it hereunder; and
- Licensor owns or controls without any limitations, restrictions or encumbrances, all (c) rights granted to Licensee hereunder and Licensor has obtained all necessary licenses and permissions required for the manufacturing, distribution, exhibition, advertising, exploitation and otherwise of the assets worldwide, as may be required for the full and unlimited exercise and enjoyment by Licensee of all of the rights herein granted to it.

### REPRESENTATIONS AND WARRANTIES BY LICENSEE 4.

Licensee represents and warrants to the Licensor as follows:

- Licensee, and each of Licensee's shareholders, officers, employees, representatives and (a) other persons acting on its behalf, has and will continue to have all necessary licenses, registrations and qualifications necessary or appropriate to enable Licensee to perform its services as described herein and Licensee shall perform its services in full compliance with all applicable laws, rules and regulations;
- Licensee has the full right, power, legal capacity and authority to enter into this (b) Agreement and to carry out the terms hereof and to exercise and fulfill the rights granted by Licensor to Licensee hereunder;

Project Drain Project and complete in all respects and shall not contain any misstatement of n MLES Smile Train Project information nor any intentional or negligent omission of any material fact; and the use of the Materials by Licensee in the train of the violate of the Materials by Licensee in the train of the violate of the Materials by Licensee in the train of the violate of the Materials by Licensee in the train of the violate of the Materials by Licensee in the train of the violate of the Materials by Licensee in the train of the violate of the Materials by Licensee in the train of the violate of the Materials by Licensee in the train of the violate of the Materials by Licensee in the train of the violate of the Materials by Licensee in the train of the violate of the Materials by Licensee in the train of the violate of the Materials by Licensee in the train of the violate of the Materials by Licensee in the train of the violate of the Materials by Licensee in the train of the violate of the Materials by Licensee in the train of the violate of the Materials by Licensee in the train of the train of the violate of the Materials by Licensee in the train of the violate of the Materials by Licensee in the train of the all information given or to be given to the Licensor by Licensee is and shall be accurate and complete in all respects and shall not contain any misstatement of material

the use of the Materials by Licensee in the Licensee Works shall not infringe upon or violate the rights of any third party.

The foregoing shall survive the termination of this Agreement for any reason.

# INDEMNITY

Rajesh S. Pd(e)ar

Medical Director & Chief Executive Medical Director & Chief Executive Medical Director & Chief Executive Specification of Licensee's performance KLES Dr. Prabhakabi fins Agreement. The Licensee agrees to indemnify and hold harmless Licensor, its affiliates, Medical Research Control officers, directors, employees, agents and representatives against all losses and damages, including reasonable attorney's fees, but excluding any lost profits, arising out of any action or proceeding by third parties resulting from any breach by the Licensee of any of the provisions hereof, or the breach of any of the warranties and representations set forth herein. Prompt written notice will be given to Licensor of any action or proceeding to which the foregoing indemnity relates.

# TERM AND TERMINATION

Board of Management K.L.E. Society, BELAGAVI

This Agreement shall become effective on the date of execution of this Agreement unless terminated in accordance with Sections 6 (b), (c) or (d) below (the "Term").

(b) usa S. Powar MLES Smile Train (C) RS Dr. Prabhakar Y MRC- Belt

This Agreement may be terminated by either party without assigning any reasons, by giving 30 days' notice of its intention to do so, in writing to the other.

\* Notwithstanding the above, Licensor reserves the right to terminate this Agreement immediately at any time, at its sole discretion, in the event the Licensee commits fraud, misrepresentation, or a substantial breach of any of the provisions contained herein or Director & Chief Executive 3 St SECRETARY

Board of Management

.... DEI ACAVI

Medica Director & Chief Executive In-284698 ES On Frabhakar Kore Hospital & with respect to its obligations to be performed without prejudice to any and all rights at law which Licensor may have.

· (d) This Agreement shall terminate immediately upon termination of the Program Agreement, in terms thereof.

#### 7. ASSIGNMENT

Licensee may not assign this Agreement, by operation of law or otherwise, without the prior written consent of Licensor, which consent may be withheld at Licensor's sole discretion.

#### 8. **RELATIONSHIP OF PARTIES**

The relationship between the parties hereto is that of licensor and licensee. Neither party hereto is an agent, partner or employee of the other and neither party has any right or any other authority to enter into any contract or undertaking in the name of or for the account of the other or to either assume or create any obligation of any kind, express or implied, on behalf of the other, nor will the acts or omissions of either create any liability for the other. This Agreement shall in no way constitute or give rise to a partnership or joint venture between the parties.

#### 9. NOTICES

(a)

All notices or other communications required or permitted to be delivered hereunder shall be in writing and (i) delivered personally, (ii) sent by registered or certified mail (return receipt requested), postage prepaid, (iii) sent by recognized national or international air courier, or (iv) Rajesh S. Powerla facsimile with confirmation of receipt, addressed to the parties at the addresses first written KLES Smile Train Project Director nerainaboye. Any such notice KLES Smile Train Project as of the date received. Rajesh Director hereinabove. Any such notice or other communication shall be deemed to have been given or

This Agreement sets forth the entire agreement and understanding between the parties hereto with respect to the subject matter hereof and supersedes all prior discussions, representations, understandings and agreements, whether written or oral, between the parties with respect to the subject matter hereof. This Agreement may be altered, modified or amended only by a written document signed by the parties hereto.

Medical Director & Chief Executive The rights and remedies provided herein shall be cumulative and not exclusive of any KLES Dr. Prabhakar Kore Hospital vights or remedies provided at law or in equity. Failure or delay on the part of either party to exercise any right remedy power and the part of either party to exercise any right, remedy, power or privilege provided for herein or by statute, by law, in equity or otherwise shall not operate as a waiver thereof, nor shall any single or partial exercise of any such right, remedy, power or privilege preclude any other or further exercise thereof or the exercise of any other right, remedy, power or privilege.

Board of Management K.L.E. Society, BELAGAVI

Dr. Rajash S. le) - Project Dire KLES Smile Train GLES Dr. Prabhakar MRC. Better

This Agreement shall be binding upon and shall ensure to the benefit of Licensor, its successors and assigns, and Licensee, its successors and permitted assigns.

Notwithstanding anything to the contrary contained herein, in the event that any clause, term or provision of this Agreement which is not material is determined by any court or administrative agency of competent jurisdiction to be illegal, unenforceable or in conflict with any applicable law, this Agreement shall continue in full force and effect as if the offending clause, term and provision hereof were no longer incorporated herein.

The parties agree that the failure or delay of any party at any time to require performance of any provision under this Agreement shall not affect the right of such party to require the full performance thereof and that a waiver by any party, which shall be in writing and signed by the party against whom such waiver is sought to be enforced, of a breach of any provision of this Agreement shall not be held to be a waiver of any further or similar breach or as nullifying the effectiveness of such provision.

and

SECRETARY

Board of Management

Medical Director & Chief Executive In-184698Dr. Phathakar Kore Hospital Medical Research Centre, BELAU

- (f) This Agreement will be governed by the laws of India and the courts at New Delhi will have exclusive jurisdiction in connection with any matters arising out of this Agreement.
- (g) This Agreement may be executed in several counterparts and via facsimile, each of which shall be deemed an original and all of which shall constitute one and the same instrument.

IN WITNESS WHEREOF, the parties hereto have duly executed this Agreement as of the date and year first written above.

For and on behalf of Smile Train Inc.

By: Date:

# For and on behalf of Karnataka Lingayat Education Society

By: SECRETARY Date: Board of Management K.L.E. Society, BELAGAVI

Board of Management K.L.E. Society, BELAGAVI

For and on behalf of KLES Prabhakar Kore Hospital & Medical Research Centre

By: ief Executive Medical Direct KLES Dr. Prabhakar Kore Hospital & Date: Medical Research Centre, BELAGAVI.

Medical Director & Chief Executive KLES Dr. Prabhakar Kore Hospital &

Medical Research Centre, BELAGAVI.

For and on behalf of Prabhakar Kore Hospital & Medical Research Centre - Project Director

Q1. 122 TORECEL MEES Smile Train Project

Date: Dr. Probakar Kore Hospital &

andl

For and on behalf of Smile Train India

Date:

By:

OL Refer S. Powar - Project Director KLES Smile Train Project RI 58 Dr. Prabhakar Koro Hospital & MRC- Belgadm.

# PARTNERSHIP AGREEMENT

This agreement is by and between Smile Train, Inc., a New York based not-for-profit corporation represented by its India office located at S-240 Panchsheel Park, New Delhi 110 017 ("Smile Train") and the KLES Hospital & Medical Research Centre, Nehru Nagar, Belgaum 590 010 in the state of Karnataka ("KLESH").

# RECITALS

A. Smile Train is a non-profit charitable organization whose mission is to provide assistance to children born with cleft lip and palate around the world.

B. KLESH is a multi specialty hospital run by the Karnatak Lingayat Education Society, where some cleft reconstructive surgeries are already being carried out within the Department of Plastic Surgery.

C. The parties, therefore, desire to enter into a cooperative, joint effort (the "Partnership") through which KLESH will, in a phased manner, augment its resources to substantially increase the number of cleft reconstruction surgeries, through financial, technical and other support from Smile Train.

D. The purpose and details of the Partnership are described in Attachment A.

# I. TERM AND EFFECTIVE DATE

Funding of the Partnership shall begin on April 1, 2001 (the "Effective Date") and shall continue for three years until March 31, 2004 (the "Funding Period"), unless extended or terminated as provided in the Renewal or Termination sections below.

# II. OBLIGATIONS OF THE PARTIES

# A. KLESH

1. KLESH shall make a full and thorough review of available resources in its existing Department of Plastic Surgery, identify those that need to be added to meet the requirements of this Agreement, and draw up an appropriate action plan for putting them in place in accordance with KLESH's personnel practices, procedures and standards.

2. KLESH shall provide Smile Train with complete patient information for each surgical case (Attachment E) conducted through funding of the Partnership. KLESH shall preferably provide these completed records to Smile Train on a continuous basis but at no time later than 10 days after the end of each calendar month. Smile Train reserves the right to hold payment until receipt of this information.

3. Immediately following the Effective Date, KLESH will implement credentialing and monitoring procedures in accordance with Smile Train's Safety and Quality Improvement Protocol (the "Protocol"), as described in Attachment E. KLESH acknowledges that (i) Smile Train has developed the Protocol for the express purpose of ensuring and maintaining high safety standards, quality improvement and quality control and (ii) the adoption and continued implementation of the Protocol by KLESH is a condition to Smile Train's obligations hereunder. In the event that any patient is harmed in any manner that is not in the ordinary course of cleft operations (Sentinel Event), KLESH will (i) immediately notify Smile Train of such event, and (ii) implement the review process set forth by Smile Train for Sentinel Event protocol. As part of the Protocol, KLESH specifically undertakes to report all sentinel events within 24 hours of the event's occurrence, using Smile Train's Reporting Form (Attachment E). KLESH will report these events to Smile Train's main office in New York and its India office in New Delhi.

4. To reach the mutually agreed goals for this Partnership, KLESH undertakes, *inter alia* to

a) Set up a separate Speech Therapy Department and recruit a full-time, appropriately qualified and trained Speech Therapist within 6 months of the commencement of this Agreement.

- b) Add at least one more fully qualified and trained Plastic Surgeon by December 31, 2001.
- c) Provide the KLES Smile Train Cleft Centre a suitably furnished, independent office of at least 400 sq. ft, one full time clerk / secretary, a dedicated PC, a digital camera & a separate internet connection.

5. On a semi-annual basis, KLESH will meet with representatives of Smile Train to evaluate the progress of the Partnership. At the time of each meeting, KLESH will provide Smile Train with a narrative report, documenting the progress of the Partnership. Included in this report should be a monthly breakdown of the number of surgeries performed split up by the categories agreed. Please see Attachment F for report guidelines. The parties will agree upon the date and time of each of the meetings.

6. KLESH agrees to participate in Smile Train Express (A free, global, cleft care database) by submitting the completed patient record information, which includes the patient consent form (Attachment E).

7. At the conclusion of each year (March 31, 2002, March 31, 2003 and March 31, 2004), KLESH will submit a final written report that includes progress of the Partnership to date and outlining the specific programs planned for the coming year.

8. At the end of every year, a duly authorized representative of KLESH shall submit to Smile Train an affidavit (as per Attachment C) confirming the use of the Funded Amount.

# B. SMILE TRAIN

1. Smile Train will contribute a *maximum* Financial Support of Rs. 12,400,000 or US\$ 270,000 (Indian Rupees Twelve Million Four Hundred Thousand or US\$ Two Hundred and Seventy Thousand), whichever is *lower*, hereinafter referred to as the "Funded Amount", during the entire Funding Period, with monthly disbursements based on the actual number and categories of cleft reconstruction surgeries performed, calculated on the basis of the formula laid down in Attachment D (the "Funded Amount").

2. The Funded Amount will be all-inclusive, and there shall be no additional reimbursement of any expenses, unless explicitly agreed by Smile Train in advance, in writing.

3. To enable KLESH to obtain some equipment needed for the effective management and control of the program envisaged under this Agreement, Smile Train will advance a sum of Rs 300,000 within 15 days of the signing of this Agreement. This advance will be free of interest and shall be adjusted in ten equal installments of Rs 30,000 each from the monthly payments due to KLESH starting with the payment for the month of September 2001. In the event of this Agreement being prematurely terminated for any reason, KLESH shall return the outstanding balance to Smile Train at the time of such termination.

# III. REPRESENTATIONS OF THE PARTIES

# A. KLESH

KLESH is part of the Karnatak Lingayat Education Society, Belgaum, a Registered Trust set up and registered under Act XXI of 1860 & the Bombay Public Trust Act of 1950, validly existing and in good standing under the laws of India and has the requisite authority to carry on its activities as now being conducted. Any change to this status shall be reported immediately to Smile Train.

# B. SMILE TRAIN

Smile Train is a not-for-profit corporation, as defined by Subparagraph (a)(5) of Section 102 of the New York Not-for-Profit Corporation Law, duly organized, validly existing and in good standing under the laws of New York and has the requisite corporate authority to carry on its business as now being conducted.

# IV. RENEWAL

A. At the review at the end of the first funding year (April 1, 2001 – March 31, 2002) representatives from KLESH and Smile Train will meet to assess the progress of funding efforts. At this time, Smile Train will determine whether funding will be renewed/extended for the next two-year period (April 1, 2002 – March 31, 2004). The decision to renew funding will be at the sole discretion of Smile Train, and it will not be

obliged to give any reasons should it decide not to renew the same. If Smile Train does not renew, funding will cease at the conclusion of the initial one-year period, ending on March 31, 2002.

# V. PUBLIC RELATIONS

Smile Train reserves the right to publicize the cooperative efforts between the two parties through the use of literature, photographs, video film production and other media. Smile Train will also issue press releases and have the option to hold press conferences to announce the Partnership and its progress over the duration of the funding period. Both parties agree to be receptive to assisting in each other's efforts for publicity and/or additional fundraising. KLESH acknowledges that the words "The Smile Train," "Changing the World One Smile at a Time," and the logo of the smiling train are the exclusive intellectual property of Smile Train. KLESH shall forthwith cease to use them in any manner, if so instructed by Smile Train. In any and all publications and other public relations vehicles describing the Partnership, both parties agree to receive prior approval from the other before using the name of that party or logo.

# VI. INDEMNIFICATION

A. KLESH agrees to indemnify and hold harmless Smile Train, its affiliates, members, officers, directors, employees, agents and representatives (each such person, an "Indemnified Party") from and against any and all losses, claims, damages and liabilities, whether joint or several (the "Indemnifiable Losses"), related to, arising out of, or in connection with, the actions contemplated by this Agreement or the performance by Smile Train of its obligations contemplated by, this Agreement.

# VII. TERMINATION

A. This agreement may be terminated by either party without assigning any reasons, by giving 90 days notice of its intention to do so, in writing to the other.

B. Notwithstanding the above, Smile Train reserves the right to terminate this agreement forthwith, at its sole discretion, in the event of fraud, gross violation of medical standards or willful and malafide misrepresentation of facts.

C. The agreement shall also stand terminated forthwith if so directed by any statutory body or government department acting within the framework of the law.

D. On the termination of this agreement, KLESH shall return all records, publicity material, brochures, etc. pertaining to the Project, and furnish to Smile Train a full accounting of the disbursement of funds and expenditures incurred under the grant up to the effective date of termination.

# VIII. AMENDMENT

This Agreement may not be amended or modified except by an instrument in writing signed by, for and on behalf of, KLESH and Smile Train.

# IX. NONDISCLOSURE

The contents of this agreement are privileged and confidential, and both parties undertake not to divulge the same to any third party without the prior, express written permission of the other. The only exceptions to this will be their duly appointed legal attorneys and advisors, or duly empowered statutory bodies and government agencies acting within the requirements of the law. Both parties also undertake to institute all reasonable steps to ensure that the confidentiality is maintained within their respective organizations.

# X. OTHERS

A. This agreement is on a 'principal-to-principal' basis and it does not confer any right to either party to represent the other, act on its behalf as its agent or authorized representative, issue public statements, make commitments of any kind or claim any relationship beyond the one provided in the agreement. It is explicitly acknowledged by both parties that the term 'partnership' in the context of this Agreement does not constitute a partnership firm.

B. In the event of any litigation arising out of this agreement, both parties accept and acknowledge that the laws of India shall apply, and the courts in New Delhi shall have the exclusive jurisdiction.

IN WITNESS WHEREOF, the Parties have caused this Agreement to be executed by their duly authorized representatives as of the dates written below:

For and on behalf of Smile Train			For and on behalf of KLESH		
Date	Signature	Designation	Date	Signature	Designation
)	J. Baxter Urist	President	14 March, 2001	Prabhakar Kore,	Chairman, KLE Society
A	NA/		14 March, 2001	ColA.K.Singh	Medical Director & CEO
0	DeLois H. Greenwood	Vice President for Strategic Projects	14 March, 2001	V.S.Sadhunavar	Director, KLE Society
Funding Sa computing through da		objective will be p from with eleft lip within KLESH,	14 March, 2001	Rajesh Powar	Consultant & H.O.D. of Plastic Surgery,
14 March, 2001	Anaha Satish Kalra	Managing Director – India	14 March, 2001	Pradip R. Shetye	Associate Prof. of Orthodontics KLES Dental College

### Attachments:

Project Summary (A) Payment Schedule (B) Affidavit (C) Schedule of Funding Support by Category of Surgery (D) Smile Train Express Package (E)

- · Safety and Quality Improvement Protocol
- Patient Record
- Patient Consent Form
- Reporting Form
- Semi-Annual Report Guidelines (F)

# ATTACHMENT A: PROJECT SUMMARY

# Title of Project: Smile Train Cleft Program at KLESH

# **Project Director: Dr Rajesh Powar**

# **Project Description/Objectives:**

It is estimated that approximately 35,000 children are born with this birth effect in India each year. A large majority of these (estimated at 80%) grow into adulthood without receiving any reconstructive surgery for want of money. The current rate of surgeries performed at KLESH is about 100 per year. The goal of the Smile Train Cleft Program at KLESH is to significantly step up the number of cleft reconstructive surgeries and provide a full and comprehensive rehabilitation package of services to as many affected children as possible.

Funding support to achieve this objective will be provided by Smile train as part of its global commitment to helping children born with cleft lips and cleft palates. Surgeries will be conducted through the Cleft Palate Center within KLESH.

It is estimated that as a result of this funding, at least 300 surgeries will be performed in Year 1, at least 500 in Year 2 and at least 750 surgeries in Year 3. Therefore, in total, at least 1,550 children will receive cleft lip and palate surgeries over the next three years. The financial support for surgeries is further outlined in Attachment D. If it is anticipated that the actual number of cases is likely to exceed these projections, a prior written request for additional funding based on the same formula and on the same terms will be favorably considered, but approval shall be at the sole discretion of Smile Train.

Initialize for Smile Train: Initialize for KLESH: Beret. U J. Baxter Urist Prabhakar Kore Date : Date: 14 March, 2001 Col..A.K.Singh Date: 14 March, 2001 DeLois H. Greenwood Date: V.S.Sadhunavar Date: 14 March, 2001 W---Rajesh Powar Satish Kalra Date: 14 March, 2001 Date: 14 March, 2001 -Pradip R. Shetye Date: 14 March, 2001

# ATTACHMENT B: PAYMENT SCHEDULE

Financial Officer:	Contract No: IN/S/5-1		
Funding Period	te stion Describen in Section 309(a)(1), (3) a. (3) of		
Start Date: April 1, 2001	End Date: March 31, 2004		
Cheques to be made payable to: KLESH & M	nRC a/c Smile Train Project		
If applicable, please provide the following for wire transfers:	Account Name:		
Name of Bank:	KLESH AMRE alc Smile Train Project		
CANARA BANK	Account No.:		
Address: KLESH EXTN., COUNTER, NEHRU NAGAR, BELGAUM-16	1621		
ABA Routing Number/Swift Code:			
Pourmont Schodule:	a purposes, or to a government instrumentality.		
Payment Schedule:			
Within 10 working days of the receipt of fully comp	elete Quarterly Reports from KLESH, due on the last da		
of October, January, April and July of every year du	ring the funding period.		
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J. Baxter Urist Date : Date : DeLois H. Greenwood Date: Maha Satish Kalra	Date: 14 March, 2001 ColA.K.Singh Date: 14 March, 2001 V.S.Sadhunavar Date: 14 March, 2001 Rajesh Powar		
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J. Baxter Urist Date : Date : DeLois H. Greenwood Date: Satish Kalra Date: 14 March, 2001	Date: 14 March, 2001 ColA.K.Singh Date: 14 March, 2001 V.S.Sadhunavar Date: 14 March, 2001 Rajesh Powar		
J. Baxter Urist Date : Date : DeLois H. Greenwood Date: Maha Satish Kalra	Date: 14 March, 2001 ColA.K.Singh Date: 14 March, 2001 V.S.Sadhunavar Date: 14 March, 2001 Rajesh Powar		
J. Baxter Urist Date : Date : DeLois H. Greenwood Date: Satish Kalra Date: 14 March, 2001	Date: 14 March, 2001 ColA.K.Singh Date: 14 March, 2001 V.S.Sadhunavar Date: 14 March, 2001 Rajesh Powar Date: 14 March, 2001 ColA.K.Singh Date: 14 March, 2001 ColA.K.Singh ColA.K.Singh Date: 14 March, 2001 ColA.K.Singh ColA.K.Singh Date: 14 March, 2001 ColA.K.Singh ColA.K.Singh Date: 14 March, 2001 ColA.K.Singh Date: 14 March, 2001 ColA.K.Singh Date: 14 March, 2001 ColA.K.Singh Date: 14 March, 2001 ColA.K.Singh ColA.K.Singh Date: 14 March, 2001 ColA.K.Singh ColA.K.Singh Date: 14 March, 2001 ColA.K.Singh ColA.K.Singh ColA.K.Singh Date: 14 March, 2001 ColA.K.Singh ColA.K.Sin		
J. Baxter Urist Date : Date : DeLois H. Greenwood Date: Satish Kalra Date: 14 March, 2001	Date: 14 March, 2001 ColA.K.Singh Date: 14 March, 2001 V.S.Sadhunavar Date: 14 March, 2001 Rajesh Powar		

# **ATTACHMENT C: AFFIDAVIT**

# Affidavit of Foreign Entity to Qualify as Organization Described in Section 509(a)(1), (2) or (3) or Section 4942(j)(3) of Internal Revenue Code

I am the \_\_\_\_\_\_ [Title] of Grantee. The Grantee was created and is operated exclusively for charitable purposes. The laws and customs applicable to Grantee do not permit any of its income or assets to be distributed to, or applied for the benefit of, a private person or non-charitable organization other than pursuant to the conduct of Grantee's charitable activities, or as payment of reasonable compensation for services rendered or as payment representing the fair market value of property which Grantee has purchased.

Grantee has no shareholders or members who have a proprietary interest in the income or assets of KLESH. In the event that Grantee were to be liquidated or dissolved, under the laws and customs applicable, or under the governing instruments, all of its assets would be distributed to another not-for-profit organization for charitable, religious, scientific, literary, or educational purposes, or to a government instrumentality.

The laws and customs applicable to Grantee do not permit KLESH, other than as an insubstantial part of its activities:

- (a) to engage in activities that are not for religious, charitable, scientific, literary or educational purposes; or
- (b) to attempt to influence legislation, by propaganda or otherwise.

The laws and customs applicable to Grantee do not permit Grantee directly or indirectly to participate or intervene in any political campaign on behalf of, or in opposition to, any candidate for public office. Grantee is not controlled by or operated in connection with any other organization.

(9) Copies of the charter, bylaws and other documents pursuant to which Grantee is governed are attached hereto as <u>Exhibit A</u>.

The undersigned has executed this affidavit as of	,,	, 2000.
	Col. A.K.Singh.	[Organization]
Deloris E. Greenwood	Ву:	[Signature]
	Name:	Marine -
	Title:	
Seal of the organization		

# ATTACHMENT D: SCHEDULE OF FUNDING SUPPORT BY CATEGORY OF INTERVENTION

# FINANCIAL SUPPORT STRUCTURE:

Type of Intervention	Financial Support per Intervention (in Rupees)	Financial Support per Intervention (in US \$*)	Inter	Number of ventions like be funded	
	1		Year 1	Year 2	Year 3
Primary Lip Repair or Nose Revision with or without anterior palate	n- 7,500	163	150	250	375
Primary Cleft Palate Repair	9,000	196	120	200	300
Secondary Rhinoplasty	6,500	141	15	25	40
Fistula Repair	6,000	130	5	10	15
Alveolar Bone Graft	7,000	152	5	5	10
'Whole-in-one'	12,000	261	• 5	10	10

\* The figure is based on the approx. exchange rate prevailing at the time of signing this agreement; it is only an indicative figure, and the actual financial support will be computed on the basis of the figures in Indian Rupees

**Initialize for KLESH: Initialize for Smile Train:** 10 to UN Prabhakar Kore J. Baxter Urist Date: 14 March, 2001 Date : Col..A.K.Singh Date: 14 March, 2001 DeLois H. Greenwood Date: V.S.Sadhunavar Date: 14 March, 2001 Satish Kalra Rajesh Powar Date: 14 March, 2001 Date: 14 March, 2001 ..... Pradip R. Shetye Date: 14 March, 2001



# INDIA NON JUDICIAL



# Government of National Capital Territory of Delhi

# e-Stamp

Certificate No. Certificate Issued Date Account Reference Unique Doc. Reference Purchased by Description of Document Property Description Consideration Price (Rs.) First Party

Second Party Stamp Duty Paid By Stamp Duty Amount(Rs.)

# IN-DL43293428071778S

- 21-May-2020 01:11 PM
- IMPACC (IV)/ dl870703/ DELHI/ DL-DLH
- SUBIN-DLDL87070395300995530589S
- SMILE TRAIN INDIA
- Article 5 General Agreement
- Not Applicable
- 0 (Zero)
- SMILE TRAIN INDIA
- Not Applicable
- SMILE TRAIN INDIA
  - 150 (One Hundred And Fifty only)



B

# ...Please write or type below this line.....

# Grant Agreement

This grant agreement ("Agreement") is made between Smile Train India, a not-for-profit company incorporated under the laws of India, having its registered office at Plot No.3, LSC Sector-C, Pocket 6/7, Vasant - Kunj New Delhi – 110070 (hereinafter referred to as "Smile Train", which expression shall unless repugnant to the context or meaning thereof mean and include its successors and permitted assigns); and Karnataka Lingayat Education Society ("Organization") which owns and operates a hospital in the name and style of KLES Prabhakar Kore Hospital & Medical Research Centre located at Nehru Nagar, Belagavi 590010, Karnataka (collectively hereinafter referred to as "the Hospital", which expression shall unless repugnant to the context or meaning thereof mean and include its successors and permitted assigns).

Smile Train and the Hospital are hereinafter individually referred to as "Party" and collectively referred to as "Parties".

Medical Director & Chief Executive lanagement Statutory Alert, KLES Dr. Prabhakar Kore Hospital & milicity of this Stamp Certificate should be verified at www.sho on the website renders it invalid. ailable on th The onus of checking the legitimacy is on the users of the certificate.

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Dr. Retain & Per Project Director

# Grant Agreement

This grant agreement ("Agreement") is made between Smile Train India, a not-for-profit company incorporated under the laws of India, having its registered office at Plot No.3, LSC Sector-C, Pocket 6/7, Vasant - Kunj New Delhi – 110070 (hereinafter referred to as "Smile Train", which expression shall unless repugnant to the context or meaning thereof mean and include its successors and permitted assigns); and Karnataka Lingayat Education Society ("Organization") which owns and operates a hospital in the name and style of KLES Prabhakar Kore Hospital & Medical Research Centre located at Nehru Nagar, Belagavi 590010, Karnataka (collectively hereinafter referred to as "the Hospital", which expression shall unless repugnant to the context or meaning thereof mean and include its successors and permitted assigns).

Smile Train and the Hospital are hereinafter individually referred to as "Party" and collectively referred to as "Partles".

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Board of Management K.L.E. Society, BELAGAVI

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Medical Difector & Chief Executive KLES Dr. Prabhakar Kore Hospital & Medical Research Centre, BELAGAVI

### RECITALS

- Smile Train is a charity whose mission is to provide assistance and support for treatments A required by underprivileged children born with cleft lips and palates.
- The Hospital has the requisite equipment, infrastructure and suitably qualified and trained В medical staff capable of providing medical treatment for cleft lips and palates.
- С The Parties now desire to enter into a cooperative, joint effort initiative through which the Hospital will undertake cleft reconstructive surgeries, extend other comprehensive care to the patients referred by Smile Train, assist Smile Train in spreading awareness/ education on cleft lips and palates and educating and training medical professionals that are part of the initiative ("Program").

#### 1. DEFINITIONS

- Capitalized terms used herein (including in the introductory paragraph and recitals) shall have 1.1. the meaning assigned to them under this Agreement.
- Clause headings and other headings in this Agreement are for reference purposes only and 1.2. shall not affect the meaning or interpretation of this Agreement.
- Words denoting the singular shall include the plural and vice-versa. 1.3.
- When the word "including" is used in this Agreement, it shall mean "including without limitation". 1.4.

#### TERM AND EFFECTIVE DATE 2.

- This Agreement shall begin on 1st April 2020 (the "Effective Date") and continue until 31st 2.1. October 2021, unless expressly terminated as provided in Section 9 (Termination) of this Agreement.
- 2.2. Upon expiration of such period, this Agreement shall stand terminated unless Smile Train in its sole discretion renews this Agreement.

#### **GRANT CONDITIONS** 3.

- Smile Train will provide grants to the Hospital towards the performance of Hospital's obligations 3.1. under the Program and this Agreement. The Hospital must ensure that the Program is carried out in accordance with this Agreement, and the grants given by Smile Train to the Hospital for carrying out the Program, are utilized only for the Program.
- 3.2. The grants provided by Smile Train in furtherance to this Agreement will be subject to the issuance of letters by Smile Train which capture the details of the grants and the manner in which such grants would need to be utilized by the Hospital ("Cover Letter"). The Hospital hereby agrees to comply with any additional condition mentioned under the Cover Letter, in addition to the conditions mentioned under this Agreement. It is hereby clarified that until the issuance of the Cover Letter, Smile Train does not undertake any representation in respect of any grants to be provided in furtherance of this Agreement, towards the Program.
- 3.3. The Hospital will not, offer, give or agree to offer or give (either alone or in agreement with others) any payment, gift or other advantage with respect to any matters which are the subject of this Agreement or which would violate any anti-corruption or bribery laws or regulations.
- Grants must never be used for any political activity or any activity to carry out religious 3.4. conversions.
- The Hospital will inform Smile Train if there has been or may be a material change: 3.5.
  - in the Hospital's ability to carry out the Program, or any adverse effect or significant (a) delay in carrying out the Program;
  - the compliance with this Agreement (including suspicion of or actual fraud, corruption, (b) financial impropriety, conflict of interest or other misuse of grants); or

financial and other information concerning you and your operations which may influence Smile Train's decision to provide or continue disbursing grants to the Hospital for the Program.

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K Rathsh & Powar - Project Director MLES Smile Train Project K.L.E. Society, BELACALAD Or. Prabhakar Kore Hospitel S. MRC-Belgatin.

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Medical Director & Chief Executive KLES Dr. Prabhakar Kore Hospital & Medical Research Centre, BELAGAVI.

- The Hospital will promptly, on demand, repay to or reimburse to Smile Train in full: 3.6.
  - any part of the grants that has not been spent by the end of each financial year. (a)
  - any part of the grants used in breach of this Agreement (and in such case, the Hospital (b) will also pay to Smile Train any amounts in respect of additional liabilities, costs, expenses, directly suffered or incurred by us arising out of, or in connection, with such breach); or
  - any monies paid by Smile Train to the Hospital in error. (c)

#### **OBLIGATIONS OF THE PARTIES** 4.

- 4.1. THE HOSPITAL
  - The Hospital shall ensure that only qualified medical personnel perform or assist in (a)Program surgeries, all of whom shall be duly certified and in good standing with appropriate medical oversight authorities. Program surgeries and treatments shall be performed only in hospitals that have been explicitly approved by Smile Train, and that are permitted to operate in accordance with and in full compliance with the governing laws, rules and standards in India, and the terms of this Agreement.
  - In addition to meeting the requirements of Section 3.1 (a), prior to commencement of (b) this Agreement, the Hospital will carry out a thorough internal medical audit of participating hospitals to ensure compliance with Smile Train's Safety and Quality Protocol, as set out under <u>Annexure A</u> (the "Protocol") and shall comply with the Protocol throughout the term of the Program. The Hospital acknowledges that (i) Smile Train has developed the Protocol for the express purpose of ensuring and maintaining high safety standards, quality improvement and quality control and (ii) the adoption and continued implementation of the Protocol by the Hospital is a condition to Smile Train's obligations hereunder. In the event of any conflict between the Protocol and Applicable Laws (defined hereinafter) or medical standards in the Hospital's territory, the Hospital shall inform Smile Train and Smile Train shall have the right, in its sole discretion, to terminate this Agreement and withdraw funding or to waive such conditions of the Protocol as may be necessary to permit compliance with such Applicable Laws and/or medical standards in the territory.
  - In the event of serious complications leading to irreversible, grievous harm or patient (C) death (a "Sentinel Event" as defined in the Protocol), the Hospital will (i) immediately notify Smile Train of such Sentinel Event, and (ii) implement the review process set forth by Smile Train for the Sentinel Event protocol. As part of the Protocol, the Hospital specifically undertakes to report all Sentinel Events within 24 hours of the event's occurrence, using Smile Train's "Sentinel Event Report Form" as set out under Annexure B. The Hospital will report any Sentinel Event to Smile Train, in the manner provided under the Protocol.
  - (d) The Hospital shall participate in Smile Train Express ("STX"), a free, global, cleft care database, by submitting the completed patient record information as set out under Annexure C ("Patient Medical Record"), and gathering patient consent forms, subject to restrictions imposed by and compliance with all Applicable Laws in the Hospital's territory regarding the treatment of medical information, including but not limited to, the Information Technology Act, 2000 Information Technology (Reasonable Security Practices and Procedures and Sensitive Personal Data or Information) Rules, 2011. Further, the Hospital hereby grants consent to Smile Train to use, disclose and transfer any information (including the Patient Medical Records and Sentinel Event Report Forms) submitted by the Hospital, to third parties, Smile Train affiliates, in accordance with this Agreement and the Protocol.
  - The Hospital shall upload only such Smile Train sponsored surgeries to STX as have (e) been performed at its own hospitals or those that have been explicitly approved by Smile Train in writing as affiliates to the Hospital's. The Hospital shall list the affiliated hospitals on the initial Smile Train application for approval. Any subsequent affiliated hospitals must be approved by Smile Train in writing before the surgery takes place. 1 gerell In the event the affiliated hospital is a separate legal entity, a separate agreement will be executed between such affiliated hospital and Smile Train.
    - The Hospital shall extend totally free cleft lip and palate surgeries to all poor patients covered under this Program with no hidden costs. The Hospital also accepts that patients paying for cleft lip and palate surgeries will not be eligible for Smile Train

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Medical Director & Chief Executive TES Smile Train Project Board of Management KLES Dr. Prabhakar Kore Hospital & TES Or. Prabhakar Kore Hospital & TES Or. Prabhakar Kore Hospital & TES Or. Prabhakar Kore Hospital &

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support under this Program and records pertaining to those paying patients shall not be submitted to STX.

- (g) The Hospital shall not solicit or accept any payment or donation from or on behalf of any patient treated as part of the Program.
- (h) The Hospital shall not claim nor accept any support, partial or complete, from any source other than Smile Train for surgeries sponsored and paid for by Smile Train under this Agreement.
- (i) The Hospital shall maintain a separate account of all grants received from Smile Train under this Agreement and all uses of such grants. Smile Train shall have the right to periodically audit the Hospital's book of accounts by independent external auditors chosen by Smile Train for which the Hospital agrees to extend all cooperation for such audits.
- (j) The Smile Train policy on Smile Train Funded Multiple Interventions during one surgery is attached to this Agreement as set out under <u>Annexure D</u>, and the Hospital shall abide by this policy.
- (k) The Hospital shall submit an online Grant Verification Form in the format provided from time to time by Smile Train prior to the remittance of any financial support by Smile Train.
- (I) The Hospital shall also comply with Smile Train's Child Protection Policy ("Policy"), by submitting the duly signed Child Protection Policy Declaration ("Declaration") at the time of execution of this Agreement. Both the Policy and Declaration are attached to this Agreement as set out under <u>Annexure E</u>.
- (m) The Hospital will not assign any part or all of this Agreement without Smile Train's prior written consent. Any attempt to assign in violation of this Section is void in each instance. Smile Train reserves the right to assign this Agreement or any of its rights or obligations under this Agreement without the Hospital's consent.
- (n) The Hospital understands and acknowledges that Smile Train in performing its obligations under this Agreement will partner with, employ or engage third parties or any entity from Smile Train's affiliates.
- (o) The Hospital shall significantly expand its continuing educational programs (including spreading awareness) in the field of reconstructive surgery for medical specialists through financial, technical and other support from Smile Train.
- (p) The Hospital has adequate Personnel (defined hereinafter), and resources with the necessary skills and qualifications to perform the obligations under the Program. The Hospital has sufficiently ascertained that the Personnel's credentials (including checking criminal track records, background investigation or references), are suitable to perform the Hospital's obligations under the Program.
- (q) The Hospital shall be solely responsible for all other compensation to its Personnel including any statutory contributions that are required and maintain all other compliance requirements as mandated under Applicable Laws in respect of its Personnel.
- (r) In the event Smile Train is required to make any payments in respect of any Personnel, Smile Train shall have the right amongst others, to adjust the same against any sum payable to the Hospital under this Agreement. In addition to the above, Smile Train shall have the right to recover any grant which has not been utilized by the Hospital towards the performance of its obligations under the Program.
- (s) The Parties agree that except as otherwise provided under this Agreement, all administrative costs and general overheads involved under the Program will be borne by the Hospital and shall not be paid by Smile Train.
- (t) The Hospital will be required to submit periodic data reports on a quarterly basis, which will be in a format as approved by Smile Train. The data report will include, information relating to the grants that have been received and utilized by the Hospital and will be submitted to Smile Train within the timelines prescribed by Smile Train.

The Hospital will keep all invoices, receipts, accounts and other relevant documents relating to the grants received from Smile Train in each financial year during the term of this Agreement and for a period of eight years thereafter and provide these to Smile Train promptly if required.

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Medical Director & Chief Executive KLES Dr. Prabhakar Kore Hospital & Medic. Medic. BELAGAVI.  The Hospital will maintain insurance policy that are sufficient to protect Hospital's business against all applicable risks and will provide Smile Train with evidence of such insurance on request.

### 4.2. SMILE TRAIN

- (a) Smile Train will contribute a mutually agreed amount as a grant (to be separately communicated for each primary cleft lip repair, primary cleft palate repair and a few specified secondary surgical interventions) carried out by the Hospital. For the purpose of receiving this grant, the surgeries will be limited to:
  - patients over the age of 3 months for cleft lips and 6 months for cleft palates; and
  - (ii). those within ASA Classes 1 and 2 only. (for clarifications please refer <u>Annexure A</u>, the Protocol).
- (b) Smile Train reserves the right to amend the above criteria at any time at its sole discretion, without any notice and without assigning any reasons.
- (c) Smile Train will remit the agreed grant on a monthly basis as set forth in the Program Summary – Attachment-A attached hereto, based on the number of Patient Medical Records uploaded to the STX server in the prior month, subject to such Patient Medical Records being verified and accepted by Smile Train.
- (d) The grants by Smile Train under this Agreement shall be used solely for the purposes specified. Diversion of these grants for any other purpose without the prior written approval of Smile Train is expressly forbidden and shall be grounds for immediate termination of this Agreement. The Hospital shall indemnify Smile Train, its directors and officers with respect to any misuse of grants. Smile Train shall also have the right to stop the grant forthwith if directed by a lawfully established authority.

### 5. REPRESENTATIONS OF THE PARTIES

### 5.1. THE HOSPITAL

- (a) The Hospital is a running, well established medical facility, validly existing and in good standing under the laws of India and in the state where it operates and has the requisite rights and authority to carry on its activities as now being conducted and to execute, deliver and perform its obligations under this Agreement, and will ensure that the hospitals where surgeries take place under this Agreement have the licenses and meet the qualifications required by law in India for providing the medical services described herein and have licensed medical professionals with the skill, experience and appropriate medical facilities to provide safe and quality care. Hospital shall report any change to this status immediately to Smile Train.
- (b) The execution, delivery and performance by the Hospital of this Agreement has been duly authorized by all required corporate action on the part of the Hospital. The obligations of the Hospital under this Agreement are valid, legal and binding obligations of the Hospital, enforceable against it in accordance with its terms.
- (c) Neither the execution and delivery by the Hospital of this Agreement, nor the performance of any other obligation of the Hospital under this Agreement will violate, conflict with, result in the breach of, constitute a default under the governing documents of the Hospital, any material contract by which the Hospital is bound, or any statute, ordinance, judgment, order, decree, regulation or rule of any court, governmental or medical body affecting or relating to the Hospital.
- (d) Except as otherwise provided in or contemplated by this Agreement, no consent of, waiver from, application or notice to any party is required in order for the Hospital to execute, deliver and perform this Agreement or to consummate the transactions contemplated hereby.
- (e) Notwithstanding the generality of the foregoing, the Hospital represents that it is authorized to receive foreign contribution in accordance with applicable Indian laws (including the Foreign Contribution Regulation Act, 2010 and the rules framed thereunder, as may be amended from time to time), and will ensure that the contribution is utilized only for the purposes as provided under this Agreement and in accordance with applicable Indian laws.

Dr. Rajast Powar Project Director RLES Smite Train Project

SECRETARY Board of Management

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Medical Director & Chief Executive KLES Dr. Prabhakar Kore Hospital & Medical Research Centre, BELAGAVI.

- The Hospital and its consultants, employees, representatives, agents, contractors, subcontractors, doctors ("Personnel") are in compliance and will comply, at the Hospital's sole cost, with all applicable ordinances, codes, standards, laws, rules, regulations and orders of any governmental authority having jurisdiction over the Hospital's performance of its obligations hereunder ("Applicable Laws"), and will hold and fully comply with all required licenses, permits and approvals as may be required under Applicable Laws.
- (g) The Personnel have not been convicted of a felony in the previous seven years, or, if they have, the Hospital has (to the extent in accordance with the Applicable Laws) provided information to Smile Train regarding the nature, severity, and date of each such conviction.
- The Personnel are its own employees and shall not be construed as employees of Smile (h) Train at any time under this Agreement.
- The Hospital has exclusive control over its Personnel, and over its labor and employee (i) relations and its policies relating to wages, hours, working conditions and other employment conditions. The Hospital has the exclusive right to hire, transfer, suspend, lay off, recall, promote, discipline, discharge and adjust grievances with its Personnel. The Hospital is solely responsible for all salaries and other compensation of its Personnel, and for making all deductions and withholdings from its employees' salaries and other compensation and paying all contributions, taxes and assessments, in accordance with the Applicable Laws. The Hospital's Personnel are not eligible to participate in any employment benefit plans or other benefits available to Smile Train's employees. For the sake of clarity, the Hospital hereby represents that it has no authority to bind Smile Train to any agreement or obligation relating to The Hospital's Personnel, its labor and employee relations and its policies mentioned in this Section. The Hospital will be responsible for all acts, omissions, negligence and misconduct of its Personnel. The Hospital will be solely responsible for all misconduct related to its Personnel.
- The Hospital will perform its obligation under Program and this Agreement with all due (j) care, skill and ability, in compliance with prevailing high standards of accepted business/ medical practice and ethics.
- (k) The Hospital will comply with Smile Train's lawful directions, policies and procedures insofar as they relate to the performance of the Hospitals obligations under the Program and this Agreement.
- (1) The Hospital will promptly give to Smile Train all such information and reports as it may reasonably require in connection with matters relating to Hospitals performance of its obligations under the Program and this Agreement.
- (m) The Hospital will comply with all reasonable standards of safety at the Hospital's premises and report to Smile Train any unsafe working conditions or practices.
- (n) The Hospital warrants that the grants will be used in compliance with all applicable Indian laws and United States anti-terrorist financing and sanction laws and regulations. In this regard, the Hospital agrees to take all reasonable steps to ensure that no person or entity expected to receive grants in connection with this Agreement (including the Hospital) is subject to sanctions or otherwise designated on any list of prohibited or restricted parties or owned or controlled by such a party, including but not limited to the lists maintained by the United Nations Security Council, the US Government (e.g., the US Department of Treasury's Specially Designated Nationals list and Foreign Sanctions Evaders list and the US Department of Commerce's Entity List), the European Union or its member states, or other applicable government authority or list of banned terrorist organisations under Section 35 of Unlawful Activities (Prevention) Act, 1967, maintained by the Ministry of Home Affairs, Government of India or any such equivalent list.

5.2. SMILE TRAIN

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(a)

The execution, delivery and performance by Smile Train of this Agreement has been duly authorized by all required corporate action on the part of Smile Train. The obligations of Smile Train under this Agreement are valid, legal and binding obligations of Smile Train, enforceable against it in accordance with its terms, except as such enforceability may be subject to or limited by bankruptcy, insolvency, reorganization, moratorium, receivership and similar laws affecting creditors' rights generally and general principles of equity.

Neither the execution and delivery by Smile Train of this Agreement, nor the

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Board of Management

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& Chief Executive Medical Di KLES Dr. Prabhakar Kore Hospital & Medical Research Centre, BELAGAVI. performance of any other obligation of Smile Train under this Agreement will violate, conflict with, result in the breach of, constitute a default under the governing documents of Smile Train, any material contract by which Smile Train is bound, or any statute, ordinance, judgment, order, decree, regulation or rule of any court or governmental body affecting or relating to Smile Train.

Except as otherwise provided in or contemplated by this Agreement, no consent of, (c)waiver from, application or notice to any party is required in order for Smile Train to execute, deliver and perform this Agreement or to consummate the transactions contemplated hereby.

#### **REPORTING, RENEWAL AND SUSPENSION** 6.

- At least 30 days prior to the end of the grant period (which would be the period between January 6.1. 1 to December 31 each year) ("Grant Period") the Hospital will submit a Final Grant Report or as may be updated from time to time and shared with the Hospital) highlighting the achievements of the goals of this Program as set out under Attachment - A (Program Summary), and representatives from the Hospital and Smile Train will meet to assess the progress of grant efforts.
- Subsequent to which, Smile Train will determine whether grant will be renewed/extended. The 62 decision to renew grant will be at the sole discretion of Smile Train, and Smile Train will not be obliged to give any reasons should it decide not to renew the same. If Smile Train does not renew, grant will cease at the conclusion of the Grant Period.
- Smile Train reserves the right to suspend this Agreement, wholly or in part, for any reason at 6.3. any time during the subsistence of this Agreement, by providing written notice to the Hospital.

#### 7. PUBLIC RELATIONS

- Smile Train reserves the right to publicize the cooperative efforts between the parties hereto 7.1. through the use of literature, photographs, video film production and other media. The Hospital permits and allows Smile Train to use any and all of its materials including its trademarks and any literature in relation to the matters that it works on with Smile Train under this Agreement. Smile Train will also issue press releases and have the option to hold press conferences to announce the Program and its progress over the duration of the Grant Period. The Hospital agrees to be receptive in assisting Smile Train's efforts for publicity and/or additional fundraising.
- The Hospital acknowledges that the words "Smile Train", "Changing the World One Smile at a 7.2. Time" and the logo of the smiling train are the exclusive intellectual property of Smile Train's affiliates ("Smile Train IP") as set out under License Agreement. The Hospital shall immediately cease use of the Smile Train IP if instructed by Smile Train or its affiliates. In any and all publications and other public relations vehicles describing the Program, the Hospital agrees to receive prior approval from Smile Train before using the Smile Train IP.

#### INDEMNIFICATION: LIABILITY 8

The Hospital shall be solely responsible for any losses arising out of Hospital's performance of this Agreement. The Hospital agrees to indemnify and hold harmless Smile Train, its affiliates, members, officers, directors, employees, agents and representatives from and against any and all losses, claims, damages and liabilities, whether joint or several, related to, or arising out of, or in connection with, Hospital's actions in performance of this Agreement, including but not limited to the performance of Hospitals obligations under the Program, or any other information, services or products that the Hospital or any director, officer, member, manager, employee, affiliate or associate of the Hospital provides to any patient.

#### TERMINATION 9.

- 9.1. This Agreement may be terminated by either party without assigning any reasons, by giving 30 days' notice of its intention to do so, in writing to the other.
- Notwithstanding the above, Smile Train reserves the right to terminate this Agreement 9.2. Standards, misuse of grant of any kind, or misrepresentation, without any further liability under immediately at any time, at its sole discretion, in the event of fraud, violation of medical Thomas

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- 9.3. This Agreement shall stand terminated immediately if, directed by any statutory body or government department acting within the framework of the law.
- 9.4. On the termination or expiry of the term of this Agreement, the Hospital shall return all records, publicity material, brochures, etc. pertaining to the Program, and furnish to Smile Train a full accounting of the disbursement of grants and expenditures incurred under the Program up to the effective date of termination within 30 days. As of the effective date of termination of this Agreement, for any reason whatsoever, Smile Train will not be required to provide any money to the Hospital except for grants required to be provided prior to the date of termination, in accordance with the terms of this Agreement and the process prescribed herein.
- 9.5. On termination of this Agreement, the Hospital shall promptly repay to Smile Train any unused sums of the grants.

### 10. AMENDMENT

This Agreement may not be amended or modified except by an instrument in writing signed by, or on behalf of, each of the parties hereto.

### 11. NONDISCLOSURE

The specific terms of this Agreement are privileged and confidential, and the parties hereto undertake not to divulge the same to any third party without the prior, express written permission of the other. The only exceptions to this will be their duly appointed legal attorneys and advisors, or duly empowered statutory bodies and government agencies acting within the requirements of the law. The parties hereto also undertake to institute all reasonable steps to ensure that the confidentiality is maintained within their respective organizations.

### 12. PRIOR AGREEMENT

This Agreement supersedes and replaces any and all previous agreements between the parties.

### 13. CONFIDENTIALITY

All information provided by Smile Train will remain Smile Train's exclusive property, and the Hospital will have no rights to use such information except as expressly provided herein. The Hospital will not and will prevent the Personnel from using any trade name, trademark, service mark, logo or commercial symbol, or any other proprietary rights of Smile Train or any of its affiliates in any manner without prior written authorization of such use by an authorised signatory of Smile Train. Smile Train will not and shall ensure that its Personnel shall not disclose, issue press releases or publicity relating to Smile Train or the existence or contents of this Agreement or reference Smile Train or its affiliates to any third party or in any brochures, advertisements, client lists or other promotional materials.

### 14. OTHERS

14.1. Notices under this Agreement are sufficient if given by nationally recognized overnight courier service, speed post with acknowledgment receipt, facsimile with electronic confirmation or personal delivery to the other Party at the address below the Party's signature line below. If no address is listed for the Hospital, notice to the Hospital will be effective if given to the last known address. Notice is effective: (a) when delivered personally, (b) three business days after sending by speed post, (c) on the business day after sending by facsimile with electronic confirmation to the sender. A Party may change its notice address by giving notice in writing in accordance with this section.

14.2. The Hospital and Smile Train are independent contractors. Nothing in this Agreement will be construed as creating any relationship such as joint venture, partnership, association of persons, employer-employee, principal-agent or franchisor-franchisee. This Agreement is on a 'principal-to-principal' basis and it does not confer any right to either party to represent the other, act on its behalf as its agent or authorized representative, issue public statements, make commitments of any kind or claim any relationship beyond the one provided in this Agreement. The duties and responsibilities of the Hospital shall be rendered solely by the Hospital and not

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Medical Director & Chief Executive KLES Dr. Prabhakar Kore Hospital & Medical Research Centre, BELAGAVI.





नेव ज Certificate No. Certificate Issued Date Account Reference Unique Doc. Reference Purchased by Description of Document **Property Description** Consideration Price (Rs.)

First Party Second Party Stamp Duty Paid By Stamp Duty Amount(Rs.)

# **INDIA NON JUDICIAL**

# Government of National Capital Territory of Delhi

# e-Stamp

IN-DL43293055411921S 21-May-2020 01:10 PM IMPACC (IV)/ dl870703/ DELHI/ DL-DLH SUBIN-DLDL87070395301682085678S : SMILE TRAIN INDIA Article 5 General Agreement Not Applicable 0 (Zero) SMILE TRAIN INDIA Not Applicable SMILE TRAIN INDIA 150 (One Hundred And Fifty only)

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# ......Please write or type below this line ....

# LICENCE AGREEMENT

This Licence Agreement (the "Agreement") is executed at New Delhi and is entered into as of the 1st day of April, 2020

# BETWEEN

SMILE TRAIN INC., having its registered office at 633, Third Ave, 9th Floor, New York 10017, USA (hereinafter referred to as "Licensor") which expression shall, unless repugnant to the context or meaning thereof, include its successors and permitted assigns of the First Part; ruch

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Medical Director & Chief Executive KLES Dr. Prabhakar Kore Hospital

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# LICENCE AGREEMENT

This Licence Agreement (the "Agreement") is executed at New Delhi and is entered into as of the 1<sup>st</sup> day of April, 2020

## BETWEEN

SMILE TRAIN INC., having its registered office at 633, Third Ave, 9<sup>th</sup> Floor, New York 10017, USA (hereinafter referred to as "Licensor") which expression shall, unless repugnant to the context or meaning thereof, include its successors and permitted assigns of the First Part;

SECRETARY Board of Management K.L.E. Society, BELAGAVI

DE Rajast S. Powar Project Director KLES Smile Train Project KLES Dr. Probhekar Kore Hochieal & MRC-Belgaton.

Medical Director & Chief Executiv KLES Dr. Prabhakar Kore Hospita Medical Research Centre, BELAGA

Karnataka Lingayat Education Society, having its registered office at Nehru Nagar, Belagavi 590010, Karnataka which owns and operates a Hospital in the name and style of KLES Prabhakar Kore Hospital & Medical Research Centre located at Nehru Nagar, Belagavi 590010, Karnataka (hereinafter referred to as "Licensee") of the Second Part;

### AND

Smile Train India, a company incorporated under the laws of India having its registered office at Plot No.3, LSC Sector-C, Pocket 6/7, Vasant - Kunj New Delhi – 110070 (hereinafter referred to as "Smile Train India") which expression shall, unless repugnant to the context or meaning thereof, include its successors and permitted assigns of the Third Part.

### **RECITALS:**

WHEREAS, Smile Train India, an affiliate of the Licensor, incorporated under Section 25 of the Companies Act, 1956, having its registered office at – Plot No.3, LSC Sector-C, Pocket 6/7, Vasant - Kunj New Delhi – 110070, has entered into an Agreement dated 1<sup>st</sup> January 2018 with the Licensee, whereby the Licensee is to extend *totally free* cleft reconstructive surgeries to poor patients who would not otherwise have been able to afford them, *and* significantly expand its continuing educational programs in the field of reconstructive surgery for medical specialists through financial, technical and other support from Smile Train India ("Program Agreement");

WHEREAS, pursuant to the Program Agreement, the Licensee desires to obtain the license for use of the Materials (as defined below), to effectively participate and comply with its obligations under the Program Agreement ("Licensee Works");

WHEREAS, Licensor is the owner of, inter alia, all right, title and interest in and to those certain materials, a copy of which is attached hereto as "Exhibit A" and made part hereof, (the "Materials"); and

WHEREAS, Licensor is willing to grant to the Licensee a non-exclusive limited license to use the Materials for the purpose(s) described herein.

NOW, THEREFORE, in consideration of the foregoing and of the covenants and agreements contained herein, and for other good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, the parties hereto do hereby agree as follows:

# 1. LICENSE OF RIGHTS

- (a) Licensor hereby non-exclusively licenses to Licensee the right to include the Materials in the Licensee Works and all related promotional materials for non-profit and noncommercial purposes only, worldwide during the Term;
- (b) Licensee may use the Materials only in strict adherence with this Agreement and may not use the Materials in connection with any commercial purposes whatsoever.

### 2. <u>APPROVALS</u>

Prior approval of the Licensor shall be required for any and all uses of the Materials who shall have the right to approve, in its own discretion, any and all uses of the Materials. Wherever in this Agreement Licensor's approval or consent is required, Licensee will request Licensor for such approval or consent in writing (which may be given by email) and provide Licensor with the information in respect of which such approval or consent is sought. Approval or disapproval of the Licensor shall be communicated within five (5) business days of receipt of such request from Licensee. Failure to respond within the stipulated period provided herein shall be deemed as denial by the Licensor of the approval or consent request.

In-284698 Bactor SECRETARY Board of Management K.L.E. Society, BELAGAVI

Dr. Rajash S. Perwar Project Director KLES Smile Train Project MINS Dr. Prabhytar Kore Hospitol 2 MRC- Bolgedm.

Medical Director & Chief Executive KLES Dr. Prabhakar Kore Hospital & Medical Research Centre, BELAGAVI

# 3. <u>REPRESENTATIONS AND WARRANTIES BY LICENSOR</u>

Licensor represents and warrants that:

- Licensor has the full right, power, legal capacity and authority to enter into this Agreement and to carry out the terms hereof and to grant to Licensee the rights and privileges granted hereunder;
- (b) There are no liens, claims, encumbrances, legal proceedings, restrictions, agreements or understandings which will or which may conflict or interfere with, limit, or are inconsistent with or otherwise affect any of the provisions of this Agreement or the enjoyment by Licensee of any right granted to it hereunder; and
- (c) Licensor owns or controls without any limitations, restrictions or encumbrances, all rights granted to Licensee hereunder and Licensor has obtained all necessary licenses and permissions required for the manufacturing, distribution, exhibition, advertising, exploitation and otherwise of the assets worldwide, as may be required for the full and unlimited exercise and enjoyment by Licensee of all of the rights herein granted to it.

# 4. <u>REPRESENTATIONS AND WARRANTIES BY LICENSEE</u>

Licensee represents and warrants to the Licensor as follows:

- (a) Licensee, and each of Licensee's shareholders, officers, employees, representatives and other persons acting on its behalf, has and will continue to have all necessary licenses, registrations and qualifications necessary or appropriate to enable Licensee to perform its services as described herein and Licensee shall perform its services in full compliance with all applicable laws, rules and regulations;
- (b) Licensee has the full right, power, legal capacity and authority to enter into this Agreement and to carry out the terms hereof and to exercise and fulfill the rights granted by Licensor to Licensee hereunder;
- (c) all information given or to be given to the Licensor by Licensee is and shall be accurate and complete in all respects and shall not contain any misstatement of material information nor any intentional or negligent omission of any material fact; and
- (d) the use of the Materials by Licensee in the Licensee Works shall not infringe upon or violate the rights of any third party.

The foregoing shall survive the termination of this Agreement for any reason.

## 5. <u>INDEMNITY</u>

The Licensee shall be solely responsible for any losses arising out of Licensee's performance of this Agreement. The Licensee agrees to indemnify and hold harmless Licensor, its affiliates, members, officers, directors, employees, agents and representatives against all losses and damages, including reasonable attorney's fees, but excluding any lost profits, arising out of any action or proceeding by third parties resulting from any breach by the Licensee of any of the provisions hereof, or the breach of any of the warranties and representations set forth herein. Prompt written notice will be given to Licensor of any action or proceeding to which the foregoing indemnity relates.

# 6. TERM AND TERMINATION

Mout Could

This Agreement shall become effective on the date of execution of this Agreement unless terminated in accordance with Sections 6 (b), (c) or (d) below (the "Term").



Pewar Dr. Raid Project Girector M.ES Smile Train Project WLEB Dr. Prabhanar Koro Mountal 3. RRC Belgy

Medical Director & Chief Executive KLES Dr. Prabhakar Kore Hospital & Medical Research Central BELAGAVI

- (b) This Agreement may be terminated by either party without assigning any reasons, by giving 30 days' notice of its intention to do so, in writing to the other.
- (c) Notwithstanding the above, Licensor reserves the right to terminate this Agreement immediately at any time, at its sole discretion, in the event the Licensee commits fraud, misrepresentation, or a substantial breach of any of the provisions contained herein or with respect to its obligations to be performed without prejudice to any and all rights at law which Licensor may have.
- (d) This Agreement shall terminate immediately upon termination of the Program Agreement, in terms thereof.

# 7. <u>ASSIGNMENT</u>

Licensee may not assign this Agreement, by operation of law or otherwise, without the prior written consent of Licensor, which consent may be withheld at Licensor's sole discretion.

### 8. <u>RELATIONSHIP OF PARTIES</u>

The relationship between the parties hereto is that of licensor and licensee. Neither party hereto is an agent, partner or employee of the other and neither party has any right or any other authority to enter into any contract or undertaking in the name of or for the account of the other or to either assume or create any obligation of any kind, express or implied, on behalf of the other, nor will the acts or omissions of either create any liability for the other. This Agreement shall in no way constitute or give rise to a partnership or joint venture between the parties.

# 9. <u>NOTICES</u>

All notices or other communications required or permitted to be delivered hereunder shall be in writing and (i) delivered personally, (ii) sent by registered or certified mail (return receipt requested), postage prepaid, (iii) sent by recognized national or international air courier, or (iv) via facsimile with confirmation of receipt, addressed to the parties at the addresses first written hereinabove. Any such notice or other communication shall be deemed to have been given or made as of the date received.

### 10. <u>MISCELLANEOUS</u>

- (a) This Agreement sets forth the entire agreement and understanding between the parties hereto with respect to the subject matter hereof and supersedes all prior discussions, representations, understandings and agreements, whether written or oral, between the parties with respect to the subject matter hereof. This Agreement may be altered, modified or amended only by a written document signed by the parties hereto.
- (b) The rights and remedies provided herein shall be cumulative and not exclusive of any other rights or remedies provided at law or in equity. Failure or delay on the part of either party to exercise any right, remedy, power or privilege provided for herein or by statute, by law, in equity or otherwise shall not operate as a waiver thereof, nor shall any single or partial exercise of any such right, remedy, power or privilege preclude any other or further exercise thereof or the exercise of any other right, remedy, power or privilege.
- (c) This Agreement shall be binding upon and shall ensure to the benefit of Licensor, its successors and assigns, and Licensee, its successors and permitted assigns.
- (d) Notwithstanding anything to the contrary contained herein, in the event that any clause, term or provision of this Agreement which is not material is determined by any court or administrative agency of competent jurisdiction to be illegal, unenforceable or in conflict with any applicable law, this Agreement shall continue in full force and effect as if the offending clause, term and provision hereof were no longer incorporated herein.

al arell

SECRETARY Board of Management K.L.E. Society, BELAGAVI DE Rajeen S. Powar - Project Director MLES Smille Train Project RLES Or, Problembar Kore Hospital & MRC- Bolgacim John

Medical Director & Chief Extendive KLES Dr. Prabhakar Kore Hospital & Medical Research Centre, BELAGAVI.

- (e) The parties agree that the failure or delay of any party at any time to require performance of any provision under this Agreement shall not affect the right of such party to require the full performance thereof and that a waiver by any party, which shall be in writing and signed by the party against whom such waiver is sought to be enforced, of a breach of any provision of this Agreement shall not be held to be a waiver of any further or similar breach or as nullifying the effectiveness of such provision.
- (f) This Agreement will be governed by the laws of India and the courts at New Delhi will have exclusive jurisdiction in connection with any matters arising out of this Agreement.
- (g) This Agreement may be executed in several counterparts and via facsimile, each of which shall be deemed an original and all of which shall constitute one and the same instrument.

IN WITNESS WHEREOF, the parties hereto have duly executed this Agreement as of the date and year first written above.

For and on behalf of Smile Train Inc.

By: B.G. Pesai 26.02, 2020. Date:

By: DR. M. V. JALI

Date: 26.03.2020

CRETARY

Board of Management K.L.E. Society, BELAGAVI

For and on behalf of Karnataka Lingayat Education Society

 Medical Director & Chief Executive -KLES Dr. Prabhakar Kore Hospital & Medical Research Centre, BELAGAVI.

For and on behalf of KLES Prabhakar Kore Hospital & Medical Research Centre Dr. Rejesh S. Powar BY: DR RAJESH POWOR Date: 26.03.2020 Project Director KES Smile Train Project For and on behalf of Prabhakar Kore Hospital & Medical Research Centre - Project Director gadan.

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By:

Date:

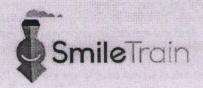
For and on behalf of Smile Train India

Mand mell Mamta Carroll

Date: March 2020

In-284698

EXHIBIT A The Materials













March Court

ß SECRE TARY Board of Management K.L.E. Society, BELAGAVI



Or. Rajesh S. Powar "> Project Director MRC- Beigadan.

6

Medical Director & Chief Executive F3.52 Or. Prabhakar Kore Hospital & KLES Dr. Prabhakar Kore Hospital & Medical Research Centre, BELAGAVI.

In-284698

Dr. Rajesh Powar KLES Prabhakar Kore Hospital & Medical Research Centre Dept. of Plastic Surgery Belgaum, 590010 Karnataka, India

December 19, 2022

Dear Dr. Rajesh Powar,

As provided in Clause 4.2 of the Services Agreement with KLES Prabhakar Kore Hospital & Medical Research Centre dated 1<sup>st</sup> April 2020, we are pleased to renew the agreement and extend its validity up to 31<sup>st</sup> December 2024 on the terms as agreed in the said agreement.

Please sign confirming your acceptance, retain a copy for your records and return *one* copy to us at:

Smile Train India Plot Number 3, LSC Sector C, Pocket 6/7 Vasant Kunj, New Delhi 110070

I take this opportunity of placing on record our sincere appreciation of the good work done by you, your team and the management of KLES Prabhakar Kore Hospital & Medical Research Centre in providing cleft reconstructive surgeries to poor patients since the start of our 'partnership'.

We deem it a privilege to be associated with a team like yours and look forward to working together with all of you.

With all good wishes to you, your colleagues and your loved ones for the coming holiday season and the New Year.

For and on behalf of Smile Train India	For and on behalf of Karnataka Lingayat Education Society
Mand Could	SECRETARY Board of Management
Name of signatory: Mamta Carrol	Name of Signatory: B. G. Desal
Designation: Director	Designation: Secretary.
Date: 19 <sup>th</sup> December 2022	Date: 20.12.2022
Mont	them.
	Name of Signatory: Dr. Rajesh Powar
Name of signatory: Dr. (col) M. Dayo	Name of Signatory: Dr. Rajesh Powar Designation: Smile Train Project Director
	Name of Signatory: Dr. Rajesh Powar Designation: Smile Train Project Director Date: Rol 12 Ros Rajesh S. Powar



# HIV TESTING LABORATORY DEPARTMENT OF MICROBIOLOGY KLE's JAWAHARLAL NEHRU MEDICAL COLLEGE, BELAGAVI-590010

JNMC/MICRO/HIVTL/Doc-1

S-12015/01/2008-NACO (LS) Government of India Ministry of Health & Family Welfare National AIDS Control Organisation

> 9<sup>th</sup> Floor, Chandralok Building 36 Janpath, New Delhi-110001 5<sup>th</sup> April, 2017

The Head Department of Microbiology JN Medical College, Belagavi, Karnataka

Subject: Nomination of SRL status to laboratory for External Quality Assurance Scheme of NACO.

Reference: Letter No. T-11013/08/2006- NACO (R&D) dated 2nd July, 2007.

Sir/Madam,

To

It is informed that "Department of Microbiology, JN Medical College, Belagavi, Karnataka" has been nominated as State Reference Laboratory for External Quality Assurance Scheme of NACO vide letter No. T-11013/08/2006-NACO dated 2<sup>nd</sup> July, 2007.

For this State Reference Laboratory, the referral laboratory is "National Institute of Mental Health and Neuro Sciences" (National Reference Laboratory).

Yours faithfully,

(Dr. Naresh Goel) DDG (Lab Services)

Copy to

1. The Project Director, Karnataka State AIDS Preventive Society, Karnataka.

2. The Dean/Principal, JN Medical College, Belagavi, Karnataka.

3. Dr. V. Ravi, Department of Neurovirology, NIMHANS, Bangalore.

Dr. M. B. Nagamot

Incharge Officer State Reference Laboratory (SRL) Department of Microbiology J. N. M. C., BELGAUM-590010 
 Phone
 : 25367033, 25367035, 25367036

 दूरमाथ
 : 25367033, 25367035, 25367036

 Telegrams
 : MEDCONCIND, New Delhi-75

 तार
 : मेडकोसिंड नई दिल्ली

 Fax
 : 0091-11-25367024

 E-mail
 : mci@bol.net.in

 Website
 : www.mciindia.org



पॉकेट - 14, सेक्टर - 8, द्वारका फेस- 1 नई दिल्ली-110 077 Pocket- 14, Sector- 8, Dwarka Phase - 1 New Delhi-110077

# भारतीय आयुर्विज्ञान परिषद् Board of Governors in Super-session of MEDICAL COUNCIL OF INDIA

No.MCI-Academics/2011/ 82058

Date: 29 03/11

Dr. Swarna Rekha Convenor, Regional Centre in MET St. John's Medical College Hospital Sarjapur Road, Bangalore-560034 Ph: 080- 22065284; 22065030 Fax: 080- 25530737; M: 09845036280 E-mail: <u>srekha74@rediffmail.com</u>

Dr. V. D. Patil Principal, Jawaharlal Nehru Mèdical College, Nehru Nagar, Belgaum -- 590 010 Karnataka PH. - 0831 - 2471350, 2471701, 2470101 (Direct) Res: - 0831 - 2470102, 2430063 Mobile: 09448190231 Fax: 0831-2470759 Email - <u>drvdpatil@jnmc.edu</u>

Dr. (Mrs.) Padmaja R. Walvekar, Convenor, Regional Centre, Associate Professor, Deptt. Of Community Medicine, Coordinator of Medical Education Cell, Jawaharlal Nehru Medical College, Nehru Nagar, Belgaum – 590 010 Karnataka Mobile: 09448102390, E-mail: padma walv@yahoo.com

Dear Sir / Madam,

I am directed inform you that one new Regional Centre is being launched at JN Medical College, Belgaum shortly. Due to this, a re-allocation of the medical colleges in the concerned region has become necessary. The list of re-allocated colleges under the two Regional Centres at St. John's Medical college, Bangalore and JN Medical College, Belgaum is given below.

The Convenors of the Regional Centres at Jawaharlal Nehru Medical College, Belgaum and St. John's Medical College, Bangalore are requested to send letters to the medical colleges under their charge intimating them of the reallocation of medical collges and also of the academic calendar of the workshops which would be held, with copy to MCI.

The Regional Centre at JN Medical College, Belgaum may intimate the date of launching of the Centre by holding the first Basic Course Workshop. A copy of the decision taken by Board of Governors, MCI regarding fund allocation to conduct the Workshop in MET is attached. The Regional Centre may charge Registration fee upto 1,500/- from the participants. TA/ DA for the participants will be paid by their respective medical college and they will be granted leave of absence. The new centre is requested to invite Principal of the medical colleges under their charge for the launching function.

 - Phone
 : 25367033, 25367035, 25367036

 दूरमाष
 : 25367033, 25367035, 25367036

 Telegrams
 : MEDCONCIND, New Delhi-75

 तार
 : मेडकॉसिंड नई दिल्ली

 Fax
 : 0091-11-25367024

 E-mail
 : mci@bol.net.in

 Website
 : www.mciindia.org



पॉकेट - 14, सेक्टर - 8, द्वारका फेस- 1 नई दिल्ली-110 077 Pocket- 14, Sector- 8, Dwarka Phase - 1 New Delhi-110077

# भारतीय आयुर्विज्ञान परिषद् Board of Governors in Super-session of MEDICAL COUNCIL OF INDIA

Various decisions arrived by the Executive Committee of the Medical Council of India and Board of Governors will be communicated to you shortly. It is requested that these are adhered to. You may feel free to contact me at any time on the following numbers 011-32430347 / 9811719527.

Yours faithfully vinder Kumar) (D Joint Secretary

### Encl.: As above: List of reallocation of Medical Colleges Decisions of BoG ? たつ

### Copy for information to:-

 Dr. Sanjiv Lewin, Co-convenor, Regional Centre Professor of Pediatrics, Member, Department of Medical Education, St. John's Medical College Hospital, Sarjapur Road, Bangalore-560034, Mobile: 09886979255, E-mail: <u>drlewin@gmail.com</u>

वरभाष :2	5367033, 25367035, 25367036 5367033, 25367035, 25367036
Telegrams	: MEDCONCIND, New Delhi-7 । শত্তকার্মিত নর্চ বিল্লী
Fax	: 0091-11-25367024
E-mail Website	: <u>mci@bol.net.in</u> : <u>www.mciindia.org</u>



पॉकेट - 14, सेक्टर - 8. द्वारका फेस- 1 नई दिल्ली-110 077 Pocket- 14, Sector- 8, Dwarka Phase - 1 New Delhi-110077

Date: 07/04/11

# भारतीय आयुर्विज्ञान परिषद् Board of Governors in Super-session of MEDICAL COUNCIL OF INDIA

No.MCI-Academics/2011/ 1824.

Dr. V. D. Patil Principal,	J. N. MEDICAL COLLEGE : BELGAUM
Jawaharlal Nehru Medical College,	11 1 APR 21
Nehru Nagar, Belgaum - 590 010	
Karnataka	Inward
PH 0831 - 2471350, 2471701, 247010	(Direct) SIG
Res: - 0831 - 2470102, 2430063	Banandanino anter como como como
Mobile: 09448190231	
Fax: 0831-2470759	
Email - drydnatil@inmo.adu	

#### Launching of the Regional Centre in Medical Education Technologies at Subject: -Jawaharlal Nehru Medical College, Belgaum

Dear Dr. Patil,

I am directed to inform you by Dr. Sita Naik, that the Board of Governors, Medical Council of India has approved the launching of the Regional Centre in Medical Education Technologies at Jawaharlal Nehru Medical College, Belgaum on 14<sup>th</sup> May, 2011. This may be followed by the first Workshop on Medical Education Technologies to faculty from participating colleges allocated to JN Medical College, Belgaum. You are requested to inform the programme details of launching of the Centre to Dr. M. Rajalakshmi, Chief Consultant, Academic Cell at e-mail: academiccell@gmail.com. Details of MCI representation at the launching function will be intimated to you in due course.

With regards,

ours faithfully Dr Davinder Kumar Joint Secretary

Copy for information to:-

Dr. Sangeeta Sharma, Secretary, Medical Council of India 1.



# भारतीय आयुर्विज्ञान परिषद् MEDICAL COUNCIL OF INDIA



पॉकेट — 14, सेक्टर — 8, द्वारका , नई दिल्ली — 110 077 Pocket — 14, Sector — 8, Dwarka, New Delhi — 110 077 Platinum Jubilee (1933 - 2008)

# No. MCI-Academics/2014 / (8863

Dr. A. S. Godhi, Dean & Principal Jawaharlal Nehru Medical College, Nehru Nagar, Belgaum – 590 010 Karnataka Ph. – 0831 – 2471350, 2471701, 2470101 (Direct) Res: – 0831 – 2470102, 2430063 Fax: 0831-2470759; M: 09844121868 E-mail: principal@jnmc.edu, drashokgodhi@jnmc.edu



9.7.19

Date:

Sub: letter No. MDC/Dome/584 dated 18-05-2014 on Nodal Centre for FDP programmereg

# Sir,

I have been directed to inform you that Medical Council of India has been pleased to upgrade the Regional Centre in MET at your Institution to Nodal Centre in MET and conduct Advance Course in Medical Education.

The Academic Cell has already sent you a letter requesting you to nominate a Convener & Co-Convener to conduct the Advance Course. Your reply, which has not been received so far, may be expedited. The Centre would continue to conduct the Basic Course Workshop in MET.

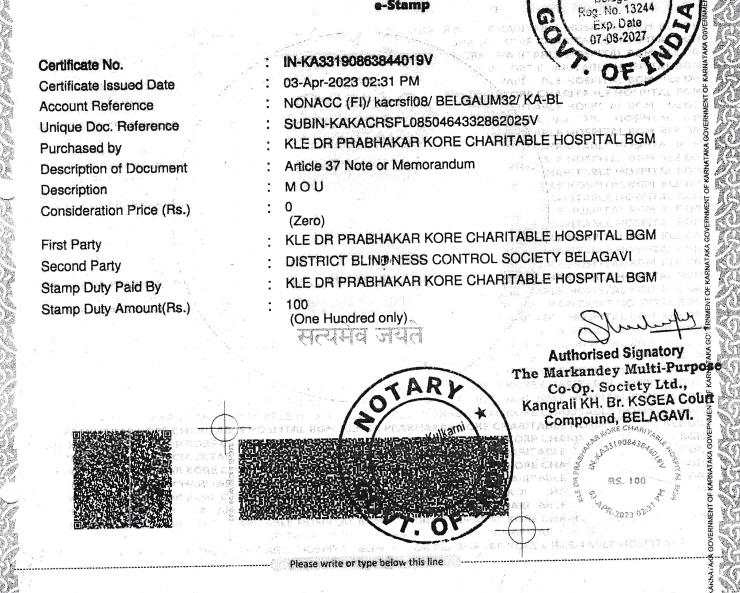
Yours faithfully, (Dr. Davinder Kumar) Joint secretary, MCI



# INDIA NON JUDICIAL

# **Government of Karnataka**

Stamp



# Memorandum of Understanding (MOU) between District Health Society and participating Non Government Organization

# 1. Preamble:

WHEREAS the Union Cabinet has approved continuation of National Program 1.1. for Control of Blindness, hereafter referred to as NPCB, for implementation in all the States of the country beyond the 12th Plan (2017-2020)



Statutory Alert: Alert: enticity of this Stamp certificate should be verified at 'www.shcilestamp.com' or using e-Stamp Mobile App of Stock Holding Belangui

Medical Superintendent KLE Dr. Prabhakar Kore Charitable Hospital

rishali P Kulkarn Belagavi

- 1.2 WHEREAS the Cabinet has also agreed to follow the strategies of "Vision" 2020": The Right to Sight" in NPCBVI as per plan of Action developed for the country.
- 1.3 WHEREAS NPCB aims to reduce prevalence of blindness by implementing various activities through State and District Health Societies established in all the districts of the country;
- 1.4 WHEREAS the NPCB seeks to involve eye care facilities in Government, Non Government and Private sectors having capacity to perform various activities under National Program for Control of Blindness;
- 1.5 AND WHEREAS schemes for Non-Government Organizations (Hereafter referred as NGO/Private Practitioner) providing eye care service are implemented as per pattern of assistance approved by the Cabinet;
- 1.6 NOW THEREFORE the signatories of Memorandum of Understanding MOU have agreed as set out here in below.

### 2. PARTIES OF MOU:

This MOU is an agreement between District Health Society of **BELAGAVI** of the State of **Karnatak**; hereafter called District Health Society and **KLE DR PRABHAKAR KORE CHARITABLE HOSPITAL**, **BELAGAVI**.

### **3. DURATION OF MOU:**

This MOU will be operative from the date of its signing by the parties and remain in force till **31**<sup>st</sup> **March 2024** period of one year. The MOU shall be renewed for further period, through mutual agreement by the parties.

- 4. General Guidelines for Diabetic Retinopathy, Glaucoma, Keratoplasty and Childhood Blindness- Squint, ROP, Retinoblastoma, Congenital Ptosis, Intra Ocular Trauma in Children and Low Vision.
  - I. Beneficiaries to include all patients irrespective of Religion, Caste, Sex and Economic Status.
  - II. Cost of the patients:- Totally free of cost to the beneficiaries.

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Vrisha

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vrisha

\*

Medical Superintendent KLE Dr. Prabhakar Kore Charitable Hospital Belagavi

### **5. COMMITMENTS OF THE NGOs:**

Through this MOU, the NGO agrees to provide following services to the general population of the district. (Write, YES" against applicable points).

Ac	tivities Ye	s/No
Ι	Screening of the population of all ages with emphasis on 50 <sup>+</sup> years in all the villages / townships including the <b>area allotted for the</b> <b>NGOs.</b> The NGO has to maintain village wise blind registers annually.	YES
II	Identification of cases fit for cataract surgery & motivation thereof and transportation to the base hospital as per GOI guidelines indicated.	YES
II	Pre-operative examination and investigation as required	YES
	Performance of cataract surgery preferably IOL, implantation through ECCE-IOL, Small incision cataract surgery (SICS) or Phaco emulsification and Diabetic Retinopathy, Glaucoma, Keratoplasty, Vitreo-retinal surgery & Childhood Blindness of patients identified in allotted areas, self-motivated walk in cases and those referred by District Health Society /ASHA etc.	YES
N. V	Post-operative care including management of complications, if any and Post-operative counseling regarding use of glasses if required.	YES
VI	Follow up service including refraction and provision of glasses ,if required providing best possible correction including presbyopic correction	YES
) A VI	Submission of cataract surgery records of operated cases online through the MIS-NPCBVI & Also submits the same hard copy to <b>DBCS Belagavi</b> .	YES
VII	I Shall be solely responsible for any & all claims & damage in connection with MOU and consequences thereof	YES

Medical Superintendent KLE Dr. Prabhakar Kore Charitable Hospital Belagavi

- III. Copy of valid photo ID of beneficiaries should be kept as record (Voters' ID) Card, Ration Card etc., any other Govt. Provided ID, employee's certificate.
- IV. A Minimum of 5% of random cases under diseases should be verified by Ophthalmic Officer, Taluka Ophthalmic Surgeon and DPM-BCD. If verified by PMOO then the records need to be further counter signed by the DPM-BCD/District Ophthalmic Surgeon on a monthly basis for release of GIA.
- V. District Health & Family Welfare Society (Blindness Control Division) of the respective District is the monitoring authority for the District.

### **FUND UTILIZATION:**

SI No	FMR Code	Component	Guidelines for Fund utilization			
1.	15.4.2/ I.1.1	Reimbursement for Cataract Operation for NGO & Private Practitioners as per norms @ Rs.2000/- per Case.	Payment of Rs. 2000/- will be made to the pay operated case if the NGO has used all facilities of their own like Druge & Consumables, surged Spectacles, Transport/POL, organization and publicity, including their own Eye Hospital and Ophthalmologists. In the cases where NGOs/Pvt. Practitioners are using Govt. OT: Normal area- @ Rs. 1200/ case.			
2.	<b>15.4.3</b> 15.4.3.1 15.4.3.2 15.5.3.1 15.4.3.4 15.4.3.5	<b>OTHER EYE DISEASES:</b> Diabetic Retinopathy Childhood Blindness Glaucoma Keratoplasty Vitreoretinal Surgery	Recurring Grant-in-aid for treatment/ management of Other Eye Diseases to Voluntry/NGO Organizations & Pvt. Practitioners (Diabetic Retinopathy, Childhood Blindness & Glaucoma- upto Rs. 2,000/- per case, Keratoplasty upto Rs. 7,500/- per case & Vitreoretinal Surgery Upto Rs. 10,000/- per case.			

Medical Superintendent KLE Dr. Prabhakar Kore Charitable Hospital

### **<u>6. Commitments of District Health Society:</u>**

Through this MOU, the District Health Society agrees to provide following support to participating NGO/Private Practitioner to facilitate service delivery (Write 'YES' against applicable clauses).

	Clause	Clause of agreement	Yes/no		
	1.	Issue a certificate of recognition about participation in NPCB (Annexure XVIII)			
	2.	Undertake random verification of operated cases not exceeding 5% before discharge of patients DBCS to verify (5%) the camp or surgery activity through personal visits or deputing PMOA as per the NPCB guidelines-ideally at the base hospital itself. Or the verification can be done at the time of follow up as informed by the NGO to DBCS.	Yes		
	3.	Sanction cost of here cataract operations and management of Diabetic Retinopathy, Glaucoma, Keratoplasty, Vitreoretinal Surgery & Childhood Blindness performed by the NGO/Private Practitioner as per GOI guidelines indicated within month of submission of claim along with cataract surgery records.	Yes		
NO	4.	Make payment of the sanctioned amount to the NGO/Private practitioner on monthly/quarterly basis	Yes		
Y	5.	Regularly disseminate literature, guidelines or any other relevant information to participating NGO/Private practitioner.	Yes		
Kulkarni 2994 3244	E	Provide a copy of the signed MOU to the NGO.	Yes		

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Medical Superintendent KLE Dr. Prabhakar Kore Charitable Hospitar Belagevi

### 7. Termination of MOU

Commitments agreed to by the Parties are meant for prevention and control of blindness and there for MOU should generally not be suspended or terminated. However, both parties can decide to suspend or terminate the MOU.

(Detailed profile of the NGO/ Pvt. Practitioner to be submitted as given at Annexure-I)

APRIL 05 Signed this day, the \_\_\_\_ of March 2023. ARY vrishali For and on behalf of for and on behalf of G Oli NGO/Private Practitioner (Blindness Contracti Division) Medical Superintendent KLE Dr. Prabhakar Kore Charitable Hospital Belagavi TAD 0 Vrishali P Kulkarni -ATTESTED BY Belagavi Reg. No. 13244 6) Exp. Date 07-08-2027 I P. KULKARNI B.S.L.,LL.M. OF Advocate & Notary No. of Correction 222/C2, Near II Rly Gate 1(one) R Congress Road, Tilakwadi Belagavi. 1 2 JUN 2023 RUE COPY P. KULKARNI B.S.L.,LL.N. Advocate & Notary

BELAGAVI

CENCENCENCENCENCENCENCENCENCENCE

Certificate No .: JD (M) HOTA 47 2022-23



### **Government of Karnataka**

Appropriate Authority for The Transplantation of Human Organs and Tissues Act, 1994 Bangalore - 560 009. Form - 17

CERTIFICATE OF RENEWAL REGISTRATION [Refer rule 25(2)]

This is with reference to application dated <u>07/12/2022</u> from <u>24/1/2023</u> K.L.E'S Dr. Pra blakar Kore Hospital 2 Medical Research centre, Nehru Nagar, Belagavi-590010 (Name of the Hospital / Tissue Bank) for renewal of Certificate of Registration for performing organ (s) / tissue (s) retrieval / transplantation / banking under the Transplantation of Human Organs & Tissues Act, 1994 (42 of 1994).

After having considered the facilities and standards of the above - said hospital / tissue bank, the Appropriate Authority hereby renews the certificate of registration of the said hospital / tissue bank for a period of five years.

EYE BANK

2. KERATOPLASTY

This renewal is being given with the current facilities and staff shown in the present application form. Any reduction in the staff and / or facility must be brought to the notice of the undersigned.

Place: Bergaturu

Date : 24 01 2023

\* Please see the conditions on the reverse

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Chairman, Appropriate Authority For the Transplantation of Human Organs & Tissues Act, 1994 And, Commissioner, Health, Family Welfare and AYUSH Services



# **Commissionerate of Health & Family Welfare Services,** Arogya Soudha, Magadi Road, Bangalore-560 023. **Government of Karnataka**

### Annexure

## E-997582 No. JD(M)/HOTA/47/2022-23

Date: /01/2023

conduct "Eye Bank & Keratoplasty" with the following recognized team of Doctors Keratoplasty" is renewed for the period of 2 years. The said Hospital is permitted to request dated: 10-09-2022 for issue the renewal registration to perform "Eye Bank & As per KLES Dr.Prabhakar Kore Hospital & MRC, Nehru Nagar, Belagavi - 590010

# List of Doctors for Keratoplasty & enucleation:

II) Keratoplasty

### J Enucleation :

- Dr. Shivanand Bubanale
- Dr. S.B.Patil
- Dr. Aravind Tenagi
- Dr. Smitha K S
- Dr. Bhagyajyothi B K
- Dr. Chethana Warad

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- Dr. Pragya Porwal
- Dr. Rohini D K
- 9 Dr. Sharvani Pai

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Dr. Sharvani Pai

Dr. Rohini D K

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Dr. Aravind Tenagi

Dr. S.B.Patil

Dr. Shivanand Bubanale

Dr. Smitha K S

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Dr.Deepashri Mutalik Dr. Chethana Warad Dr. Bhagyajyothi B K

- 10. Dr. Farheen Maniyar.
- 11. Dr. Daisy Vishwakarma
- 12. Dr. Samantha A Gomes
- 13. Dr. Dhruv Goyal

III) Anesthesia Team :

Dr.Manjunath C. Patil Dr.Rajesh S. Mane 11. Dr.Daisy Vishwakarma

10. Dr.Farheen Maniyar

- 14. Dr. Shashwat Porwal.
- 15. Dr. Mitali Mangoli
- 16. Dr. Samvedya Veenish
- 17. Dr. Ashly Biju
- 18. Dr. Keerti M Naik
- 19. Dr. Mehak Bhutani
- 20. Dr.Reshma Premanandan

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Dr.Mahantesh Mudakanagoudar

Dr.Sridevi Yenni

Dr.Chaitanya A. Kamat Dr.Kedareshwara K. S.

- 21. Dr.Zeel Prajapati
- 22. Dr.Shah Nisarg Sanjaykumar
- 23. Dr.Ashitha.E
- 24. Dr.Muskan Shyam Gaba
- 25. Dr.Suganya S

- 26. Dr.Yesha Savani
- 27. Dr.Annu Placid

31. Dr.Meloize Celianne Carvalho 30. Dr.Swikrity Chakraborty

32. Dr.Pradhosh M

- 29. Dr.Surumy S 28. Dr.Mona Rani

33. Dr.Vatsala Prasad

34. Dr.B K Jayanth Reddy

35. Dr. Tannu Bhanot

36. Dr.Shubhra Bhargava

37. Dr.Ritika Wani

38. Dr.Uman Bhadani

39. Dr.Shalaka Bhagat

40. Dr.Poojan M Patel

41. Dr.Shreya Mundada

42. Dr.Chaitra Shekar

43. Dr.Manali Sagare

44. Dr.Ruchi Kachoriya

W. 40

# Transplant Co-ordinator : Mr.Neeraj Dixit

Mrs.Parveen Y Pathan Mr.Vijay Piragane

further renewal cannot be taken up. 24.01.2025, within which Fire safety compliance report should be submitted failing which Authority and take permission for the new team of doctors. This annexure valid till If the team of doctors changes, the Hospital authority has to inform the Appropriate

du. 1.23

Commissioner Health and Family Welfare Services & Chairman, Appropriate Authority Transplantation of Human organs & Tissue Act, 1994

b

Certificate No .: JD(N)/HOTA/37/2021-22



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### **Government of Karnataka**

Appropriate Authority for The Transplantation of Human Organs and Tissues Act, 1994 Bangalore - 560 009.

Form - 17

CERTIFICATE OF RENEWAL REGISTRATION [Refer rule 25(2)]

This is with reference to application dated <u>11-11-2021</u> from <u>22-03-2022</u> (Name of the Hospital / Tissue Bank) for renewal of Certificate of Registration for performing organ (s) / tissue (s) retrieval / transplantation / banking under the Transplantation of Human Organs & Tissues Act, 1994 (42 of 1994).

After having considered the facilities and standards of the above - said hospital / tissue bank, the Appropriate Authority hereby renews the certificate of registration of the said hospital / tissue bank for a period of five years.

1. KIDNEY TRANSPLANTATION 2.

This renewal is being given with the current facilities and staff shown in the present application form. Any reduction in the staff and / or facility must be brought to the notice of the undersigned.

Place : Bengaluru

Date : 22/03/2022

\* Please see the conditions on the reverse

Chairman, Appropriate Authority For the Transplantation of Human Organs & Tissues Act, 1994 And, Commissioner, Health, Family Welfare and AYUSH Services 880 C880 C88

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### CONDITIONS

- The Certificate is valid only for the period mentioned and renewal application should be submitted 3 months before expiry of the validity
- The appropriate Authority shall have the right to inspect the Hospital at any time and suspend cancel the registration, if the facilities shown to be available do not exist during the inspection.
- The hospital must obtain informed consent both from the donor and recipient before undertaking the transplant. To enable the patient to give the informed consent, the hospital shall
  - a. Thoroughly counsel both the recipient and the donor about the possible complications, which may be experienced before, during and after the transplantation.
  - b. The counseling should also cover the possible costs of transplantation and maintenance after the transplantation in terms of follow up, the drugs to be used and precautions to be taken at home, etc.
  - c. Both the recipient and the donor shall be given booklets in Kannada and English with detailed information about the investigation required to be carried out on both of them, the possible complication during investigations, transplantation thereafter, approximate assessment of the costs, the precautions required to be taken by the patient after the transplantation, the possible adverse consequences if each of these precautions required are not taken. This booklet should be given to the patient at-least 15 days before the scheduled date of transplantation to enable the donor and recipient to give informed consent.
  - d. Subject both the donor recipient to psychiantric evaluation.

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- The hospital shall prominently display in the respective departments :
  - "Under Section 19 and 19A of Transplantation of human organs And tissues Act 1994, whoever"
  - a. Makes or received any payment for the supply of ,or for an offer to supply, any human organ / issue;
  - b. Seeks to find a person willing to supply for payment of any human organ / tissue;
  - c. Offers to supply any human organ / tissue for payment;
  - d. Initiates or negotiates any arrangement involving the making of any payment for the supply of, or for an offer to supply, any human organ / tissue;
  - e. Takes part in the management or control of a body of person, whether a society, firm or company, whose activities consist of or include the initiation or negotiation of any arrangement referred to in clause (d); or
  - f. Publishes or distributes or causes to the published or distributed any advertisement
    - 1. Inviting persons to supply for payment of any human organ / tissue;
    - 2. Offering to supply any human organ / tissue for payment; or
    - 3. Indicating that the advertise is willing to initiate or negotiable any arrangement referred to in clause (d)
  - g. Abets in the preparation or submission of false documents including giving false affidavits to establish that the donor is making the donation of the human organs / tissue as a near relative or by reason of affection or attachment towards the recipient.

Shall be punishable with imprisonment as per section 19/19A of the Act.

- 5. The hospital shall provide free treatment for all ailments of the donor for a period of atleast one year after the transplantation and the records of follow up shall be maintained.
- 6. Proper registers indicating surgery, anesthesia etc. and consent forms shall be maintained for each and every patient. (Donor / Receiver of human organs)
- 7. Whenever the donor is unrelated to the recipient, the permission of the Authorisation Committee shall be obtained.
- 8. For cadaveric transplant, necessary brain death certificate shall be obtained observing all formalities as per rules.
- 9. Every case of death of recipient / donor within one year of Transplantation should be reported to the Appropriated Authority within seven days from the date of death.
- 10. The Hospital shall send a Monthly report of Transplantation cases performed to the the Appropriate Authority in the prescribed format by the 15th of the following month,
- 11. Approved team and Doctors list is enclosed in the Annexure.

### Annexure

# No. JD(M)/HOTA/37/2021-22

# Date: 24/03/2022

following recognized team of Doctors. years from the date of issue of Certificate of registration. The said Hospital is registration to perform "Kidney Transplantation" is given for a period of 5 Belagavi permitted to conduct the above said organ transplantation surgeries with the As per of KLES 590010 request dated 11-11-2021 for issue Dr.Prabhakar Kore Hospital & MRC,Nehru Nagar, the renewal

## Surgical Team: Kidney Transplantation Team :

- Ŀ Dr.R.B.Nerli
- Dr.S.I.Neeli
- Dr.Vikram Prabha
- Dr.Shivagouda Patil

# Anesthesia Team :

- 1 Dr Rajesh Mane
- N Dr Vinay Jannu
- ω Dr Guruprasad Shetty

# Medical Team:

- Dr.M.S. Khanpet (Karishetti)
- -Dr.Ritesh Vernekar
- N Dr.Ravi Sarvi
- ω Dr. Mahatesh Patil

# ICU/ Critical Care Team:

Dr Manjunath Shivapujimath

# Transplant Co-ordinator : 1. Mr.Neeraj Dixit

3. Mr.Rudra gouda Patil 2. Mrs. Parveen Y Pathan

Appropriate Authority and take permission for the new team of doctors. If the team of Doctors changes, the Hospital authority has to inform the

Health and Family Welfare Services & Commissioner 3.24

Transplaµtation of Human organs & Tissue Act, 1994

🕅 Chairman, Appropriate-Authority

### Department of Health & Family Welfare KARNATAKA STATE AIDS PREVENTION SOCIETY 2<sup>rd</sup> Floor, Sir. C. V. Raman Hospital, 80 feet Road, Indiranagar, Bengaluru -560 038.

No.: KSAPS/Lab service/Viral Load/02/2017-18

Date: 27.04.2017

### To

The Director/Principal/District Surgeon, Medical Institute/Medical College/District Hospital, Karnataka.

Dear Sir/Madam,

### Sub: Scaling up Viral Load testing in the National HIV Programme at Karnataka State for the FY: 2017-18

### \*\*\*\*\*

With reference to the above subject, I am please to inform you that NACO has planned to procure Viral Load Machine and all other necessary equipment related to the viral load testing and also providing Rs.10, 00,000/- for renovation work. Hence requested to prepare budget in the prescribed attachment and make sure that your institute to be ready before setting up the laboratory. Thanking you,

Yours faithfully,

Project Director, KSAPS, Bengaluru.

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### Copy to:

- 1, Additional Project Director, KSAPS, Bengaluru.
- 2. Joint Director (CST), KSAPS, Bengaluru.
- 3. Director, NIMHANS, Bengaluru.
- 4. Director, JSS MC, Mysuru.
- 5. Director, VIIMS, Bellari.
- Director, BMCRI, Bengaluru.
   Principal, BLDEMC, Vijayapura.
- 8. Director, KIMS, Huballi.

9 Director, INMC, Belga

- 10. District Surgeon, District Hospital, Kalburgi.
- 11. District Surgeon, District Hospital, Shivmogga.
- 12. NRL/SRL, In -Charge's (NIMHANS, JSS, JNMC, KIMS, BLDEMC, VIMS, BMCR)
- 13. Regional Coordinator, KSAPS, Bengaluru.
- 14. Quality Manager (Lab Services) KSAPS, Bengaluru.
- 15. Office Copy

Email:jdfinksaps@gmail.com



### DEPARTMENT OF HEALTH AND FAMILY WELFARE KARNATAKA STATE AIDS PREVENTION SOCIETY

Sir. C.V. Raman General Hospital, 2nd Floor, 80 feet Road, Indiranagar, Bengaluru-39

### No: KSAPS/Lab Services/Viral Load02/2017-18

Date: 31.03.2018

### RELEASE ORDER (GFATM FUND RRC-IV)

Sub: Payment of advance for 9 SRL Centres towards setting up

Viral Load Lab - reg

Ref: Approval by PD para no.(23) Date: 31.03.2018

\*\*\*\*\*

Approval is accorded for payment of Rs.46,50,000/- (Rupees Forty Six Lakhs Fifty

**Thousand only)** towards 9 SRL Centre's as mentioned below towards setting up Viral Load Laboratory:

Sl.No	District	Name of the ART Centres	Bank Account No.	IFSC Code No.	Advance
1	Bangalor e	BB NIMHANS, BANGALURU KAR	64026237300	SBIN0040675	600,000
2	Bangalor e	Dept of Microbiology Victoria haspital bangalore medical college	54018114189	SBIN0070242	600,000
3	Bellary Dept of Microbiology, Vijayanagar institute of medical science Bellary 64051136253		SBIN0040456	600,000	
4	Hubli	SRL Dept of Microbiology Karnataka Institute of Medical Sciences Hubli	64017454406	SBIN0040493	600,000
5	Belgum	SRL Dept of Microbiology JN Medical College Belgum (Private)	05042010064815	SYNB0000504	350,000
6	BijapurDept of Microbiology BLDEU sri patil medical college Bijapur (Private)64019705415SBIN0014429 3		50,000		
7	Mysore         SRL Dept of Microbiology JSS Medical College Mysore (Private)         64137295345		SBIN0040547	350,000	
8	Gulbarga	DAPCU Gulbarg	30341210643	SBIN0003304	600,000
9	Shimoga	DAPCU Shimoga	64026236533	SBIN0040580	600,000
	1	TOTAL			46,50,000

Dantey ups.

The advance is released under Global Fund IV under Component 2.2.6 - subject to the following conditions:

- 1. The Amount released shall be utilized for the same purpose for which it has been released.
- 2. Programme Officer shall communicate the Component wise allocation.
- 3. The Expenditure shall be incurred as per the guidelines issued by KSAPS.
- 4. The Expenditure shall be limited to the component wise budget allocation communicated by KSAPS.
- 5. Excess expenditure incurred (if any) under any of the activities will not be admitted.
- 6. The unspent of the advance if any, shall not be utilized for un approved activities and the unspent amount and the interest accrued on SB account shall be remitted back to KSAPS by PFMS only.
- 7. Utilization Certificates and Statement of Expenditure duly certified by AMO's shall be submitted to Finance Section of KSAPS.
- 8. All the Payments shall be made in PFMS only.

### Assistant Director (Finance) KSAPS, Bangalore





080 - 2528143 Fax:080 - 25281430 E-Mail: jdfinksaps@gmail.com

### DEPARTMENT OF HEALTH AND FAMILY WELFARE KARNATAKA STATE AIDS PREVENTION SOCIETY

Sir. C.V. Raman General Hospital, 2nd Floor 80 Feet Road, Indiranagar, Bengaluru-38.

No.KSAPS/Lab Service/Viral/load/02/17-18

Date:29.03.2019

### RELEASE ORDER (DBS FUND)

Sub: Release of advance towards Setting up Viral Load at SRL's for the year 2018-19

Sanction is accorded for payment of Rs 10,50,000/- (Rs Ten lakhs thousand only) to Institution as mentioned below through PFMS to their concerned SB accounts towards Setting up Viral Load at SRL's.

SI No	Name of the SRL	Name of theAccount Holder	A/c No	Total Amount
J	Dept.of Microbiolgy, JN Medical College, Belgaum	M/s ICHAP Project	05042010064815	<mark>(350,000)</mark>
2	Dept.Microbiology. BLDEU's Shri BM Patil Medical College, Bijapur	SR <b>L Department of</b> Mic <b>robiology</b>	37595420172	350,000
3	Dept.of Microbiology, JSS Medical College. Mysore.	State Reference Laboratory	64137295345	350,000
;		Total		1,050,000

The advance is released under DBS Fund subject to the following conditions:

- I The amount released shall be utilised for the same purpose for which it has been released.
- 2 The programme officer shall communicate the component wise budget allocation to the concerned.
- 3 The expenditure shall be limited to the component wise budget allocation communicated by KSAPS.
- 4 Excess expenditure incurred (if any) under any of the activities will not be admitted.

5 It is instructed to operate the funds through PFMS as per Circular No. KSAPS/ JD(F)/PFMS/2016-17 dated 09.10.2017 and the unspent amount of grant released including the Interest accrued on SB account shall be returned back to KSAPS through PFMS only.

Jude 1/s/19

- 6 The UC and monthly SOE submitted to KSAPS should clearly specify under which fund the amount was released and Utilised along with the original Bills or certified bills & Vouchers by
- 7 State Programme Officers shall certify on the Utilisation certificates and statement of Expenditure and confirmation of the programme on which purpose fund released then 8 The advance Settlement within One month from the date of release of advance.
- 9 The unspent amount should be remitted to KSAPS Account No.64094979930 through PFMS with out fail, acknowledgement of PPA sent to KSAPS through mail. With out

acknowledgement of PPA we are unable to receipt of unspent amount.

PPA NO C031933660625 dt.29.03.2019 Rs.3,50,000/-PPA NO C031933929020 dt.29.03.2019 Rs.7,00,000/-

Assistant Director(Finance) KSAPS, Bangalore

Copy & Necessary action

- 1 Additional Project Director, KSAPS, Bangalore
- 2 Quality Manager Lab Service, KSAPS, Bangalore
- 3 All District AIDS Prevention and Control Units (DAPCUs)
- 4 Office Copy











### MEMORANDUM OF UNDERSTANDING

### Hospital Based Cancer Registries in India

National Cancer Registry Programme ICMR-National Centre for Disease Informatics and Research, Bengaluru

The broad and overall objective of ICMR-National Centre for Disease Informatics and Research (ICMR-NCDIR), Bengaluru is to sustain and develop a national research data-base on cancer, diabetes, CVD, stroke, other NCDs and their risk factors through recent advances in electronic information technology with a national collaborative network, so as to undertake etiological, epidemiological, clinical and disease control research in these areas.

The National Cancer Registry Programme (NCRP) was initiated in 1981 by the ICMR, and is presently coordinated at ICMR-NCDIR, Bengaluru. It operates through a network of Population Based Cancer Registries(PBCRs) and Hospital Based Cancer Registries(HBCRs) across different parts of the country. The data collected enables to estimates cancer incidence, mortality, trends, burden, clinical management, outcome and survival. The information aids efforts towards cancer prevention and control in the country.

This Hospital Based Cancer Registry is being implemented by ICMR- NCDIR, Bengaluru at KLE'S DR PRABHAKAR KORE HOSPITAL & MRC BELAGAVI \_\_\_\_\_ with the following aim / objectives.

- 1. Profile and patterns of cancer in patients attending the hospital/health facilities
- 2. Describe the diagnostic, clinical, treatment and outcome parameters
- Contribute to the respective PBCRs in India under ICMR-NCDIR-NCRP

The basic methodology for the project "Hospital Based Cancer Registries in India" envisages capturing core patient information on demography, clinical details, treatment and outcome of all cancers reported/registered at all departments/units/sections who are involved in cancer diagnosis/ treatment/care in the hospital.

Agreement for co-operation in the performance of work on "Hospital Based Cancer Registries in India" through ICMR-NCDIR, Bengaluru between Dr. Prashant Mathur, Director, ICMR-National Centre for Disease Informatics and Research, Bengaluru, hereinafter called Principal Investigator (PI) and DR KUMAR VINCHURKAR hereinafter called Principal Investigator of Participating Centre (C-PI).

The project sanction is up to March 2027 and it is effective from 1<sup>st</sup> April 2023. The funds will be released on installment basis based on quality of data submission and overall performance. The C-PI is responsible for the following:

- Collection, collation and transmission of data of all malignant neoplasms reported/diagnosed/treated from the above centre from 1<sup>st</sup> January 2023 onwards.
- Follow the terms and conditions (as specified in Annexure I) are necessary for uniformity and successful execution of the study.
- 3. Managing funds provided for the said purpose as per guidance and rules applicable.
- Submission of duly signed utilization certificate on a regular basis.

In consideration of the above, an annual budget of up to ₹ **3,15,000**/- (In Rupees Three Lakh and Fifteen Thousand only ) per year is provided for the financial year 2023-24, and will be released in installments after receiving duly completed MoU and other codal formalities.

The undersigned parties hereby agree and conclude the present agreement:

Signature:

Signature:

Name, title & Institution: Dr. Prashant Mathur Principal Investigator & Director ICMR-NCDIR, Bengaluru Email ID: <u>director-ncdir@icmr.gov.in</u> Date: Principal Investigator (C-PI)

Name:Dr Kumar Vinchurkar Designation: Consultant Surgical Oncology

Mobile: 8277538780

Email:vkumar\_007@yahoo.com

Date: 11/05/2023 . (77

Head of the institution

Dr. M. V. Jali, D., FRCP (LONDON), D.L.R. Name: stor and CEO Designation: **(LES Cencer Hot** Mobile: betologist, sor & Chie C Reg. No. 16554 Email: KLES Dr. Prabhakar Kore Hospital & MRC KAHER'S J. N. Medical College, Full Postal adgeisgavi - 590010 INDIA website: Armvjali@gmail. Com Hmedicaldinector@klehospital org medicaldirector@klehospital org Institutional website: Date: hospital.org

### ANNEXURE-I

### Terms and Conditions

### **Roles and Responsibilities:**

### A. Principal Investigator (PI), ICMR-NCDIR

- Deploy standard protocol, tools and methods of National Cancer Registry Programme (NCRP) for collection of data at HBCRs. This includes provision of Core forms for abstraction of cases, procedure manuals and technical support to the participating center or study tools, as per needs of the study.
- 2. Access to the online software along with secure login credentials to the C-PI.
- To organize periodic training, re-training of registry staff. This will employ physical onsite programs as well as online electronic methods
- Monitor the quality of data being collected, transmitted to ICMR-NCDIR, completeness and clarifications
- The cancer data collected through this collaboration will be used to augment the NCRP database.
- ICMR- NCDIR does not accept any responsibility for persons hired for the activity by the participating centre and thus will have no legal liability relating to the implementation of this MoU.

### B. Principal Investigator of the participating centre (C-PI)

- C-PI will be nominated by the respective Head of Institution. All other Co-PIs will be identified by the C-PI as relevant (i.e., clinicians from surgical/radiation/medical oncology departments and a pathologist) to the implementation of the project with the approval of Head of the Institution.
- 2. C-PI will have overall responsibility for the execution of the project in the participating centre as per guidelines. This basically includes collection and collation of data of all malignant neoplasms reported/diagnosed/treated in the participating centre from the 1<sup>st</sup> January 2023, with specific attention to capture of complete and correct residential address, including patient identification details, exact anatomical site of cancer, stage and treatment. HBCR should cover the cases from various departments/units (surgery, radiation, medical oncology, pediatrics, general medicine/surgery, obstetrics and gynaecology, ophthalmology and other departments) from the entire institution whenever any case of cancer is diagnosed or managed to cover complete details. Data collection has to be done in the prescribed format (HBCR coreform) as per guidelines provided in the procedure manual. The same data should be entered into the online software provided by ICMR-NCDIR and transmitted preferably daily to ICMR-NCDIR.
- The C-PI will be the main corresponding / contact person for all matters including utilization of funds and be the overall in-charge of the project Hospital Based Cancer Registry in India.
- 4. C-PI should have Co-Principal Investigators (Co-PI) from all the oncology and cancer related departments. If for any reason the C-PI leaves, an eligible clinician/Co-PI with the concurrence of the Head of the Institution should be nominated and a request for approval of ICMR-NCDIR should be sent well in advance along with detailed Biodata and letter of acceptance for the position and responsibility.
- 5. Based on local set-up the C-PI /Co-PIs could also identify junior staff members as Faculty-in-charge. This person(s) along with the senior most staff employed under the project would be responsible for the day to day working of the project. This day to day working includes ensuring:
  - Completion of core proforma for "Hospital Based Cancer Registry in India" and regular data transmission.

- Maintain the quality of data during abstraction and transmission.
- iii) Ensure that the hired manpower is acquainted with the methodology of data collection and abstraction through interim in-house reviews.
- iv) Internal meetings with all the investigators and concerned staff should be conducted periodically.
- Assist in order to provide any clarifications sought by ICMR-NCDIR;
- Facilitate the Principal Investigator/representative(s) during their visits for monitoring, supervision and quality assurance of the data collected.
- The C-PI and Co-PIs along with the concerned staff should strictly adhere to participate in the meetings along with suitable representative who will also participate in workshops / training programmes and present the progress of work.
- 8. As ICMR-NCDIR is providing the funds for the project Hospital Based Cancer Registries in India, the primary data of HBCR belongs both to your centre and to ICMR-NCDIR. Therefore, the C-PI should take approval from ICMR-NCDIR before providing/sharing the primary data with any third party / any agency. The ICMR-NCDIR policy on data processing and disclosure shall be followed as applicable from time to time.
- The space and basic equipment, furniture and other assistance required for the smooth working of the project shall be provided by the host institution. No assets should be procured from the project fund.
- Hiring of manpower for the purpose of project as per the rules and regulations of the participating centre and should take the overall responsibility.

### C. Accounts:

1. Grant-in-aid: General, Lump sum grants would be released.

- -

- Submission of Utilization Certificate along with Receipts and Payments Accounts after completion of the financial year (duly certified and signed by C-PI and Accounts Officer / Head of the Institution to be submitted).
- ii) Adjustment of closing balance of previous year as shown in Utilization Certificate.
- Head of the Institution / C-PI will have the liberty of allocation of the funds for functioning of registry and its requirements such as hiring of manpower, training, workshop, contingencies etc. as such C-PIs may get work done in an effective manner. No person should be hired on very long term basis continuously.
- The funds provided should be spent for the purpose for which it has been sanctioned and should not exceed the allocated budget. Any deviation in budget utilization needs prior approval from ICMR-NCDIR, Bengaluru
- 4. Funds would be provided to your institutional bank account or specific account dedicated for this project and details of records of expenditure incurred shall be maintained. The accounts will be subjected to audit by the authorized auditors/accounts officer of the centre.
- Bank interest accrued in a financial year should not be utilized by the centre and should be refunded to ICMR-NCDIR.
- The grant released by ICMR-NCDIR shall be refunded as per unspent amount available at the participating centre if and when ICMR-NCDIR or grantee concerned discontinues mid-way or does not follow the terms and conditions laid down and approved.

7. The C-PI must keep track of all circulars/ Notices/ Letters sent by ICMR-NCDIR.

### D. Core and Patient Information Form:

- The project core forms will be printed and provided to the respective participating centre by ICMR-NCDIR.
- A hard copy of the core form should be completed (and updated) for all malignant cases reported in the respective participating centre.
- The filled hard copy of the core form shall be preserved for a minimum of 5 years from the date of termination of the project.

### E. Data Transmission:

- Transmission of data on each patient has to be done regularly through the website <u>https://www.ncdirindia.org</u>. The login credentials to access the online software will be provided by ICMR-NCDIR.
- The centre has to place a request for replenishment of HBCR core forms at least one month in advance through the portal.
- The core identifying and diagnostic information/ Treatment details has to be transmitted within two weeks of data collection.
- Methods for coordination with other departments, verification of quality errors and data entry should be developed by each participating centre.
- 5. ICMR-NCDIR will monitor the completeness and quality of data transmitted periodically.
- 6. Poor quality of data will not be accepted for publication in the periodic reports of the NCRP.

### F. Quality of data:

HBCR data which is submitted undergoes following processing steps at ICMR-NCDIR:

- ICMR NCDIR assess the coverage of the data from the respective hospital. Data abstraction should be done from all departments including pathology, surgical oncology, radiation oncology, medical oncology and any other departments where cancer is diagnosed and treated. If there is a lack of coverage, the registry will be informed to ascertain missing cases. Once the data is complete, the following steps are taken to make it complete, free from errors as per standards and international norms.
- 2. Quality Control -
  - Data should be complete in all aspects, especially the treatment and follow up details.
  - b. Registries can perform checks on the data transmitted through the HBCR software. NCDIR shall also perform checks on the data to evaluate the quality of the submitted data. The generation of error tables is followed by the dispatch of erroneous data to respective registries for inputs/corrections. The corrections are made in the HBCR software by the respective registries.
  - c. Duplicates are identified and shared with the registry for concurrence and subsequently the elimination is done by ICMR -NCDIR.
  - d. Data is further evaluated for consistency checks and if the coverage and quality of data is found to be satisfactory, data of the centre is finalized and will be used for analysis and report preparation.

### G. Data Access:

- a. Each centre is provided access to download its own raw data for quality control (above Point no. 2. a,b,c) at any time for purposes of data monitoring, and any further analysis. It is to be noted that this data has not completed the Quality control steps and therefore is not final data. The C-PI is responsible for the access of data at this stage, and its further use.
- b. Data that has completed all steps of QC (2.a to d) is final and will be included in the analysis for reports and publications prepared by ICMR-NCDIR.
- c. The finalized data will be also available for access to each participating centre for further use as deemed fit.

### H. Report of Work Done:

- The grant is being sanctioned on the condition that reports on the progress of work done on the project will be submitted by the participating centre to the ICMR-NCDIR, as and when called for as per format.
- Timely release of grants necessitates timely submission of data to ICMR-NCDIR. The deadlines for submission of data have to be adhered.

### I. Data use and Publication:

- The HBCR can share information with another HBCR under NCRP only based on specific request from another HBCR under information to ICMR-NCDIR.
- HBCR data shall be used by ICMR-NCDIR to strengthen the information in case diagnosis/treatment/follow up/outcome in any PBCR/HBCR under the NCRP.
- 3. iCMR-NCDIR shall finalize datasets of each HBCR on an annual basis.
- 4. The individual C-PI is responsible for publication of the collected / verified data from the participating centre, after the data is accepted by ICMR-NCDIR, with due acknowledgement of ICMR-NCDIR-NCRP
- It is encouraged that HBCRs should publish the data periodically in the form of annual reports/manuscripts with due acknowledgment of the ICMR-NCDIR and proper citation of the ICMR-NCDIR and HBCRDM software.
- The analysis, report preparation and publication of the verified / collected pooled data is the responsibility of the ICMR-NCDIR-NCRP.
- A list of papers published on the work carried out for this study by the HBCR under the auspices of the ICMR-NCDIR shall be submitted along with reprints of the papers periodically.
- Data collected and finalized can be used for thesis/publication/sharing with government departments.

### J. Ethical Clearance:

 The participating centre shall obtain IEC approval for the project before commencement of data collection and submit the same to ICMR-NCDIR as per the ICMR 'National Ethical Guidelines for Biomedical and Health Research involving Human Participant-2017'. The necessary ethical clearance including patient consent will be the responsibility of the participating centre.

### K. Data Confidentiality:

- The participating centre will abide by the concerned ICMR-NCDIR policy on data processing and disclosure to ensure a stable, reliable, ethical and legally compliant framework for data collection, use and dissemination by the NCDIR.
- The C-PI should ensure that the staff of the participating centre maintain patient confidentiality and also maintain data confidentiality and data security. Measures to maintain data security and protection as per the ICMR-NCDIR policy will be followed by the centre.

### L. Specific Conditions on Use of Software:

- No part of this software may be copied or used without the written consent of ICMR-NCDIR. Copyright © 2014, ICMR, New Delhi, All Rights Reserved.
- 2. Software, database and login credentials should be used only by authorized persons at authorized locations. Change of C-PI or discontinuation of the services of any hired manpower having knowledge of the login credentials must be intimated to ICMR-NCDIR so that the previous password is invalidated and fresh credentials will be issued to the participating centre. Undertaking on data confidentiality must be taken from staffs. Any violation of terms and conditions shall attract discontinuation of contract.

### M. Termination of the project:

- 1. Either party can terminate the project, with valid reasons and adequate time.
- 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 ICMR-NCDIR within a month from the date of termination of the research scheme.

This MoU is valid for two calendar years and needs to be renewed by both parties.



### FIRST AMENDMENT TO THE INDIA CENTER AT JEFFERSON FOR HEALTH PROFESSIONS EDUCATION AND RESEARCH AFFILIATION AND SUPPORT AGREEMENT

This **FIRST** AMENDMENT TO THE INDIA CENTER AT **JEFFERSON** FOR HEALTH PROFESSIONS EDUCATION AND RESEARCH AFFILIATION AND SUPPORT AGREEMENT ("First Amendment") is entered into by and between THOMAS JEFFERSON UNIVERSITY ("Jefferson") and KLE ACADEMY OF HIGHER EDUCATION AND RESEARCH-BELGAUM ("KLE").

WHEREAS, Jefferson and KLE entered into THE INDIA CENTER AT JEFFERSON FOR HEALTH PROFESSIONS EDUCATION AND RESEARCH AFFILIATION AND SUPPORT AGREEMENT ("Agreement") effective July 26, 2017; and

WHEREAS, in accordance with Agreement Paragraph 2.2, Amendment, the parties desire to modify the terms of the Agreement to renew the term of the Agreement and change the funding support.

NOW, THEREFORE, in consideration of the mutual covenants herein contained and intending to be legally bound hereby, the parties agree as follows:

- Article 1.1 shall be revised to read as "in priority areas that may include Integrative Medicine, 1. Urology, Neurology, Psychiatry, Radiology, Nursing Public Health. Sciences, Physical/Rehabilitative/Occupational therapy and other areas that may be identified by mutual consultation".
- 2. Paragraph 2.1, Term shall be revised to read as follows:

Term. This Agreement shall be effective as of the Agreement Effective Date and will 2.1. remain in force for a period of two (2) years until 2019. The Term shall be renewed for an additional three (3) year period beginning July 1, 2019 and ending June 30, 2022 (the "Renewal Term"). All terms of the Agreement shall apply to the Renewal Term.

3. Paragraph 3.1, Support Funding shall be revised to read as follows:

> Support Funding. KLE shall provide funding to Jefferson for the India Center, which 3.1 funding may be used to provide general program support to accomplish the goals and purpose of the India Center for the term of the Agreement, including but not limited to, salaries and personnel costs, materials and services, telephone, and overhead. KLE shall pay Jefferson One Hundred Thousand Dollars (\$100,000 US) annually during the Renewal Term.

- 4. Paragraph 3.2.1, shall be revised to read as "for two visitors for visits of one (1) to two (2) weeks in priority areas to include Integrative Medicine, Public Health, Urology, Neurology, Psychiatry, Radiology, Nursing Sciences, Physical/Rehabilitative/Occupational therapy and other areas that may be identified by mutual consultation".
- The address noted in paragraph 9.8 for Jefferson's legal counsel shall be changed to: Thomas 5. Jefferson University, Office of Legal Affairs, 834 Chestnut Street, Suite 400, Philadelphia, PA 19107, Attention: Chief Counsel.
- 6. This First Amendment is effective on June 1, 2019, (the "Amendment Effective Date").

This First Amendment to the Agreement is incorporated into and made part of the Agreement and all provisions of the Agreement not expressly modified or amended hereby shall remain in full force and effect.

**IN WITNESS WHEREOF**, the duly authorized representatives of Jefferson and KLE have executed this First Amendment to the Agreement as of the Amendment Effective Date.

**KLE ACADEMY OF HIGHER EDUCATION AND RESEARCH, BELGAUM** 

### THOMAS JEFFERSON UNIVERSITY, PHILADELPHIA

By: Dr. VD Patil Its: Registrar

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By: Dr. Vivek A Saoji Its: Vice Chancellor

Richard Derman, MD

By: Richard Derman, MD Its: Associate Provost, Global Affairs

By: Mark L. Tykocinski, MD Its: Provost

Dr. Prablakar B. Kore

By: Dr. Prabhakar B. Kore Its: Chancellor and Chairman

By: Steplen K Klasko, MD, MBA Its: President Chief Executive Officer



### MEMORANDUM OF UNDERSTANDING



### **KLE University**

(Formerly known as KLE Academy of Higher Education and Research),

herein represented by Dr. Prabhakar Kore, Chancellor, KLE University and Dr. V.D.Patil, Registrar, KLE University A Deemed University u/s 3 of the UGC Act 1956 vide Government of India notification No.9-19/2000-U.3A Belagavi-590010, Karnataka, India

### AND

### Thomas Jefferson University, Philadelphia, USA,

herein represented by

Dr. Stephen K.Klasko, MD, MBA President and Chief Executive Officer, Thomas Jefferson University and Jefferson Health

> Dr. Richard J.Derman, MD, MPH Associate Provost, Global Affairs, Thomas Jefferson University

THOMAS JEFFERSON UNIVERSITY

Dr. Stephen K.Klasko, MD, MBA President and Chief Executive Officer, Thomas Jefferson University and Jefferson Health

Dr. Richard J.Derman, MD, MPH Associate Provost, Global Affairs, Thomas Jefferson University

KLE UNIVERSITY-BELAGAVI

Dr. Prabhakar B. Kore Chancellor and Chairman

Dr. V.D.Patil Registrar

### THE INDIA CENTER AT JEFFERSON FOR HEALTH PROFESSIONS EDUCATION AND RESEARCH

### AFFILIATION AND SUPPORT AGREEMENT

This Affiliation and Support Agreement ("Agreement") is entered into on \_\_\_\_\_\_, 2017 ("Effective Date") by and between Thomas Jefferson University ("Jefferson") and KLE University-Belgaum ("KLE") JEFFERSON and KLE are collectively referred to as the "Parties".

### BACKGROUND

WHEREAS, Jefferson and KLE desire to collaborate to work toward the creation of The India Center at Jefferson (the "India Center") to promote collaboration in the fields of health professions education and research as more fully set forth herein; and

WHEREAS, the Parties recognize that with the establishment of the Center, meaningful exchanges of health professionals will be possible through an organized system for coordinating these visits that will be provided by the India Center.

WHEREAS, the Parties further believe that the India Center has the potential to facilitate international research between the Parties.

NOW, THEREFORE, the Parties agree as follows:

### ARTICLE I: THE GOALS, PURPOSE, AND STRUCTURE OF THE INDIA CENTER

1.1 **Goals.** The goals of the India Center are to support education, research and professional collaboration of health professionals in three (3) priority areas to include Integrative Medicine, Public Health and Urology.

1.2 **Purpose.** The purpose of the India Center is to achieve the following:

- Provide support for the newest, best clinical practices at KLE in the priority areas;
- Provide for the sharing of clinical protocols to support practice change directed at improving clinical outcomes for KLE patients in the priority areas;
- Supplement the development of health professionals in each of the priority areas by facilitating the exchange of health personnel by providing educational experiences at Jefferson for KLE health professionals and identifying opportunities for similar experiences at KLE for Jefferson health professionals;
- · Collect information on the exchanges to assess the satisfaction of the exchanges;
- Support academic collaborations for generating scholarly publications;
- Facilitate the development of research collaborations and the potential for conducting research as resources permit, including generating fundable research;
- Explore the development of data registries;
- Develop a platform of distance learning including online programs for health care professionals including medical students and medical residents in each of the priority areas; and
- Establish a collaborative clinical conference for India that will be held annually, alternating the site between India and Philadelphia, Pennsylvania, USA.

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1.3 Structure. Jefferson shall work toward establishing the India Center at Jefferson and appoint a Director of the India Center and provide personnel to staff the India Center to accomplish its purpose. Academicians from Jefferson and KLE shall be appointed to the India Center's Advisory Committee. The Advisory Committee will work to achieve the goals and purpose of the India Center. The Advisory Committee will also provide appropriate advice to the Director of the India Center to enhance satisfaction with the exchange program. The Advisory Committee will assess the progress of the India Center in meeting its goals and purposes on an annual basis.

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### ARTICLE II: TERM, AMENDMENT, RENEWAL AND TERMINATION

2.1 Term. This Agreement shall be effective as of the Effective Date and will remain in force for a period of two (2) years until 2019 (the "Expiration Date").

2.2 Amendment. This Agreement may be amended by written agreement signed by authorized representatives of the Parties.

2.3 **Renewal.** The Agreement shall be automatically renewed for an additional one (1) year period without change unless one party gives the other party at least three (3) months written notice prior to the Expiration Date.

2.4 **Termination.** The Agreement may be terminated with three (3) months advance notice to the other party at any time for any reason by the appropriate authority of the party, unless an earlier date is mutually agreed upon. In this case, the Parties shall talk in good faith before terminating the Agreement.

### **ARTICLE III: FUNDING OF THE INDIA CENTER AND VISITATION COSTS**

3.1 **Support Funding.** KLE shall provide funding to Jefferson for the India Center, which funding may be used to provide general program support to accomplish the goals and purpose of the India Center for the term of the Agreement, including but not limited to, salaries and personnel costs, materials and services, telephone, and overhead. KLE shall pay Jefferson One Hundred and Fifty Thousand Dollars (\$150,000 US) annually.

3.2 Visitation Costs.

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**3.2-1** No visitation fees shall be charged for annual planned visits of KLE professionals to Jefferson for two (2) visitors for visits of one (1) to two (2) weeks in duration in each of the three (3) priority areas to include Integrative Medicine, Public Health and Urology with follow up visits by Jefferson professionals to KLE. In addition, for these visitors, Jefferson shall be responsible to pay the reasonable cost of hotel accommodations for visits by KLE professionals to Jefferson and KLE shall be responsible to pay the reasonable cost of hotel accommodations for visits by KLE professionals to KLE.

3.2-2 Jefferson agrees to accept additional visitors from KLE during the term of the Agreement. For such additional visitors, KLE shall pay Jefferson visitation costs as follows:

<b>Discounted Costs</b>	for KLE ba	ased on dura	tion of the e	xchange (US	\$)
	1 week	2 weeks	1 month	2 months	3 months
Medical Students	600	1,200	1,800	3,600	5,400
Physicians	900	1,800	3,000	6,000	9,000
Nurses	450	900	1,500	3,000	4,500
Other health					
professionals	450	900	1,500	3,000	4,500

KLE agrees to pay visitation costs at the rates specified in Section 3.2-2, according to the type of Exchange Visitors sent to Jefferson and the duration of the exchange. Payment for the visitation costs of each exchange (single or group) shall be paid in full a minimum of thirty (30) days before the arrival of the visitor(s).

Online Course and Distance Learning Costs. When developed, KLE shall be offered a 3.3 discount for online courses and distance learning to include online courses and distance learning in certain Masters' degree programs (Safety, Quality and Health Outcomes) through the Jefferson College of Population Health.

### ARTICLE IV: EXCHANGE VISITORS AND PROGRAMS 4.1 **Definitions:**

4.1-1 "Home Facility" means the party sending staff or students to the Host Facility.

- 4.1-2 "Host Facility" means the facility accepting the staff or students from the Home Facility.
- "Inviting Facility" means the facility requesting a staff or student to participate in a 5.1-3 cultural exchange program.

### 4.2 Staff Exchange Programs

### 4.2-1 Reciprocal Exchange of Academic Staff/Staff Program

The Parties may select staff to participate in an exchange for the purpose of studying or lecturing in the other facility on a reciprocal basis. The visiting staff participant (each, an "Exchange Visitor") shall be subject to all applicable laws of the host country, including but not limited to immigration laws, and subject to approval by the Host Facility. The Host Facility will assist the Exchange Visitor in locating living accommodations and in matters of health, language and local custom.

### 4.2-2 Visiting Academic Staff/Cultural Exchange Program

In addition to the reciprocal exchanges, either facility may invite members of the other facility for the purpose of participating in conferences, attending symposia, lecturing or consulting for a specified period of time, subject to the approval of the Home Facility. In such cases, the Inviting Facility makes appropriate funding arrangements with the invited faculty member. Each invited faculty member shall be considered an Exchange Visitor.

### 4.3 Student Exchange Program

Each party may send students to the other to participate in appropriate fields of study, subject to the availability of a Host Facility supervisor and resources. In such cases, students will submit a proposal, signed by both the Home Facility and the Host Facility supervisors, outlining how the study undertaken at the Host Facility shall contribute towards the student's degree at their Home Facility. Each student shall be considered an Exchange Visitor.

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### 4.4 Selection of Exchange Visitor Candidates

Each Exchange Visitor must meet applicable requirements of the Host Facility. Exchange Visitors selected for the exchange will be required to have sufficient knowledge of the language appropriate to the Host Facility to carry out their studies and research at the Host Facility. A Host Facility may not discriminate against an Exchange Visitor candidate based on the candidate's race, sex, color, religion, or age. Selection in an exchange program does not entitle the Exchange Visitor to pursue a degree at the Host Facility. The India Center will also be the agent for any exchange involving Jefferson personnel visiting India through this Agreement.

### 4.5 Description of Exchange Experiences

- 4.5-1 <u>General Terms for Each Exchange Experience.</u> Prior to the beginning of each exchange experience for Exchange Visitors, the Parties shall discuss and agree upon a curriculum for the Exchange Visitors, which shall be placed in writing. The Parties understand that each exchange experience will be dependent on the availability of funds.
- 4.5-2 <u>Description of Exchange Experiences.</u> The curriculum of exchange experiences shall be set by the India Center with the advice and consultation of KLE. While consideration will be given to the individual interests and objectives of the visitor(s) in establishing the curriculum for a specific visitor or group of visitors, the objective of the program, especially for groups of visitors, is to develop and offer a specific model program for a given type of visitor or group of visitors. Further, because the India Center must rely on the availability of Jefferson facilities including its Thomas

Jefferson University Hospitals, Inc. ("Hospital") and personnel at the time of the visit to prepare and organize a specific program or educational experience, the template of a given model experience may not be able to be reproduced as presented.

4.6 Joint Research Program

Parties may seek opportunities to cooperate in research through the India Center. The details of specific research proposals will be determined by the mutual agreement of the Parties. The form of research cooperation may vary with the goal of each research project. Prior to the initiation of a specific research project, the parties shall discuss each project and agree that, *prior to the commencement of each research project*, a Research Program Agreement ("Program Agreement") must be entered into that shall include terms to address the policies of the Parties on intellectual property, any event of research collaboration leading to patent rights, copyrights and other intellectual property rights, the timing of the program, and details deemed relevant to the program.

Each Program Agreement entered into will form an Appendix and be attached to and incorporated into this Agreement. Research exchange will also be coordinated through the India Center contingent on fulfilling the obligations under this Agreement and the availability of funds.

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### 4.7 Exchange Visitor Status

The Parties shall be responsible to notify each student Exchange Visitor that the student shall not be deemed to be a student of Jefferson or KLE. Parties agree that the exchange program for degree training should follow the educational system and regulations of the Home Facility.

### 4.8 Exchange Visitor Requirements

- 4.8-1 Exchange Visitor Discipline and Removal. Parties agree to terminate the participation of any Exchange Visitor assigned to Jefferson, upon request of Jefferson, if Jefferson has determined that the Exchange Visitor failed to abide by the standards, practices, rules, policies, or procedures of Jefferson or in any way threatens to impair the delivery of education to Jefferson students or clinical care to its patients. In addition, each Host Facility shall have full responsibility for conducting any Exchange Visitor disciplinary proceedings in accordance with its own rules and regulations. Notwithstanding the above, the Home Facility agrees to terminate the participation of any Exchange Visitor assigned to the Host Facility, upon request of the Host Facility, if the Host Facility has determined that the Exchange Visitor fails to abide by the practices, rules, policies, or procedures of the Host Facility or in any way threatens to impair the delivery of educational services to the Host Facility.
- 4.8-2 <u>Educational Records</u>. Jefferson shall maintain all educational records and reports relating to the participation by each student assigned to the classroom experience at Jefferson for a reasonable period. In the event of pending litigation involving such records, those records shall be maintained until a resolution of the legal action is reached. The India Center shall provide KLE with an annual report detailing the activities of the India Center.
- 4.8-3 Exchange Visitor Health Status/Prerequisites. Jefferson shall require KLE, as appropriate considering the training period and type of professional, to provide to Jefferson satisfactory evidence that each Exchange Visitor assigned to Jefferson has: (a) proof of an acceptable criminal background check, including without limitation, no criminal history related to health care or adult or child abuse or neglect; (b) qualifying health status to work directly with patients; (c) immunization documentation and compliance with health requirements established by Home Facility; (d) infection control and universal precautions training; (e) certification in basic cardiac life support; and (f) any other prerequisite reasonably requested by Host Facility prior to the exchange and from time to time during the exchange. The Exchange Visitor shall be responsible to provide a copy of all such prerequisites to Host Facility and to maintain a record documenting these prerequisites.

Some or all of the above requirements may be waived by Jefferson out of consideration for the nature of the exchange program and the visit.

- 4.8-4 <u>Emergency Medical Treatment</u>. If any of the Exchange Visitors participating at Jefferson covered by this Agreement should require emergency medical treatment while at Jefferson, Jefferson shall follow its procedures for handling such emergencies. Any expenses related to the emergency transport and treatment shall be the sole responsibility of the Exchange Visitor.
- 4.8-5 <u>Health and Accident Insurance</u>. Parties shall require each Exchange Visitor to maintain health and accident insurance during participation in a program at Jefferson. Jefferson shall accept the travel insurance that includes health and accident insurance provided by KLE for Exchange Visitors to satisfy this requirement as long as this insurance coverage satisfies the US Department of State's minimum requirements. Parties are aware that the US Department of State requires no less than \$100,000 US for accident or illness, plus \$25,000 US for repatriation of remains and a \$50,000 US for medical evacuation for each Exchange Visitor.
- 4.8-6 <u>Exchange Visitor Expenses.</u> Jefferson shall not be responsible for any compensation for services or expenses including but not limited to meals, travel or other incidental expenses incurred by Exchange Visitors assigned to Jefferson. Each Exchange Visitor is responsible for travel (airfare and local transportation); accommodations and other expenses related to his/her participation in the exchange program, except for invited Exchange Visitors for whom appropriate funding arrangements have been made.
- 4.8-7 <u>Housing</u>. KLE will advise Exchange Visitors that room and board will not be provided by Jefferson. KLE will advise Exchange Visitors that they will be responsible for obtaining housing and will be required to pay all expenses associated with room and board.
- 4.8-8 <u>Publications</u>. Exchange Visitors must obtain prior written approval of KLE and Jefferson before publishing any material relating to the experience at Jefferson. Upon approval, Exchange Visitors shall be able to publish material relating to the exchange in accordance with the Home Facility's policies, provided however, that the Exchange Visitor shall give the Host Facility an advance copy of the proposed publication and allow Host Facility at least a sixty (60) day opportunity to remove any confidential information of the Host Facility prior to publication.

4.8-9 <u>Exchange of Academic Materials.</u> Each party shall exchange all relevant materials, such as those relating to the library, on a regular basis. The libraries can also exchange reference materials for research purposes. The exchange of academic materials shall be consistent with applicable legal and contractual requirements including U.S. laws applicable to international studies governing universities.

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- 4.8-10 <u>Assigning.</u> KLE shall assign only those Exchange Visitors who meet the requirements and prerequisites set forth in this Agreement.
- 4.8-11 <u>Scheduling Exchange Visitors</u>. Parties shall annually agree upon the number and schedule for Exchange Visitors prior to placement at Jefferson.
- 4.8-12 <u>Compliance with Host Facility Policies</u>. Each Exchange Visitor must comply with applicable policies of the Host Facility throughout his/her participation in the exchange program.
- 4.8-13 <u>Visas</u>. Each Exchange Visitor is responsible for obtaining and maintaining any visa needed for participation in the exchange program. The Host Facility will provide the Exchange Visitor with the documents necessary for obtaining a visa. Each Exchange Visitor must keep the Host Facility apprised of any changes in his/her visa status.
- 4.8-14 Patient Confidentiality. Home Facility shall ensure that each Exchange Visitor placed at Host Facility has been educated as to the concepts of privilege and confidentiality in a health care system. The Parties recognize that personal information of patients and protected health information as defined in HIPAA described below ("Patient Information") is confidential and the Exchange Visitors are under an obligation to maintain the confidentiality of such Patient Information in accordance with State and Federal laws of the United States of America. Notwithstanding the generality of the foregoing, the Parties specifically covenant and agree to comply, and the Home Facility covenants to cause its Exchange Visitors to comply, with the Health Insurance Portability and Accountability Act of 1996 (HIPAA) in all respects and to amend this Agreement as may be required to be HIPAA compliant, including without limitation to: (1) refrain from using or disclosing any Patient Information for any unauthorized purpose; (2) maintain safequards as necessary when using, disclosing or accessing Patient Information, such as not talking about patients in public areas, not removing patients official medical records from a health care facility, and not downloading Patient Information on personal electronic devices; and (3) report to the Host Facility any use or disclosure of Patient Information of which the Home Facility or exchange visitor become aware that is not authorized.

### ARTICLE V: CONFIDENTIALITY.

KLE agrees that any information and documents including, without limitation, data, educational materials, medical records, materials relating to business, protocols, guidelines, pricing, strategies, compensation levels, financial information, trade secrets, and technology (collectively, the "<u>Confidential Information</u>") concerning Jefferson, its patients, affiliates, employees, agents, or representatives that are submitted under this Agreement or which KLE or its Exchange Visitors become aware of during term of the Agreement are confidential and proprietary to Jefferson. KLE shall hold all Confidential Information in the strictest confidence and shall protect all Confidential Information with the same degree of care that it exercises with respect to its own proprietary information and in accordance with any and all applicable laws and regulations and Jefferson's policies and procedures. KLE shall obtain no proprietary rights (directly or indirectly) in or to any such materials. KLE shall not disclose the Confidential Information to any third party without the prior written consent of Jefferson unless required by law, in which event KLE will promptly notify Jefferson of such request. Upon the expiration or termination of this Agreement, for any reason, KLE shall promptly turn over and return to Jefferson all Confidential Information (in whatever form or media) or upon the written direction of Jefferson, destroy the Confidential Information.

### ARTICLE VI: INSURANCE.

Each party shall provide and maintain Comprehensive General Liability and such insurance for itself, its agents, its employees, at levels sufficient to support the indemnification obligations assumed herein. Upon request of a party, the other party shall supply certificates of insurance evidencing such coverage.

### ARTICLE VII: INDEMNIFICATION.

Each party shall indemnify, defend and hold the other party, their respective trustees, directors, officers, agents, employees, and Exchange Visitors participating in a program at Jefferson, harmless from and against any and all liabilities, suits, actions, claims, demands, damages, losses, expenses and costs of every kind and character, including defense cost and legal fees, suffered or incurred by or asserted or imposed against the party seeking indemnification and resulting from, connected with, or arising out of any negligent or wrongful act or omission of the indemnifying party or any other agent or employee of the indemnifying party occurring at any time during the term of this Agreement. This section shall survive the expiration or termination of this Agreement.

### ARTICLE VIII: NAME AND LOGO.

No party shall use, or permit others to use, the other's name, trademark or logo for any purpose or in any descriptive or promotional literature or communication of any kind without the other party's prior written approval. Ł.

### ARTICLE IX: GENERAL PROVISIONS

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9.1 <u>Exclusivity</u>. This Agreement is not intended to conflict with or affect any existing or future affiliation between the Parties and institutions not a party to this Agreement. This Agreement is not exclusive.

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9.2 <u>Applicable Law</u>. This Agreement shall be deemed to have been made and shall be construed in accordance with the laws of the Commonwealth of Pennsylvania, United States of America, without regard to its choice of law doctrine. All disputes related to this Agreement shall be brought in federal or state courts located in Philadelphia, Pennsylvania, USA and the Parties agree to the exclusive jurisdiction of those courts and waive any rights or defenses to such exclusive jurisdiction.

9.3 <u>Entire Agreement</u>. This Agreement constitutes the entire agreement between the Parties with respect to the subject matter hereof and all prior discussions, agreements or understandings, whether verbal or in writing, are hereby merged into this Agreement.

9.4 <u>Non-Discrimination</u>. Neither party shall discriminate in the performance of this Agreement because of race, color, sex, sexual orientation, age, religion, handicap, marital status, or national origin in violation of any applicable federal, state or local law or regulation.

9.5 <u>Assignment</u>. No party shall assign any of its rights or obligations under this Agreement without the prior written consent of the other party. Any such assignment is expressly prohibited and shall be deemed null and void.

9.6 <u>Severability</u>. If any provision of this Agreement shall be declared by a court of competent jurisdiction to be invalid, or the Parties determine any provision to be in conflict with any applicable federal, state or local law or regulation, then the remaining provisions of this Agreement shall be unaffected thereby and shall remain in full force and effect.

9.7 <u>Authority.</u> Each party represents that it has the authority to enter into and be bound by this Agreement.

9.8 <u>Notices</u>. Any notice required to be provided under the terms and provisions of this Agreement shall be in writing, and shall be deemed to be delivered when deposited in the United States mail or national delivery service such as UPS or Federal Express, postage prepaid, certified mail, return-receipt requested, and addressed to the respective party at the address set forth below, or any such address as specified by written notice given to the other party in the manner described herein:

If to JEFFERSON:

Thomas Jefferson University 1020 Walnut Street, 6<sup>th</sup> Floor Philadelphia, PA 19107 Attn: Provost

With a Copy To: Office of University Counsel Thomas Jefferson University 1020 Walnut Street, 6th Floor Philadelphia, PA 19107 Attn: University Counsel

> If to KLE: Office of the Registrar, KLE University, JNMC Campus, Belagavi-590 010, Karnataka, India

With a Copy To:

Office of the Chancellor, KLE Society, Head Office, College Road, Belagavi-590 001, Karnataka, India

Notwithstanding the above, any party may also provide notice by personal delivery. 9.9 <u>Cooperation Regarding Claims</u>. The Parties agree to fully cooperate in assisting each other and their duly authorized employees, agents, representatives and attorneys, in investigating, defending or prosecuting incidents involving potential claims or lawsuits arising out of or in connection with this Agreement. This Paragraph shall be without prejudice to the prosecution of any claims which any of the parties may have against each other and shall not require cooperation in the event of such claims.

9.10 <u>Relationship of Parties</u>. Nothing in this Agreement gives rise to a relationship of agency among or between the Parties.

9.11 <u>Compliance with Laws</u>. Each party shall comply with all relevant laws applicable in its jurisdiction, including taxation and privacy laws.

9.12 <u>Misunderstandings</u>. If any misunderstandings arise during the term of this Agreement, the Parties will seek to resolve the matter by discussion between them.

9.13 <u>Reputation</u>. Notwithstanding other clauses in this Agreement, the parties will use their best endeavors not to carry out any action that is likely to damage the reputation of any other party.

9.14 <u>English</u>. This Agreement has been made in English in two identical copies for signature by each of the Parties.

IN WITNESS WHEREOF, this Agreement has been executed by each party's duly authorized representatives as of the Effective Date.

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Department of Health and Human Services National Institutes of Health EUNICE KENNEDY SHRIVER NATIONAL INSTITUTE OF CHILD HEALTH & HUMAN DEVELOPMENT

Recipient Information	Federal Award Information	
1. Recipient Name THOMAS JEFFERSON UNIVERSITY		
1020 WALNUT ST STE 1	11. Award Number	
PHILADELPHIA, PA 19107	2UG1HD076457-11	
2. Congressional District of Recipient 03	<b>12. Unique Federal Award Identification Number (FAIN)</b> UG1HD076457	
<b>3. Payment System Identifier (ID)</b> 1231352651A1	<b>13. Statutory Authority</b> 42 USC 241 31 USC 6305 42 CFR 52	
<b>4. Employer Identification Number (EIN)</b> 231352651	<b>14. Federal Award Project Title</b> TJU-JNMC Global Network for Women's and Children's Health Resear	rch Unit
5. Data Universal Numbering System (DUNS) 053284659	<b>15. Assistance Listing Number</b> 93.865	
6. Recipient's Unique Entity Identifier R8JEVL4ULGB7	<b>16. Assistance Listing Program Title</b> Child Health and Human Development Extramural Research	
7. Duainat Divertan av Duivainal Investigator	17. Award Action Type	
7. Project Director or Principal Investigator RICHARD J DERMAN, MD	Competing Continuation	
Associate Provost, Global Affairs		
richard.derman@jefferson.edu	18. Is the Award R&D?	
215/955-2153	Yes	
8. Authorized Official	Summary Federal Award Financial Information	n
Jeanmarie Johnston	<b>19. Budget Period Start Date</b> 08/01/2023 – End Date 07/31/2024	
Jeannane Jonnston	20. Total Amount of Federal Funds Obligated by this Action	\$615,958
	20 a. Direct Cost Amount	\$548,574
	20 b. Indirect Cost Amount	\$67,384
	<b>21.</b> Authorized Carryover	
Federal Agency Information	22. Offset	
9. Awarding Agency Contact Information	23. Total Amount of Federal Funds Obligated this budget period	\$615,958
Marianne Galczynski	24. Total Approved Cost Sharing or Matching, where applicable	\$0
Grants Management Specialist	25. Total Federal and Non-Federal Approved this Budget Period	\$615,958
EUNICE KENNEDY SHRIVER NATIONAL		
INSTITUTE OF CHILD HEALTH & HUMAN	<b>26.</b> Project Period Start Date 07/01/2013 – End Date 07/31/2030	6645.050
DEVELOPMENT	27. Total Amount of the Federal Award including Approved Cost Sharing or Matching this Project Period	\$615,958
marianne.galczynski@nih.gov (240) 276-5588		
10. Program Official Contact Information	28. Authorized Treatment of Program Income	
Nahida Abdo Chakhtoura	Deduction	
EUNICE KENNEDY SHRIVER NATIONAL	29. Grants Management Officer - Signature	
INSTITUTE OF CHILD HEALTH & HUMAN	Marianne Galczynski	
DEVELOPMENT		
nahida.chakhtoura@nih.gov		
(301) 435-6872		
20. Bomarks		

#### 30. Remarks

Acceptance of this award, including the "Terms and Conditions," is acknowledged by the recipient when funds are drawn down or otherwise requested from the grant payment system.

Notice of Award



Cooperative Agreement Department of Health and Human Services National Institutes of Health



EUNICE KENNEDY SHRIVER NATIONAL INSTITUTE OF CHILD HEALTH & HUMAN DEVELOPMENT

SECTION I - AWARD DATA - 2UG1HD076457-11

Principal Investigator(s): RICHARD J DERMAN, MD

Award e-mailed to: resadmin@jefferson.edu

Dear Authorized Official:

The National Institutes of Health hereby awards a grant in the amount of \$615,958 (see "Award Calculation" in Section I and "Terms and Conditions" in Section III) to THOMAS JEFFERSON UNIVERSITY in support of the above referenced project. This award is pursuant to the authority of 42 USC 241 31 USC 6305 42 CFR 52 and is subject to the requirements of this statute and regulation and of other referenced, incorporated or attached terms and conditions.

Acceptance of this award, including the "Terms and Conditions," is acknowledged by the recipient when funds are drawn down or otherwise requested from the grant payment system.

Each publication, press release, or other document about research supported by an NIH award must include an acknowledgment of NIH award support and a disclaimer such as "Research reported in this publication was supported by the Eunice Kennedy Shriver National Institute Of Child Health & Human Development of the National Institutes of Health under Award Number UG1HD076457. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health." Prior to issuing a press release concerning the outcome of this research, please notify the NIH awarding IC in advance to allow for coordination.

Award recipients must promote objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct and reporting of research funded under NIH awards will be free from bias resulting from an Investigator's Financial Conflict of Interest (FCOI), in accordance with the 2011 revised regulation at 42 CFR Part 50 Subpart F. The Institution shall submit all FCOI reports to the NIH through the eRA Commons FCOI Module. The regulation does not apply to Phase I Small Business Innovative Research (SBIR) and Small Business Technology Transfer (STTR) awards. Consult the NIH website <a href="http://grants.nih.gov/grants/policy/coi/">http://grants.nih.gov/grants/policy/coi/</a> for a link to the regulation and additional important information.

If you have any questions about this award, please direct questions to the Federal Agency contacts.

Sincerely yours,

Marianne Galczynski Grants Management Officer EUNICE KENNEDY SHRIVER NATIONAL INSTITUTE OF CHILD HEALTH & HUMAN DEVELOPMENT

Additional information follows

Cumulative Award Calculations for this Budget Period (U.S. Dollars)	
Salaries and Wages	\$78,180
Fringe Benefits	\$8,148
Personnel Costs (Subtotal)	\$86,328
Travel	\$9,000
Subawards/Consortium/Contractual Costs	\$453,246
Federal Direct Costs	\$548,574
Federal F&A Costs	\$67,384
Approved Budget	\$615,958
Total Amount of Federal Funds Authorized (Federal Share)	\$615,958
TOTAL FEDERAL AWARD AMOUNT	\$615,958
AMOUNT OF THIS ACTION (FEDERAL SHARE)	\$615,958

	SUMMARY TOTALS FOR ALL YEARS	(for this Document Number)
YR	THIS AWARD	CUMULATIVE TOTALS
11	\$615,958	\$615,958
12	\$601,958	\$601,958
13	\$601,958	\$601,958
14	\$601,958	\$601,958
15	\$601,958	\$601,958
16	\$601,958	\$601,958
17	\$601,958	\$601,958

Recommended future year total cost support, subject to the availability of funds and satisfactory progress of the project

#### **Fiscal Information:**

Payment System Identifier:	1231352651A1
Document Number:	UHD076457D
PMS Account Type:	P (Subaccount)
Fiscal Year:	2023

IC	CAN	2023	2024	2025	2026	2027	2028	2029
HD	8014707	\$615,958	\$601,958	\$601,958	\$601,958	\$601,958	\$601,958	\$601,958

Recommended future year total cost support, subject to the availability of funds and satisfactory progress of the project

#### NIH Administrative Data:

PCC: PPB -NC / OC: 41027 / Released: Galczynski, Marianne 07/21/2023 Award Processed: 08/01/2023 12:32:00 AM

#### SECTION II – PAYMENT/HOTLINE INFORMATION – 2UG1HD076457-11

For payment and HHS Office of Inspector General Hotline information, see the NIH Home Page at <a href="http://grants.nih.gov/grants/policy/awardconditions.htm">http://grants.nih.gov/grants/policy/awardconditions.htm</a>

#### SECTION III – STANDARD TERMS AND CONDITIONS – 2UG1HD076457-11

This award is based on the application submitted to, and as approved by, NIH on the above-titled project and is subject to the terms and conditions incorporated either directly or by reference in the following:

- a. The grant program legislation and program regulation cited in this Notice of Award.
- b. Conditions on activities and expenditure of funds in other statutory requirements, such as those included in appropriations acts.
- c. 45 CFR Part 75.
- d. National Policy Requirements and all other requirements described in the NIH Grants Policy Statement, including addenda in effect as of the beginning date of the budget period.
- e. Federal Award Performance Goals: As required by the periodic report in the RPPR or in the final progress report when applicable.
- f. This award notice, INCLUDING THE TERMS AND CONDITIONS CITED BELOW.

(See NIH Home Page at http://grants.nih.gov/grants/policy/awardconditions.htm for certain references cited above.)

**Research and Development (R&D):** All awards issued by the National Institutes of Health (NIH) meet the definition of "Research and Development" at 45 CFR Part§ 75.2. As such, auditees should identify NIH awards as part of the R&D cluster on the Schedule of Expenditures of Federal Awards (SEFA). The auditor should test NIH awards for compliance as instructed in Part V, Clusters of Programs. NIH recognizes that some awards may have another classification for purposes of indirect costs. The auditor is not required to report the disconnect (i.e., the award is classified as R&D for Federal Audit Requirement purposes but non-research for indirect cost rate purposes), unless the auditee is charging indirect costs at a rate other than the rate(s) specified in the award document(s).

Carry over of an unobligated balance into the next budget period requires Grants Management Officer prior approval.

This grant is excluded from Streamlined Noncompeting Award Procedures (SNAP).

This award is subject to the requirements of 2 CFR Part 25 for institutions to obtain a unique entity identifier (UEI) and maintain an active registration in the System for Award Management (SAM). Should a consortium/subaward be issued under this award, a UEI requirement must be included. See <a href="http://grants.nih.gov/grants/policy/awardconditions.htm">http://grants.nih.gov/grants/policy/awardconditions.htm</a> for the full NIH award term implementing this requirement and other additional information.

This award has been assigned the Federal Award Identification Number (FAIN) UG1HD076457. Recipients must document the assigned FAIN on each consortium/subaward issued under this award.

Based on the project period start date of this project, this award is likely subject to the Transparency Act subaward and executive compensation reporting requirement of 2 CFR Part 170. There are conditions that may exclude this award; see <a href="http://grants.nih.gov/grants/policy/awardconditions.htm">http://grants.nih.gov/grants/policy/awardconditions.htm</a> for additional award applicability information.

In accordance with P.L. 110-161, compliance with the NIH Public Access Policy is now mandatory. For more information, see NOT-OD-08-033 and the Public Access website: <u>http://publicaccess.nih.gov/</u>.

This award provides support for one or more clinical trials. By law (Title VIII, Section 801 of <u>Public Law</u> <u>110-85</u>), the "responsible party" must register "applicable clinical trials" on the <u>ClinicalTrials.gov Protocol</u> <u>Registration System Information Website</u>. NIH encourages registration of all trials whether required under the law or not. For more information, see <u>http://grants.nih.gov/ClinicalTrials\_fdaaa/</u>

Recipients must administer the project in compliance with federal civil rights laws that prohibit discrimination on the basis of race, color, national origin, disability, age, and comply with applicable conscience protections. The recipient will comply with applicable laws that prohibit discrimination on the

basis of sex, which includes discrimination on the basis of gender identity, sexual orientation, and pregnancy. Compliance with these laws requires taking reasonable steps to provide meaningful access to persons with limited English proficiency and providing programs that are accessible to and usable by persons with disabilities. The HHS Office for Civil Rights provides guidance on complying with civil rights laws enforced by HHS. See <a href="https://www.hhs.gov/civil-rights/for-providers/provider-obligations/index.html">https://www.hhs.gov/civil-rights/for-providers/provider-obligations/index.html</a> and <a href="https://www.hhs.gov/civil-rights/for-providers/providers/providers/providers/providers/providers/providers/providers/providers/providers/providers/providers/providers/providers/providers/pro

- Recipients of FFA must ensure that their programs are accessible to persons with limited English
  proficiency. For guidance on meeting the legal obligation to take reasonable steps to ensure
  meaningful access to programs or activities by limited English proficient individuals,
  see <a href="https://www.hhs.gov/civil-rights/for-individuals/special-topics/limited-english-proficiency/fact-sheet-guidance/index.html">https://www.hs.gov/civil-rights/for-individuals/special-topics/limited-english-proficiency/fact-sheet-guidance/index.html</a> and <a href="https://www.lep.gov">https://www.lep.gov</a>.
- For information on an institution's specific legal obligations for serving qualified individuals with disabilities, including providing program access, reasonable modifications, and to provide effective communication, see

http://www.hhs.gov/ocr/civilrights/understanding/disability/index.html.

- HHS funded health and education programs must be administered in an environment free of sexual harassment; see <a href="https://www.hhs.gov/civil-rights/for-individuals/sex-discrimination/index.html">https://www.hhs.gov/civil-rights/for-individuals/sexdiscrimination/index.html</a>. For information about NIH's commitment to supporting a safe and respectful work environment, who to contact with questions or concerns, and what NIH's expectations are for institutions and the individuals supported on NIH-funded awards, please see <a href="https://grants.nih.gov/grants/policy/harassment.htm">https://grants.nih.gov/grants/policy/harassment.htm</a>.
- For guidance on administering programs in compliance with applicable federal religious nondiscrimination laws and applicable federal conscience protection and associated antidiscrimination laws, see <a href="https://www.hhs.gov/conscience/conscience-protections/index.html">https://www.https//www.https://www.https://www.https://www.https://www.https://www.https://www.https://www.https://www.https://www.https//www.https://www.https//wwww.https/

In accordance with the regulatory requirements provided at 45 CFR 75.113 and Appendix XII to 45 CFR Part 75, recipients that have currently active Federal grants, cooperative agreements, and procurement contracts with cumulative total value greater than \$10,000,000 must report and maintain information in the System for Award Management (SAM) about civil, criminal, and administrative proceedings in connection with the award or performance of a Federal award that reached final disposition within the most recent five-year period. The recipient must also make semiannual disclosures regarding such proceedings. Proceedings information will be made publicly available in the designated integrity and performance system (currently the Federal Awardee Performance and Integrity Information System (FAPIIS)). Full reporting requirements and procedures are found in Appendix XII to 45 CFR Part 75. This term does not apply to NIH fellowships.

Treatment of Program Income: Deduction

#### SECTION IV - HD SPECIFIC AWARD CONDITIONS - 2UG1HD076457-11

**Clinical Trial Indicator: Yes** 

This award supports one or more NIH-defined Clinical Trials. See the NIH Grants Policy Statement Section 1.2 for NIH definition of Clinical Trial.

#### **Foreign Clearance**

**RESTRICTION:** No funds may be expended, and no activities may be conducted at **JNMC**, **KLE Academy of Higher Education and Research** in **INDIA** until all NIH administrative requirements have been met. These activities and funds will remain restricted until a revised Notice of Award has been issued rescinding this restriction.

Failure to comply with the above requirement may result in suspension and/or termination of this award, withholding of support, audit disallowances, and/or other appropriate action.

#### **Dissemination Plan**

**RESTRICTION:** In absence of a plan for the dissemination of NIH-funded clinical trials information, all funds for this award are restricted [with the exception of those costs associated with supporting currently enrolled patients].

No funds may be drawn down from the payment system and no obligations may be made against Federal funds, [except for those associated with patient care for currently enrolled patients] prior to NICHD notification to the recipient via a revised Notice of Award that the identified issues have been resolved and this restriction removed.

#### **Cooperative Agreement**

This award is issued as a cooperative agreement, a financial assistance mechanism in which substantial NIH scientific and/or programmatic involvement is anticipated in the performance of the activity.

This award is subject to the terms and conditions of award as set forth in **NOFO NUMBER** <u>RFA-HD-23-008</u>, "NICHD Global Network for Women's and Children's Health Research: Research Units (UG1 Clinical Trial Optional)," posted August 03, 2022, which are hereby incorporated by reference as special terms and conditions of award. See the <u>NIH Funding</u> site for more information.

These special terms and conditions of award are in addition to, and not in lieu of, otherwise applicable OMB administrative guidelines; Federal Regulations including HHS Grant Administration Regulations at 45 CFR Part 75; other HHS regulations; and the <u>NIH Grants Policy</u> <u>Statement</u> (rev. 12/22).

#### **Project Scientist Contact Information:**

Project Scientist: Marion Koso-Thomas, MD Email: <u>kosomari@mail.nih.gov</u> Phone: (301) 435 - 6873

#### Foreign Component

This award includes foreign component at the following site(s): JNMC, KLE Academy of Higher Education and Research in INDIA

#### Human Subjects - Delayed Onset

**RESTRICTION:** This award is issued with the knowledge that subjects may be involved within the period of support, but definite plans were not set forth in the application as per 45 CFR 46.118. No human subjects may be involved in any project supported by this award until all requirements for human subjects' research as identified in the PHS398/SF424 instructions have been provided to and approved by NICHD.

For all competing applications or new protocols, the NICHD expects investigators for ALL NICHD Clinical Trials to abide by the requirements stated in NIH Guide Notice <u>NOT-HD-20-036</u> "NICHD Data Safety Monitoring Guidelines for Extramural Clinical Trials and Clinical Research". All NICHD applications which include Clinical Trials must include a Data Safety Monitoring Plan. All NIH-sponsored multi-site clinical trials, NIH-defined Phase III clinical trials and some single site clinical trials that pose potential risk to participants require Data and Safety Monitoring Board (DSMB) oversight. Applicants are expected to establish an independent, external DSMB when required by this policy.

For all competing applications or new protocols, the NICHD expects investigators for ALL human subject research to abide by the requirements stated in NIH Guide Notice <u>NOT-HD-20-035</u> "NICHD Serious Adverse Event, Unanticipated Problem, and Serious Adverse Event Reporting Guidance".

#### AWARD NUMBER: 2UG1HD076457-11

#### **INSTITUTION:** THOMAS JEFFERSON UNIVERSITY

Budget	Year 11	Year 12	Year 13	Year 14	Year 15	Year 16	Year 17
Salaries and Wages	\$78,180	\$78,180	\$78,180	\$78,180	\$78,180	\$78,180	\$78,180
Fringe Benefits	\$8,148	\$8,148	\$8,148	\$8,148	\$8,148	\$8,148	\$8,148
Personnel Costs (Subtotal)	\$86,328	\$86,328	\$86,328	\$86,328	\$86,328	\$86,328	\$86,328
Travel	\$9,000	\$9,000	\$9,000	\$9,000	\$9,000	\$9,000	\$9,000
Subawards/Consortium/Contra	\$453,246	\$453,246	\$453,246	\$453,246	\$453,246	\$453,246	\$453,246
ctual Costs							
TOTAL FEDERAL DC	\$548,574	\$548,574	\$548,574	\$548,574	\$548,574	\$548,574	\$548,574
TOTAL FEDERAL F&A	\$67,384	\$53,384	\$53,384	\$53,384	\$53,384	\$53,384	\$53,384
TOTAL COST	\$615,958	\$601,958	\$601,958	\$601,958	\$601,958	\$601,958	\$601,958

Facilities and Administrative	Year 11	Year 12	Year 13	Year 14	Year 15	Year 16	Year 17
Costs							
F&A Cost Rate 1	56%	56%	56%	56%	56%	56%	56%
F&A Cost Base 1	\$120,328	\$95,328	\$95,328	\$95,328	\$95 <i>,</i> 328	\$95 <i>,</i> 328	\$95,328
F&A Costs 1	\$67,384	\$53,384	\$53,384	\$53,384	\$53 <i>,</i> 384	\$53,384	\$53,384



# IND'A NON JUDICIAL

# **Government of Karnataka**

Patson Multi-Purpose Souldard Sahakari Niyamit Belagava Mahantesh Nagar, Branch

GOVERNMEW! OF KARNATAKA GOVERNMENT OF KANNA

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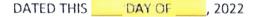
tho

Medical Director & Chief Executive KLES Dr. Prabhakar Kore Hospital & Medical Research Centre, BELAGAVI.

**Statutory Alert:** 

- The authenticity of this Stamp certificate should be verified at 'www.shcilestamp.com' or using e-Stamp Mobile Any discrepancy in the details on this Certificate and as available on the website / Mobile App renders it invalid
   The onus of checking the legitimacy is on the users of the certificate. App of Stock Holding
- 3. In case of any discrepancy please inform the Competent Authority.

#### MEMORANDUM OF UNDERSTANDING



#### BETWEEN

#### KLES DR. PRABHAKAR KORE HOSPITAL AND MEDICAL RESEARCH CENTRE, BELAGAVI

AND

ROTARY CLUB OF BELGAUM, BELAGAVI (ROTARY DISTRICT 3170)

AND

#### NATIONAL BURNS CENTRE (NBC) & ROTARY CLUB OF BOMBAY NORTH (RCBN)

THIS MEMORANDUM OF UNDERSTANDING is made and confirmed into at Belagavi on this day of 2022.

#### BETWEEN

**KLES Dr. Prabhakar Kore Hospital and Medical Research Centre, Belagavi** having their office Nehru Nagar, Belagavi by represented by their duly authorised representive, Medical Director & Chief Executive, (hereinafter referred to as the "KLESH");

AND

**Rotary Club of Belgaum, Belagavi, (**Rotary District 3170) an unregistered association of persons, represented by its Club President (hereinafter referred to as "RCB")

#### AND

(i) **NATIONAL BURNS CENTRE** a public charitable society registered under the Bombay Trusts Act, and having their office at National Burns Centre, Sector 13, Plot No.1, Samarth Ramdas Swami Marg, Airoli, Navi Mumbai- 400708 represented by their duly authorised representative, Dr. Sunil Keswani, (hereinafter referred to as "NBC"); and (ii) **ROTARY CLUB OF BOMBAY NORTH**, an unregistered association of persons, represented by its Club President (hereinafter referred to as "RCBN") which together operate the RCBN Skin Bank as an registered association ( hereinafter referred to as "RN") (which expression shall unless it be repugnant to the context or meaning thereof be deemed to mean and include the members of the Governing Council / Board of RN, their successors or successor the survivors or survivor of them and the heirs, executors and administrators of the last surviving member and his / her / assigns) of the First Part, **KLESH, RCB** AND **RN** hereinafter collectively called the 'Parties",

AND WHEREAS KLESH has a 11 Bedded Burns Care facility serving over 100 Burns victims annually and has the necessary infrastructure and expertise in treating victims of skin burns.

AND WHEREAS the RCB is a charitable organization bringing together business and professional leaders to provide philanthropic and humanitarian service, encourage high ethical standards in all vocations and help build goodwill and peace and is a part of the Rotary International.

WHEREAS RCBN has set up a skin bank known as RCBN Skin Bank at NBC situated at Plot No 1, Sector 13, Samarth Ramdas Swami Marg, Airoli, Navi Mumbai 400 708 in collaboration and with the guidance of the Euro Skin Bank for promoting and spreading awareness of skin donation and is in the process of setting up skin banks in various places in India.

AND WHEREAS THE RCB desires to set the Skin Bank/Skin Collection Centre through KLESH as part of its Community Service Poject (CSP) and desires to participate in the Project.

AND WHEREAS KLESH with the objective to reduce the intensity of suffering and the number of deaths due to burns, intends to participate in setting up of a skin bank within the city of Belagavi with the assistance from RCBN and NBC, in the space provided by KLESH within KLES Dr. Prabhakar Kore Hospital premises. The purpose of such a skin bank/ skin collection centre shall be harvesting of cadaver skin on call, processing, preservation of the skin and dispensing the skin to the burn victims being treated within nearby Hospitals and elsewhere ("the Project") at a reasonable cost without any discrimination to any group, caste, colour, creed or place and to make available this service to the public at large as a HUMANITARIAN SERVICE.

AND WHEREAS the Parties have willingly agreed to participate in the collective Project and provide all resources and assistance to establish a skin bank to make it a success.

NOW THIS MEMORANDUM OF UNDERSTANDING WITNESSETH AND IT IS HEREBY AGREED AND UNDERSTOOD BY AND BETWEEN THE PARTIES HERE TO AS FOLLOWS:

- The Project shall be implemented in accordance with the technical guidance from NBC/RCBN Skin Bank and the funds of \$ 31500 required for the implementation of the Project will be provide by RCB & through The Rotary Foundation. The Project will be implemented as Global grant project no. 1746862 registered with Rotary Foundation and after the necessary sanction and disbursal of funds from the Rotary Foundation.
- 2. The Skin Bank/ Skin Collection Centre shall have the plaque in the following format

KLES Rotary SKIN BANK / SKIN COLLECTION CENTRE in technical collaboration with RCBN Skin Bank and NBC financed by Rotary Club of Belgaum under the Global Grants of the Rotary Foundation

- 3. The Parties have agreed to cooperate with each other in collectively executing the Project and to achieve the objectives of the Project and for this purpose the Parties shall constitute a joint committee comprising of three nominees of KLESH, one nominee of NBC and three nominees of RCB (hereinafter called the "Supervising Committee"). The Supervising Committee shall be responsible for taking all decisions relating to the Project. The Supervising Committee meetings should be conducted as and when required, but at least once every month to review the progress of the Project and to take necessary steps for the smooth establishment and functioning of a skin bank and reports of all aspects of its activities shall be recorded in the minutes of such meetings and provided to the Parties.
- 4. The Supervising Committee will supervise the setting up of the Skin Bank / Skin Collection Centre and monitor the functioning of Skin bank/ Skin Collection Centre thereafter, in consultation with and under the supervision and guidance of RN.
- 5. The roles and responsibilities of the parties to this MOU are defined as follows:

#### 5.1. KLESH : HOST

- 5.1.1. KLESH shall be responsible to maintain and operate a state of the art Skin Bank / Skin Collection Centre as per international guidelines with guidance from NBC/RCBN Skin Bank and maintain adequate records and report statistics of Beneficiaries periodically to RCB and RCBN.
- 5.1.2. KLESH shall provide and maintain a dedicated air-conditioned, clean room space of about 1000 square feet with adequate lighting, furniture and partitions within KLES Hospital Premises.
- 5.1.3. KLESH shall procure all necessary clearances, approvals and/or permissions from the local, municipal, civil, government departments such as Tissue Bank License for the purpose of legitimate execution and functioning of Skin Bank/ Skin Collection Centre.
- 5.1.4. KLESH shall provide and maintain a dedicated skin harvest vehicle, spacious enough to harvest skin from cadavers on board and which shall be available 24 hours a day and for 365 days as well as an alternative vehicle in case of its breakdown.
- 5.1.5. KLESH shall be responsible for recruitment, training and monitoring of dedicated human resources required for harvesting, processing, preservation, dispensing the cadaver skin and also the remuneration payable to the human resources, including their salaries, fees, ESI, Provident Fund Contribution, Gratuity and all other statutory dues. The staff appointed shall be of KLESH only and they shall not have any relation or privity of contact with RCB/RCBN/NBC.

Non:

- 5.1.6. KLESH shall ensure uninterrupted supply of all essential Consumables, electricity, water, gas, telephone and anything else that may be required for the smooth functioning of Skin Bank.
- 5.1.7. KLESH will provide all their expertise and assistance to RCB in procuring all the necessary equipment as well as consumables.
- 5.1.8. KLESH shall maintain and keep all equipment provided by RCB for the Project in good working condition and shall enter into AMC contracts for the maintenance of the equipment at the Skin Bank.
- 5.1.9. KLES surplus to be reinvested for maintenance shall reinstate any equipment owned and provided by RCB for the Skin Bank after the expiry of its useful life or break down after its warranty period.
- 5.1.10. KLESH shall maintain a daily log record book and registries wherein, it shall record the calls for donation, requests, registered volunteers, details of skin donations, size of skin harvested, size of skin in store, details of beneficiaries in such format and periodically as may be mutually agreed amongst the Parties. Upon request, one copy of this shall be sent to RCB and the Donor every month for their records.
- 5.1.11. KLESH shall dispense the skin from its Skin Collection Center at a very nominal fee on the non-profit basis to make it affordable to all segments of the public. KLES Rotary Skin Bank shall set up a separate Bank Account to secure the funds raised from dispensing of skin and donations received towards the Project. Such funds shall be exclusively used towards up keeping, expansion and promoting the benefits of the Skin Bank.
- 5.1.12. KLESH shall designate a Faculty member of the Department of Plastic Surgery, as an In-Charge of the Skin Bank to ensure the smooth functioning of Skin Bank at any given point of time.
- 5.1.13. KLESH shallmanage day to day activities of the centre.
- 5.1.14. KLESH along with RCB shall be responsible for creating awareness and creating publicity for the Skin Bank and the importance of skin donation in consultation with the RCBN Skin Bank.
- 5.1.15. All the responsibilities of KLES Rotary Skin Bank under this MOU shall be at the expense of KLES Rotary Skin Bank Account.

#### 5.2. RCB : ROTARY COMMUNITY SERVICE

5.2.1. RCB shall procure and deliver the Capital equipment and instruments as required for a full-fledged Skin Bank (hereinafter referred to as the "said equipment" and

more particularly listed in Schedule 1 hereto). RCB shall take into account the recommendations made by KLES & NBC & RN in respect of the equipment to be procured.

- 5.2.2. RCB shall be responsible for the Installation of the said equipment as prescribed by NBC and RCBN Skin bank from time to time.
- 5.2.3. RCB shall provide a dedicated skin harvest vehicle spacious enough to harvest skin from cadaver on board and shall ensure that at all times the Skin Harvest Vehicle has the necessary capital instrumentation.
- 5.2.4. RCB shall be entitled to monitor the functioning of the Skin Bank and check the records, reports, impact on beneficiaries as well as the maintenance of the said equipment.
- 5.2.5. RCB shall support KLESH in creating public awareness about skin donation and promoting the usage of cadaver skin in burn care in the region using its Rotary Network.

## 5.3. RCB : DONOR

RCB shall provide funds to, own and provide the equipment required for the function of the Skin Bank and to implement and monitor the Project for betterment of care of burn victims.

## 5.4. RCBN & NBC: GUIDE

- 5.4.1. RN shall provide all the necessary guidance required during the establishment of the Skin Bank.
- 5.4.2. The RCBN Skin Bank shall provide Standard Operating Procedures (SOPs) and Protocols to be adhered to by the Skin Bank as per International Guidelines.
- 5.4.3. RN shall train the human resources, recruited and designated by KLESH to operate SKIN BANK.
- 5.4.4. RN shall conduct periodic audits of the Skin Bank annually. The audit will take 2 days. The expenses on local hospitality and travelling for the two skin bank auditor team have to be borne by your hospital. The result of the audits shall be conveyed in a timely manner to both the parties.
- 5.4.5. RN shall conduct yearly meetings with the entire Skin Harvesting Team and the Supervising Committee of the Skin Bank and give necessary technical assistance and guidance and share the experiences and research in skin harvesting, processing and storage with them.

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- 5.4.6. RN shall be entitled to provide all the details in respect of the Skin Bank, including contact details of members of KLESH and RCB involved with the Project on its website along with direct links to the websites of the Skin Bank, RCB and RCBN.
- 6. KLESH shall be solely responsible for obtaining all statutory permissions and consents as may be required for harvesting cadaver skin and neither NBC, nor RCBN shall be held responsible for any non-compliance by KLESH in respect of obtaining permission and consent.
- 7. KLESH & RCB shall have the right to nominate the person who will inaugurate the Skin Bank on the inauguration date.
- 8. KLESH shall have the right, but not an obligation to monitor and supervise the operations of the Skin Bank and also collect data and reports of the patients and other hospitals who receive support from the Skin Bank every quarter.
- 9. KLESH, RCB and RCBN shall organize a press meet to promote the importance of skin donation and creating a Skin Bank. All Parties will make all efforts to promote the message of skin donation.KLESH & RCB will have a complete right to carry out their PR activity before, during and after the inauguration of the Skin Bank. Any public announcement with regard to the Project, contents or subject matter of this MOU shall be made only with the mutual agreement of the Parties as to the content and timing of such announcement.
- 10. KLESH shall permit visitors introduced by and RCB/or RN to showcase the Skin Bank as well as to inspect its functioning with prior appointment and without disturbing the operations of the Skin Bank.
- 11. All intellectual property rights belonging to each of the Parties as well as the RCBN Skin Bank shall belong to each of them respectively, and none of the Parties hereto shall utilize or misuse any such intellectual property of the others of them or claim any rights in respect thereof. It is agreed that wherever any names, trademarks or other intellectual property of the Parties hereto or the RCBN Skin Bank is to be used by any one or more of the parties hereto for the Project, they will seek written permission of the party owning such name, trademark or other intellectual property before any such use.
- 12. This MOU has been entered into with good faith by the Parties for providing service to burns victims with the intention to save more lives. NBC will make all efforts to provide good technical training to the KLESH technicians and help set up the Skin Bank using their expertise and RCB together with RN will use their respective organizations for facilitating the development of the Skin Bank and KLESH will use the Skin Bank to provide better treatment and outcomes to burns patients.
- 13. The Parties undertake not to operate the facility as a commercial enterprise and agree to providing the Skin Bank services on HUMANITARIAN CONSIDERATIONS only.

Medical Director & Chief Executive KLES Dr. Prabhakar Kore Hospital & Medical Research Centre, BELAGAVI.

- 14. The tenure of this MOU shall be for a period of five years. Subsequently, upon evaluation, if the RN and KLESH & RCB are satisfied with the functioning of the Skin Bank, this MOU will be renewed on such terms as may be mutually agreed upon at that time. Notwithstanding what is stated in this MOU if in the opinion of RN the Skin Bank is not running as per the standards suggested or laid down by RN then RN may at its discretion and without being subject to any liability terminate this MOU forthwith.
- 15. KLESH hereby indemnifies, and agrees to defend and hold harmless NBC, RCBN, RCB and their nominees from any and all actions, losses, claims, demands actions, causes of action, suits, costs, damages, expenses, compensation, penalties, liabilities and obligations of any kind (hereinafter collectively referred to as 'Loses') resulting from acts, misconduct or omissions of KLES Rotary Skin Bank or the **Supervising Committee**its agents or employees including but not limited to obtaining all statutory permissions and consents for harvesting, processing and storing of cadaver skin.
- 16. All disputes, differences and/ or claims arising out of this MOU or the construction, meaning or effect thereof or the rights, obligations and liabilities of the parties hereto or otherwise relating to the Skin Bank shall be referred to arbitration to be conducted in accordance with the Arbitration and Conciliation Act, 1996 or any statutory amendments or re-enactment thereof by appointing a Sole Arbitrator as mutually agreed upon between the parties and such Arbitration shall be held in Belagavi. The Award of the Sole Arbitrator shall be final and binding.
- 17. This MOU shall be executed in four counterparts, each of which shall be deemed to be an original and each party to this MOU shall retain a counterpart. All four counterparts shall constitute one and the same MOU.
- 18. This MOU may be reviewed and renewed by mutual agreement of the parties to this MOU.

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Medical Director & Chief Execution KLES Dr. Prabhakar Kore Hospital & Medical Research Centre, BELAGAVI.

IN WITNESS WHEREOF, the Parties hereto have set and subscribed their respective hands the names to this writing on the day and the year first hereinabove written.

Signed and delivered by the Within named KLES Dr. Prabhakar Kore Hospital & MRC, Belagavi Represented by Dr. M. V. Jali Medical Director & Chief Executive KLES Dr. Prabhakar Kore Hospital & MRC, Belagavi

#### Witnesses:

- 1. Dr. Rajesh Powar Chief Consultant Department of Plastic Surgery KLES Dr. Prabhakar Kore Hospital & MRC, Belagavi
- 2. Mr. Vinay Bedre Administrator - Finance & Accounts KLES Dr. Prabhakar Kore Hospital & MRC, Belagavi

Signed and delivered by the Within named Rotary Club of Belgaum Represented by its Trustee President Dr. Satish Dhamankar Rotary Club of Belgaum

Witnesses:

- 1. Mr. Milind Patankar President Rotary Club of Belgaum
- 2. Mr. Basavraj Vibhuti President Elect Rotary Club of Belgaum

Signed and delivered by the Within named National Burns Centre & Rotary Club of Bombay North Represented by: Dr. Sunil Keswani

or & Chief Executive Medica KLES Dr. Prabhakar Kore Hospital &

Medical Research Centre, BELAGAVI.

Signatures: Dr. Raiesh & Powar Senior Consultar Rept. of Plastic & Reconstructive Surgery

Framanla

Signatures:

v- Caton Autor







आई सी एम आर - राष्ट्रीय रोग सूचना विज्ञान एवं अनुसंधान केंद्र स्वास्थ्य अनुसंधान विभाग, स्वास्थ्य एवं परिवार कल्याण मंत्रालय, भारत सरकार

ICMR - National Centre for Disease Informatics and Research Department of Health Research, Ministry of Health

and Family Welfare, Government of India

No. NCDIR/HBCR/11/075/2022 556 4

6<sup>th</sup> February, 2023

Dr. Kumar Vinchurkar Consultant Department of Surgical Oncology KLES Dr. Prabhakar Kore Hospital and MRC Nehru Nagar, Belagavi (Karnataka) – 590 010.

Sir,

Sub: Extension of "Hospital Based Cancer Registries in India" project for the period from 01-04-2023 to 31-03-2024

I am directed to inform you that, the above project extended for 2<sup>nd</sup> year from 01-04-2023 to 31-03-2024 at your institute. The Grant-in-Aid: General, annual budget for the financial year 2023-24 will be shared in due course.

The unspent balance for the financial year 2022-23 can be utilised for the next financial year 2023-24.

This issues with the approval of Director.

Your faithfully,

Lunier

(Ramesha N. M.) Administrative Officer

निर्मल भवन, आई सी एम आर कॉप्लेक्स, पूजनहन्नी रोड, कन्नमंगला पोस्ट, बेंगलुरु - 562 110. कर्नाटक (भारत)

Nirmal Bhawan-ICMR Complex, Poojanahalli Road, Kannamangala Post, Bengaluru - 562 110. Karnataka (India)



# ICMR- Collaborating Centre of Excellence (ICMR-CCoE)

The Indian Council of Medical Research has designated the **Jawaharlal Nehru Medical College, Belagavi** led by **Dr Shivaprasad Sadashivappa Goudar** as ICMR-Collaborating Centre of Excellence (ICMR-CCoE) in recognition of the commendable achievements in biomedical research

Rajni Ball

DR. RAJIV BAHL

Director General, Indian Council of Medical Research 4 November, 2023

#### 2023 Centres of Research Excellence

#### **CIA - Homer**



## Australian Government

National Health and Medical Research Council



#### In reply, please quote: NHMRC 2023 Centres of Research Excellence Application 2024658

Professor Caroline Homer

caroline.homer@burnet.edu.au

#### \*\*\*\*\*\*\* UNDER EMBARGO AND PROVIDED IN CONFIDENCE \*\*\*\*\*\*\*

This advice and document/s referred to below are provided under strict <u>embargo</u> and as such, on an in confidence basis. **The document/s and the information are not to be made public at this time by institutions or recipients**. NHMRC will notify your Administering Institution when your outcome is no longer under embargo.

\*\*\*\*\*\*

Dear Professor Homer

#### Application ID: 2024658 Grant Opportunity: 2023 Centres of Research Excellence Application Title: ARPAN - Accelerating Research and Progress in maternal And Newborn health: A Centre for Research Excellence to improve maternal and newborn health in the post-COVID-19 pandemic era

I am pleased to advise that the Minister for Health and Aged Care has approved your application (2024658) for National Health and Medical Research Council (NHMRC) 2023 Centres of Research Excellence commencing in 2023.

This letter provides you with important information about the offer of Funding made to Burnet Institute for this application.

#### **Assessment Details**

Where available<sup>1</sup>, information about the assessment of your application is provided in a separate Application Assessment Summary.

#### Accepting this offer

The offer of Funding for your Application is made under NHMRC's Funding Agreement (the Funding Agreement) between the Australian Government and your Administering Institution. Your Administering Institution is responsible for informing you about the requirements of the Funding Agreement (including its Schedules), the Direct Research Costs guidelines and other applicable policies<sup>2</sup>.

Your Administering Institution has until 15/10/2023 to certify that the information required prior to payment being made (see below) has been entered into NHMRC's Grant Management System, and to advise NHMRC of its acceptance of the offer. If the offer is not accepted by this date it may lapse. If you wish to discuss this offer of Funding, or have any queries, please contact your Research Administration Officer (RAO).

<sup>1</sup> An Application Assessment Summary is not available for applications to grant opportunities where NHMRC does not perform the peer review.

<sup>&</sup>lt;sup>2</sup> Funding Agreement, Direct Research Costs Guidelines and other policies are available on the webpage at: (https://nhmrc.gov.au/funding/manage-your-funding/funding-agreement).

#### Information required prior to payment being made

Where applicable, and except where otherwise indicated, NHMRC will temporarily withhold some or all of the Funding under subclause 15.2.a of the Funding Agreement with your Administering Institution until Specified Personnel with outstanding obligations from previous NHMRC grants, including submission of a Final Report, have met those obligations.

In some circumstances, CIAs may need to provide additional ethics information. This information must be entered into NHMRC's Grant Management System by the CIA and certified by the RAO. Should you have any questions concerning the provision of such information, please speak to your RAO.

If you need to seek approval to defer the start date of this grant, please refer to the Grantee Variations webpage or speak with your RAO.

#### Funding

As set out in the Schedule to the Funding Agreement, the 2023 Centres of Research Excellence 2024658, has been awarded \$2,500,000.00. Where applicable, this budget has been assessed by the peer review panel as sufficient to complete the aims and objectives of the research proposal stated in the application for funding. Any conditions relevant to receiving the Funding are set out in the Schedule to the Funding Agreement and, where applicable, the associated Funding Policy. All expenditure must be in accordance with the requirements of the Funding Agreement.

#### Participation in NHMRC Peer Review

NHMRC relies on the ongoing participation of the research community to ensure that every application receives expert peer review. NHMRC is grateful for this contribution which is acknowledged on its website's peer review honour roll.

To ensure that applications for future rounds are appropriately assessed, all Specified Personnel working on NHMRC Funded Research Activities are reminded that they may be requested to make themselves available to contribute to the peer review process, in accordance with clause 23.1 of the Funding Agreement.

Accordingly, we ask that you ensure your CV/Profile information is up to date in Sapphire to assist in the identification of appropriate peer reviewers.

Yours sincerely

[Authorised for electronic transmission]

Alan Singh Executive Director Research Translation Branch

# Cover Page (1 page)

ARPAN - <u>A</u> ccelerating <u>R</u> esearch and <u>P</u> rogress in maternal <u>A</u> nd <u>N</u> ewborn health: A Centre
for Research Excellence to improve maternal and newborn health in the post-COVID-19 era

Chief Investigators		
Chief Investigators		
CIA Prof Caroline Homer	Burnet Institute	Australia
		*
CIB A/Prof Joshua Vogel	Burnet Institute	Australia
		*
CIC Prof Pisake	Khon Kaen University	Thailand
Lumbiganon		
		<b>X</b> 11
CID Prof Shivaprasad	KLE Academy of Higher Education and	India
Goudar	Research, Jawaharlal Nehru Medical College	0
CIE Prof William Pomat	PNG Institute for Medical Research	Papua New
		Guinea
CIE A /Drof Mashar Dahran	L'airrensiter of Molle arms	
CIF A/Prof Meghan Bohren	University of Melbourne	Australia
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CIG Dr Lisa Vallely	Kirby Institute, UNSW and PNG Institute for	Australia
	Medical Research	*
		PNG
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CIH Prof Kirsten Black	University of Sydney	Australia
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CII Prof Adrienne Gordon	University of Sydney, Stillhighth Contro for	Australia
CII Proi Adrienne Gordon	University of Sydney, Stillbirth Centre for	
	Research Excellence	
CIJ Dr Susannah Leisher	International Stillbirth Alliance	USA
Associate Investigators		
AI Ms Catherine Breen	United Nations Population Fund (Bangkok)	Asia-Pacific
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Kallikolig		legion
AI Dr Titilola Duro-Aina	United Nations Population Fund (Fiji)	Pacific region
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AI Ms Anayda Portela		
Mi Wis Milayda i Ortora	World Health Organization	Switzerland
	World Health Organization	Switzerland
	World Health Organization	Switzerland
AI A/Prof Porjai	World Health Organization Khon Kaen University	
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Pattanittum	Khon Kaen University	<b>+</b> Thailand
Pattanittum AI A/Prof Kiattisak		+
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Pattanittum AI A/Prof Kiattisak	Khon Kaen University Khon Kaen University KLE Academy of Higher Education and	Thailand Thailand India
Pattanittum AI A/Prof Kiattisak Kongwattanakul AI Prof Yeshita Pujar	Khon Kaen University Khon Kaen University KLE Academy of Higher Education and Research, Jawaharlal Nehru Medical College	Thailand Thailand India
Pattanittum AI A/Prof Kiattisak Kongwattanakul	Khon Kaen University Khon Kaen University KLE Academy of Higher Education and	Thailand Thailand India
Pattanittum AI A/Prof Kiattisak Kongwattanakul AI Prof Yeshita Pujar	Khon Kaen University Khon Kaen University KLE Academy of Higher Education and Research, Jawaharlal Nehru Medical College	Thailand Thailand India India
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Pattanittum AI A/Prof Kiattisak Kongwattanakul AI Prof Yeshita Pujar AI Prof Manjunath Somannavar	Khon Kaen University Khon Kaen University KLE Academy of Higher Education and Research, Jawaharlal Nehru Medical College KLE Academy of Higher Education and Research, Jawaharlal Nehru Medical College Modillon Hospital, Madang province and the	Thailand Thailand India India PNG
Pattanittum AI A/Prof Kiattisak Kongwattanakul AI Prof Yeshita Pujar AI Prof Manjunath Somannavar AI Dr John Bolnga	Khon Kaen University Khon Kaen University KLE Academy of Higher Education and Research, Jawaharlal Nehru Medical College KLE Academy of Higher Education and Research, Jawaharlal Nehru Medical College Modillon Hospital, Madang province and the PNG Institute for Medical Research	Thailand Thailand India India PNG
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Pattanittum AI A/Prof Kiattisak Kongwattanakul AI Prof Yeshita Pujar AI Prof Manjunath Somannavar AI Dr John Bolnga AI Dr Michelle Scoullar	Khon Kaen University Khon Kaen University KLE Academy of Higher Education and Research, Jawaharlal Nehru Medical College KLE Academy of Higher Education and Research, Jawaharlal Nehru Medical College Modillon Hospital, Madang province and the PNG Institute for Medical Research Burnet Institute	Thailand Thailand India India PNG Australia
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Pattanittum AI A/Prof Kiattisak Kongwattanakul AI Prof Yeshita Pujar AI Prof Manjunath Somannavar AI Dr John Bolnga AI Dr Michelle Scoullar	Khon Kaen University Khon Kaen University KLE Academy of Higher Education and Research, Jawaharlal Nehru Medical College KLE Academy of Higher Education and Research, Jawaharlal Nehru Medical College Modillon Hospital, Madang province and the PNG Institute for Medical Research Burnet Institute	Thailand Thailand India India PNG Australia

# GRANT PROPOSAL – 2023 Centres of Research Excellence funding commencing 2023

# Response to Assessment Criteria (20 page limit)

# **EXECUTIVE SUMMARY**

**The problem:** Maternal and perinatal morbidity and mortality rates worldwide remain unacceptably high, particularly in low- and middle-income countries (LMICs).<sup>12</sup> The Asia-Pacific region exemplifies this problem – amongst the 36 LMICs (22 in Asia and 14 in the South Pacific), ten women die due to pregnancy-related causes every hour.<sup>3</sup> Driving these deaths is a lack of quality, respectful care for women and newborns, and knowledge gaps in the care of small and sick newborns. In addition, the problems with routine health management information systems and a paucity of other data monitoring systems means that evaluating the magnitude, causes and trends in maternal and perinatal morbidity and mortality to determine health system responses is challenging.

**The COVID-19 pandemic has significantly worsened women's and newborn's health across the region, with three years of major disruptions in health services**. Many Asia-Pacific LMICs are unlikely to meet their 2030 Sustainable Development Goal (SDG) targets for reducing maternal and newborn mortality, and ensuring universal health coverage.<sup>4</sup> Disruptions in essential services and reduced use of life-saving interventions have worsened maternal and newborn health.<sup>5</sup> The next 7 years is a critical window for intensifying efforts – regaining the progress lost to COVID-19, and ensuring SDG maternal and newborn mortality targets are reached by 2030. Research that drives improvement in women's and newborn's health services in the Asia-Pacific region will not only save lives, but lead to healthier communities, greater civil stability and better economic opportunities.<sup>6</sup>

We will establish the <u>Accelerating Research and Progress in maternal And Newborn health: A</u> Centre for Research Excellence (*ARPAN CRE*). This unique collaborative network will improve outcomes for women and newborns by strengthening reproductive, maternal and newborn research across the Asia-Pacific region. We will create evidence and grow international and crossdisciplinary partnerships to drive improvements women's and newborn's health.

The *ARPAN CRE* builds on greater than 20 years of our team's collective efforts that have generated real improvements in women and newborn health in the Asia-Pacific region and other LMICs. We bring together researchers, clinicians, policymakers and parent advocates from across the region to identify problems, co-create solutions and strengthen local research and translational capacity. We will build on our existing strong linkages with key organizations including the World Health Organization (WHO) in Geneva, WHO Collaborating Centres in India, Thailand and Australia, the United Nations Population Fund (UNFPA), global professional associations, consumer and advocacy organisations and the NHMRC Stillbirth Centre for Research Excellence. Together we will address the region's major maternal and newborn health priorities and help reach SDG targets.

**Our team** includes international experts in reproductive, maternal and newborn health (midwifery, obstetrics, neonatology, paediatrics, sexual and reproductive health, public health, epidemiology, infectious diseases, social sciences, knowledge synthesis and research translation). We bring together three outstanding international research groups (India, Thailand and Papua New Guinea), leaders from five Australian institutions (see Cover Page) with expertise in research and implementation, and a global consumer and advocacy organisation, the International Stillbirth Alliance (ISA). The *ARPAN CRE* will conduct much needed research and knowledge translation across the region, collaborate with WHO and UNFPA on shared priority areas, build collaborative networks to share skills and expertise, and develop the next generation of researchers. The *ARPAN CRE* will be a regionally-owned, multilateral platform that enables significant and sustainable collaborations between research groups and countries.

Many Asia-Pacific countries will not meet their 2030 targets for reducing maternal and newborn deaths and stillbirths. Approximately 800 women die each day worldwide from preventable causes related to pregnancy and childbirth, and an estimated 20 to 30 times that number experience pregnancy-related severe morbidity.<sup>7</sup> Globally, approximately 2 million babies are stillborn after 28 weeks' gestation<sup>89</sup> while 2.4 million infants die in the first month of life<sup>10</sup>. Efforts to reduce maternal and newborn deaths are working, but are well behind the SDG global targets of 70 maternal deaths per 100,000 live births and 12 newborn deaths per 1000 live births by 2030.<sup>511</sup> Global progress toward the 'Every Newborn Action Plan' goal of 12 stillbirths per 1000 births is also falling short.<sup>8</sup> More than 90% of maternal deaths, stillbirths and neonatal deaths occur in LMICs and our work has shown that around 80% of these could be prevented through universal access to quality maternal and newborn care, as well as contraception and reproductive health services.<sup>12 13</sup> Stillbirths rates are a sensitive indicator of the quality of care during pregnancy, labour and birth.<sup>8</sup> For women in the Asia-Pacific region, the risk of experiencing a stillbirth is 4 to 8 times greater than for women in Australia.<sup>8</sup> Most of these stillbirths can be prevented through goodquality maternity care, but new knowledge is needed to optimise stillbirth prevention in limitedresource settings.

**Inadequate coverage and quality of reproductive, maternal and newborn care services, worsened by the COVID-19 pandemic, is a major driver.** Good-quality care in the antenatal period (pregnancy), intrapartum period (onset of labour until 1 hour after the birth) and the early postnatal period (first 24 hours after childbirth) are critical to improving maternal, fetal and newborn survival and well-being, with quality antenatal care critical to identifying at risk pregnancies and preventing small and sick newborns.<sup>14</sup> However, even in those LMICs where women can access health facilities during pregnancy and childbirth, rates of preventable maternal and perinatal mortality and morbidity remain high.<sup>5</sup> This is due to substantial gaps in the quality of care provided in many health care facilities.<sup>15</sup>

The COVID-19 pandemic has dealt a significant blow to decades-long efforts to improve the coverage and quality of maternal and newborn health services in LMICs.<sup>45</sup> The re-direction of staff and resources to COVID-19 activities has de-prioritised essential healthcare for pregnant women and babies. This has manifested as lower rates of attendance to antenatal care and childbirth facilities and an increase in otherwise preventable maternal deaths, stillbirths and neonatal deaths.<sup>16</sup> Contraception access and coverage has significantly reduced in many countries<sup>17</sup> with a concomitant increase in unintended pregnancies, a leading contributor to unsafe abortion, maternal deaths and stillbirths.<sup>18</sup> Australia's regional neighbours include 36 LMICs in the Asia-Pacific – many experienced multiple COVID-19 waves that disrupted reproductive, maternal and newborn health services and strained resources. This caused avoidable maternal and newborn mortality and stillbirths and worsened the wellbeing of women and girls.<sup>5 19</sup> A WHO scoping review<sup>20</sup> (led by AI Portela) showed that the inability to provide face-to-face care during the pandemic was far more extreme and longer-lasting than during other disruptive events, such as natural disasters. Challenges with 'access to maternal, sexual and reproductive healthcare amongst vulnerable populations' and 'access to healthcare for children' are highly ranked global research priorities post COVID-19.21 While the pandemic may be in a new phase in many countries, the impact of nearly three years of disruptions to essential health services will be felt for decades.

**Reliable national health information systems on maternal and newborn care are lacking in** LMICs. Even prior to COVID-19, there were major challenges to reproductive, maternal and newborn health across the Asia-Pacific region. Most LMICs, including in the Asia-Pacific, have few or no health system mechanisms in place for continual monitoring of quality of care indicators or health outcomes at facility and national levels. Critical indicators such as maternal<sup>7</sup> and

## GRANT PROPOSAL – 2023 Centres of Research Excellence funding commencing 2023

Application ID: 2024658 CIA Surname: HOMER

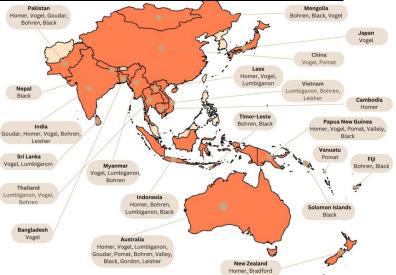
newborn<sup>22</sup> mortality and morbidity, stillbirth<sup>8</sup> and preterm birth (CIs Vogel, Lumbiganon),<sup>23</sup> are not collected or reported, and there is considerable variation in how preterm birth and stillbirth is measured (CIs Vogel, Homer, AI Scoullar)<sup>24</sup>, as well as a high burden of severe maternal morbidity (CI Vogel).<sup>25</sup> Our team's review in The Lancet Regional Health (Western Pacific) (*accepted and in press*)<sup>26</sup> (CIs Vallely, Vogel, Homer, Leisher, AIs Duro-Aina, Bolnga) highlighted unique challenges in measuring and monitoring maternal and perinatal outcomes across 22 Pacific Island Countries and Territories, including Papua New Guinea. Inadequacies in the measurement of stillbirth and a lack of clear initiatives to address preventable stillbirth were key findings. Policymakers, clinicians and healthcare managers across our region lack reliable data to guide, optimise and evaluate quality improvement initiatives.

**Contraception, especially postpartum contraception, is a critical intervention to improve the lives of women, girls and communities.** Contraception can significantly improve maternal and child wellbeing by ensuring healthy birth spacing and reducing unintended pregnancies. Postpartum contraception has the potential to have a major impact on maternal and child morbidity and mortality by reducing unintended pregnancies and high risk births and ensuring healthy birth spacing. Access to contraception can prevent over 70,000 maternal deaths annually. However, globally over 200 million women still have an unmet need for contraception; this unmet need is particularly high amongst postpartum women.<sup>27</sup>Amongst LMICs in the Asia-Pacific region, there are persistent gaps in women's access to modern contraception, as well as significant shortages in the reproductive health workforce and essential commodities.<sup>28 29</sup> While new WHO Guidelines for Postnatal Care<sup>30</sup> (including contraception) are available (co led by AI Portela and CI Homer was a member of the expert panel), LMICs are currently unable to fully implement them.

ARPAN CRE will address the major gaps across the Asia-Pacific region to improve outcomes for women and newborns: These gaps include:

- Lack of a <u>regional approach to monitoring quality of care</u> using harmonised data, especially in the intrapartum and early neonatal period, that can be easily used to drive local improvements in maternal and newborn care service delivery
- The need for feasible and context-appropriate interventions to address preventable stillbirth
- The need for novel, acceptable and cost-effective models of care that can improve women's access and use of <u>postpartum contraception</u>.
- A need to improve critical elements of quality of care including <u>implementing global</u> <u>recommendations for antenatal, intrapartum and postnatal care</u> and ensuring systems and processes for <u>maternal and perinatal death surveillance and response</u> are functional.

*ARPAN CRE's* scope is across the reproductive, maternal and newborn care continuum in the Asia Pacific region. This is reflected in specific research, knowledge translation and capacity strengthening activities related to pregnancy, childbirth and the postnatal period, encompassing both mother and baby. The focus on preventing stillbirth, reducing maternal and newborn mortality and morbidity, and increasing access to postpartum contraception, reflects areas that have been most negatively impacted by COVID-19.<sup>20</sup>



The Investigator team has deep experience conducting research, training and implementation across our region (see Map). *ARPAN CRE* unites three region-leading research institutions from India,

GRANT PROPOSAL – 2023 Centres of Research

Application ID: 2024658 CIA Surname: HOMER

Excellence funding commencing 2023 CIA Surname: HOMER Thailand and Papua New Guinea, five Australian institutions, the International Stillbirth Alliance (a global organization of bereaved parents, researchers and clinicians), the World Health Organization (WHO) and the United Nations Population Fund (UNFPA).

Our linkages ensure our activities are highly feasible and well-integrated with other national and regional initiatives, as well as with workplans of Ministries of Health and international agencies. *ARPAN CRE* takes a decolonising approach – focusing on equitable, "country to country" cross-collaboration and capacity strengthening. Skills, experience and expertise can thus be shared between countries, institutions and researchers who face similar challenges. Australian and international investigators will utilise their collective expertise to build up early investigators and emerging institutions in other Asia-Pacific LMICs, where research, funding and collaborative opportunities are rare or non-existent.

**The** *ARPAN CRE* **Vision:** a multi-national, collaborative network that builds and sustains research, knowledge translation and capacity strengthening, driving improvements in the Asia-Pacific's reproductive, maternal and newborn healthcare services.

**Criterion 1:** *ARPAN CRE* will **generate new knowledge to improve health outcomes** through three key interlinked streams of work:

(1.1) The Global Platform for Maternal and Newborn Health in the Asia-Pacific region (1.2) Innovative interventions to prevent stillbirth

(1.2.1) Testing the feasibility of maternal sleeping position in two countries

(1.2.2) Developing stillbirth prevention care bundles for the Asia-Pacific context

(1.3) Innovative models of care to improve access to postpartum contraception

Our flagship multicounty project - **Global Platform for Maternal and Newborn Health** - will also be a mechanism for translation of evidence into practice (CRE Criterion 2), as well as being a key to successful capacity strengthening (CRE Criterion 3) and strengthening collaborations across the Asia-Pacific Region (CRE Criterion 4).

Criterion 2: ARPAN CRE will ensure effective transfer of research outcomes by:

(2.1) Implementation research on the WHO Labour Care Guide for labour and childbirth and early postnatal care

(2.2) Optimising national Maternal and Perinatal Death Surveillance and Response programs (2.3) Regional scale up of key elements of WHO recommendations on antenatal, intrapartum and postnatal care

(2.4) Dissemination and implementation of ARPAN CRE findings and products

**Criterion 3:** ARPAN CRE will develop the health and medical research workforce by:

(3.1) Research training and education, staff development, and other collaborative activities to strengthen maternal and newborn research capability across the Asia-Pacific;

(3.2) Establishing a mentoring and development program between Australia, India, Thailand, PNG and Pacific Island researchers.

(3.3) Establishing a regional network of consumers and advocates to better engage consumers in research activities and ensure *ARPAN CRE* workplan meets the needs of diverse communities.

**Criterion 4:** ARPAN CRE will **facilitate collaboration** by:

(4.1) Establishing a **Pacific Perinatal Health Research Community of Practice** with the Pacific Society for Reproductive Health

(4.2) Establishing a **Regional Stillbirth Alliance** with the NHMRC Stillbirth CRE and the International Stillbirth Alliance to identify regional research priorities for stillbirth prevention and bereavement care

(4.3) Collaborating with UNFPA and WHO to enhance training, use guidelines and improve access to postpartum contraception.

# **Criterion 5: Record of research and translation achievement**

(5.1) Team expertise, research record, reputation, and discipline contribution ARPAN CRE brings together an exceptional team of chief investigators, associate investigators, and organisational and individual partners to deliver this CRE. In the last 5 years, our CI team have collectively received >\$A150M funding, published >1300 papers and have >65,000 citations (5.2) Research Translation: In this proposal, our CVs and 10 Best Publications we demonstrate our superb record of transition into guidelines, clinical practice updates and policy reforms

# **CRITERION 1: GENERATING NEW KNOWLEDGE TO IMPROVE HEALTH OUTCOMES**

# (1.1) The WHO Global Platform for Maternal and Newborn Health in the Asia-Pacific

**Project Steering Group:** All CIs and AIs, National Principal Investigators in each country, WHO-Geneva. Supported by a **Consumer Reference group**. **Collaborators**: WHO and UNFPA

The WHO Global Platform for Maternal and Newborn Health is a new multi-country network (~50 countries worldwide) to conduct research and improve quality of intrapartum and early postnatal care in health facilities. This Platform builds on previous WHO-led multi-country studies on maternal near-miss (CI Vogel), abortion, sepsis, and mistreatment of women and newborns during childbirth and postnatal care (CIs Bohren, Vogel). Collecting observational data every 3 years until 2030, it will provide periodic, globally-representative "snapshots" on intrapartum and early postnatal care quality and associated health outcomes for the SDG era. The Platform will also support dissemination and training in evidence-based products and drive epidemiological research capacity strengthening at local and national levels. Through *ARPAN CRE*, Burnet Institute will be the **Co-ordinating Institution for the Asia-Pacific region**, overseeing study conduct and capacity strengthening activities for 10 countries and their ~120 facilities (the first wave is already funded).

# **OBJECTIVES**:

- 1. Evaluate the quality of intrapartum and early postnatal care in facilities and measure the burden of maternal and newborn morbidity and mortality: The Platform will be the main international platform for global situational analyses on intrapartum and early postnatal care practices and health outcomes. Women's experiences of maternity care will also be evaluated.
- 2. **Supporting data-driven approaches to improving quality of maternal and newborn care:** Platform data will identify the knowledge translation gaps for key WHO maternal and newborn care guidelines, which will help facility and national stakeholders target quality improvement initiatives (CRE Criterion 2). It also provides the multinational network through which evidence-based products can be disseminated. This includes: WHO intrapartum and postnatal care recommendations,<sup>31 32</sup> WHO Labour Care Guide toolkits,<sup>33</sup> the digital Caesarean section monitoring tool<sup>34</sup> and a postnatal care toolkit (forthcoming 2023).
- 3. **Strengthening maternal and newborn health research capacity in LMICs:** Through the Platform, the *ARPAN CRE* will support local, national and regional research leadership, embedding research scholarships, training and supervision into data collection, analysis and quality improvement activities. It will also be a collaborative network within which further *ARPAN CRE* research activities will be conducted. Further funds will be sought for opportunistic observational, interventional and qualitative studies (CRE Criteria 3 and 4).

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**APPROACH:** In ~120 facilities across 10 Asia-Pacific countries, we will collect prospective data for all women who give birth in a 3-month period. Individual- level data will be collected on intrapartum and early postnatal care quality measures, maternal and newborn health outcomes, and women's experiences of care. The latter will be collected via audio computer-assisted self-interviews with randomly-sampled women prior to discharge. The Consumer Reference Group (3-4 consumer representatives from 2-3 countries) will advise on women and community priorities around experiences of childbirth and postnatal care. We will also conduct a survey of all maternity care providers in participating facilities on their self-reported clinical practices, and a separate survey of the Head of Department on their obstetric care capacity, intrapartum and postnatal care policies, physical environment, equipment and commodities.

**OUTPUTS**: Establishment of WHO Global Platform for Maternal and Newborn Health in 10 Asia-Pacific countries, which will be a sentinel network for maternal and newborn health surveillance until 2030. Data will inform facility- and national-level decision-making on quality improvements, as well ensure standardised monitoring of care quality and health outcomes over time.

# (1.2) Innovative interventions to prevent stillbirth

# (1.2.1) The feasibility of maternal sleeping position in two countries

*Project Steering Group:* CIs Vogel, Homer, Vallely, Leisher, Gordon, Goudar, Lumbiganon and AI's Bradford, Scoullar, Pujar. Supported by a **Consumer Reference Group**. *Collaborators*: NHMRC Stillbirth CRE, International Stillbirth Alliance

In Australia, giving women "going to sleep on the side" advice is now embedded into antenatal care, following studies in New Zealand, Australia and the UK showing that supine sleep position in late pregnancy was associated with stillbirth.<sup>35-38</sup> An estimated 6% of stillbirths could be avoided through this low-cost intervention.<sup>39</sup> Midwives, doctors and community health workers who provide maternity care in LMICs do not usually recommend "sleep on side", and it is not known whether sharing such advice with pregnant women would change their behavior, or improve outcomes. Our systematic review on safe sleeping position in LMICs (CIs Vogel, Homer) showed insufficient evidence on what constitutes normal sleep position for pregnant women in LMICs.<sup>40</sup> It is not known whether "sleep on side" advice is effective, practical or feasible in these settings.

# **OBJECTIVES:**

- 1. Explore what constitutes a normal going-to-sleep position among pregnant women in India, Thailand and Papua New Guinea
- 2. Assess the knowledge, attitudes and practices on sleep position advice during pregnancy among maternity care providers in these three countries
- 3. Identify if health education messages about side sleeping would be feasible and acceptable for healthcare workers and pregnant women in these three countries; and
- 4. Build mixed-methods research capacity for LMIC-based investigators through embedded research training, PhD/postdoc engagement and cross-country senior researcher mentoring.

**APPROACH:** *ARPAN CRE* will lead a mixed-methods formative study on maternal sleep position in six facilities across 3 Asia-Pacific countries, to explore whether and how this intervention can be used. We will use focus group discussions, interviews and surveys of pregnant women and providers to explore current practices, feasibility and acceptability. Consumer Reference Group (1-2 representatives from each country) will advise on strategies for engaging with pregnant women for study participation, and interpretation of data on acceptability of health messaging.

**OUTPUTS:** Evidence base to inform development of this novel intervention for stillbirth prevention in limited-resource settings, with expanded capacity in LMIC-based institutions for

GRANT PROPOSAL - 2023 Centres of ResearchApplication ID:2024658Excellence funding commencing 2023CIA Surname: HOMERconducting mixed-methods research. If we identify that safe side-sleeping advice is transferrable toLMIC contexts, a larger effectiveness trial will be planned.

# (1.2.2) Developing stillbirth prevention care bundles for the Asia-Pacific context

*Project Steering Group:* CIs Homer, Vogel, Bohren, Gordon, Goudar, Lumbiganon, Vallely, and AIs Bolnga, Bradford. Supported by **Consumer Reference Group**. *Collaborators*: Stillbirth CRE

The Stillbirth CRE (CIs Homer, Gordon) has led the development of a bundle of care to address the priority evidence practice gaps in stillbirth prevention.<sup>41</sup> A care bundle includes three to five evidence-based elements designed to formalise care, reduce practice variation and improve outcomes.<sup>42</sup> The Australian Safer Baby Bundle (see the Figure) is being implemented in several Australian states and is endorsed by multiple advocacy groups and professional colleges. It consists of five elements (smoking cessation, fetal movements, fetal growth restriction, side sleeping and timing of birth). The bundle is showing promising results with a 30% reduction in stillbirth in participating maternity services in Victoria in 2020.43 However, it is not clear whether the Australian bundle would be appropriate or applicable in LMICs in the Asia-Pacific region.



We have undertaken studies exploring stillbirths<sup>13</sup> and newborn deaths<sup>12</sup> in PNG<sup>18 19</sup> (CIs Vallely, Pomat, Homer, Vogel, AI Bolnga) and these highlight the need for effective stillbirth prevention programs, and potentially an adapted or novel stillbirth prevention bundle.<sup>20</sup>

# **OBJECTIVES:**

- 1. Conduct stakeholder consultations with maternity care providers, healthcare administrators and consumer representatives in 4 countries to co-design a stillbirth prevention bundle for LMICs in the Asia-Pacific region.
- 2. Explore facilitators and barriers to implementing a stillbirth prevention bundle for LMICs in PNG, Thailand, India and one other Pacific Island country.

**APPROACH:** CI's Bohren and Vogel will lead development of a 'clinical care bundle' using a codesign process, similar to their multinational study on a postpartum haemorrhage care bundle.<sup>44</sup> This process uses behaviour change and implementation science frameworks [e.g. capability, opportunity, motivation and behaviour (COM-B) and theoretical domains framework (TDF)] to guide data collection and analysis. Data collection includes qualitative interviews and surveys with providers, administrators and consumer representatives, as well as systematic reviews. We will triangulate findings across data sources, participant groups, and countries to explore factors that influence stillbirth prevention and how the Australian Safer Baby Bundle might be adapted. Collected data will inform and guide stakeholders participating in co-design workshops, where they will develop the tailored bundle and associated implementation strategies. The Consumer Reference Group (4-6 representatives from across 4 countries) who will participate in data collection and co-design workshops.

**OUTPUTS:** A bespoke stillbirth prevention bundle, co-designed with stakeholders for LMICs in the Asia-Pacific, that could be implemented across the region and in other LMICs internationally.

(1.3) Innovative models of care to improve access to postpartum contraception *Project Steering Group:* CIs Black, Vallely, Homer, Bohren, and AIs Bolnga, Duro-Aina, Bradford. Supported by a **Consumer Reference Group**. *Collaborators*: Pacific Society for Reproductive Health

The postnatal period is a crucial time for women, newborns, partners and their community. Postnatal women are among those with the greatest unmet need for contraception, but they often do not obtain the services they need to support longer birth intervals or avoid unintended pregnancies.<sup>27</sup> Reducing the unmet need for contraception in this period can result in fewer unplanned pregnancies, resulting in reduced maternal and child mortality, morbidity and malnutrition.<sup>45-48</sup> Vitally it can also ensure healthy birth spacing of 2-3 years as recommended by the WHO.48 In the Pacific, PNG and Solomon Islands have amongst the world's lowest contraceptive prevalence rates (32% and 26% amongst married women, respectively).<sup>49</sup> A recent UNFPA report of Pacific Island nations (CI Homer was a contributing researcher) - including the Solomon Islands, Kiribati, Samoa, Solomon Islands, Tonga and Vanuatu - estimated that if the unmet need for contraception were reduced to zero between 2020 and 2030, there would be 28% fewer stillbirths and a 29% reduction in maternal mortality.<sup>50</sup> Our research in PNG has found that more than half of pregnancies are unintended (CIs Vallely, Pomat, AI Scoullar), and that access to effective methods of contraception (such as contraceptive implants) are not only acceptable to women (CI Black, AI Bolnga)<sup>21</sup> but can reduce maternal and neonatal morbidity<sup>22</sup> (CI Black, AI Bolnga). CI Black is leading the development of an international consortium on postpartum contraception which will directly relate to this project.

# **OBJECTIVES**

- 1. To determine contraceptive preferences, barriers and facilitators to postpartum contraception access, as well as delivery systems and health workforce capacity in three Pacific Island countries
- 2. Develop, pilot, and evaluate a midwife/nurse-led model of care to deliver postpartum contraception in the three countries.
- 3. Assess the impact of the model of care on contraception use and short birth intervals

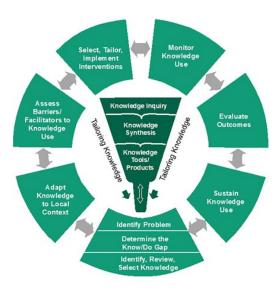
# APPROACH

We will undertake semi-structured interviews in each country with at least 10 consumers, 10 midwives/nurse and 10 other stakeholders to identify current issues and opportunities in postpartum contraception provision. With this information and, informed by the collective co-design experience of the CI and AI team as well as input from key stakeholder organisations such as UNFPA, we will develop a context specific model of care that will involve upskilling of health care professionals and resources for consumers and staff. The impact of the model of care will be evaluated with a before and after study that will survey women before and after the model of care has been implemented at 3 and 12 months postpartum. We will document the proportion of women using effective contraception (those methods with typical use effectiveness>90% efficacy including intrauterine devices, contraceptive implants, injectables, oral contraceptive pills and correct use of lactational amenorrhoea) at 3 months and effective contraception use and repeat pregnancy at 24 months.

**OUTPUT**: a midwife/nurse led model of care will be developed and tested that will deliver postpartum contraception in three Pacific Island countries (PNG, Solomon Islands and Samoa) that institutionalises consumer preferences, evidence-based interventions, tools, and approaches that ensure access and provide sustained improvements in services and impact positively on contraceptive uptake and birth spacing.

# GRANT PROPOSAL - 2023 Centres of ResearchApplication ID:2024658Excellence funding commencing 2023CIA Surname: HOMERCRITERION 2: EFFECTIVE TRANSFER OF RESEARCH OUTCOMES

The *ARPAN CRE* will by guided the Knowledge to Action (KTA) framework to link knowledge creation with knowledge application (Figure, right).<sup>51</sup> The framework has two components: a 'knowledge creation' funnel and an 'action cycle', each containing multiple phases. We will use the knowledge we have created in **Criterion 1**, combined with evidence-based WHO maternity guidelines (see 2.2). The action cycle requires analyses of local context, barriers and facilitators, which we will conduct through projects within **Criterion 2**. Collectively, these will enhance the translation of local evidence and global guidelines into real-world practice and policy upgrades. The KTA framework will support engaging with regional, national and local stakeholders, and help to tailor implementation efforts.



(2.1) Implementation research on the WHO Labour Care Guide for labour and childbirth Project Steering Group: CIs Vogel, Goudar, Lumbiganon, Homer, Bohren and AIs Bradford, Pujar, Somannavar. Supported by a Consumer Reference Group. Collaborators: WHO

In 2018, WHO's recommendations on intrapartum care for a positive childbirth experience<sup>29</sup> were released. A key consequence was the need for a new clinical tool to replace the old WHO partograph, so health workers can monitor a woman during labour and offer timely, evidence-based interventions. The LCG emphasises respectful maternity care and helps ensure supportive interventions (labour companionship, pain relief, mobility in labour, food/fluid intake and birth position) are routinely offered.

Our collaboration (CIs Vogel, Homer, Goudar, AI Pujar) has led a six-country study that tested this "next-generation" partograph, the **WHO Labour Care Guide (LCG)** in 12 hospitals. We demonstrated that the LCG is acceptable and feasible for providers in limited-resource settings,<sup>52</sup> and it is now WHO's "standard of care" tool for worldwide use.<sup>31</sup> We (CIs Vogel, Goudar, Homer, AIs Pujar and Somannavar) recently completed a cluster-randomised, stepped-wedge trial that evaluated the effects of introducing LCG in four hospitals in India. For this trial, we developed LCG training curricula, implementation tools, and technical expertise on how to implement LCG at scale in limited-resource contexts. The trial (completed, not yet published) showed that routine LCG use **can safely reduce unnecessary obstetric interventions and promote woman-centred care** during labour and childbirth. Building on our experience, we will co-ordinate further implementation research using the LCG in hospitals in two additional Asia-Pacific countries.

# **OBJECTIVES**:

- 1. Undertake a follow-up study in India to evaluate whether the benefits of LCG implementation are sustained long term, and its cost-effectiveness
- 2. Utilise findings from LCG-India trial to co-develop and evaluate a strategy for implementing the LCG in another site in India and two other Asia-Pacific countries.

**APPROACH:** For Aim 1 (funded), we will conduct a follow-up evaluation of the four India hospitals where LCG is currently implemented, to assess sustainability of LCG use, as well as its effects on intrapartum care practices and Maternal and Newborn outcomes in the longer term. An alongside economic evaluation will demonstrate whether and how implementing LCG can reduce health system costs. For Aim 2, we will conduct an implementation trial across 3 countries (another

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Indian state, and 2 other Asia-Pacific countries). This larger trial will expand our LCG-India implementation strategy to different contexts, and evaluate its effects on health, process-of-care and experience outcomes. We will engage our Consumer Reference Group (4-5 individuals from these 3 countries) in how to improve our measurement of women's experiences during childbirth, and how study findings can be best communicated to local communities. We will also conduct an alongside process evaluation to 1) identify the challenges to implementing LCG in different contexts, 2) explore acceptability, sustainability, and any adaptations that can optimise LCG use. We will use a nested, realist evaluation approach using mixed-methods to evaluate stakeholder experiences (e.g. qualitative interviews and surveys with postpartum women and health workers), labour ward observations, and document analyses. We will use the COM-B and TDF as overarching frameworks to guide data collection and analysis, with the goal of improving understanding of "*what worked, for whom, where and why*".

**OUTPUTS**: LCG and corresponding implementation strategies and tools adapted for three different contexts and implemented and evaluated in 12 hospitals in 3 countries. This will generate necessary implementation evidence base to drive further LCG scale-up at regional and global levels.

# (2.2) Optimising national Maternal and Perinatal Death Surveillance and Response

**Project Steering Group:** CIs Homer, Vogel, Vallely, Leisher, Gordon, Pomat, Lumbiganon, Goudar, Black. AIs Bolnga, Breen Kamkong, Duro-Aina, Bradford, Portela, Kongwattanakul, Pattanittum, Pujar, Somannavar. **Collaborators**: UNFPA, WHO

Maternal and perinatal death surveillance systems are essential to ensuring quality of care however they are not well developed in a number of Asia-Pacific countries. We have undertaken two studies in PNG<sup>12,13</sup> (CIs Vallely, Homer, Vogel, Pomat, AI Bolnga) that highlighted deficiencies in perinatal (stillbirth and newborn) death classification and identified preventable factors, especially around essential quality of care at birth. In 2021-22, CI Homer and AI Breen Kamkong reviewed the impact of COVID-19 disruptions on maternal and perinatal death surveillance and response (MPDSR) in 16 Asia Pacific countries and showed significant gaps, especially where the surveillance systems were implemented less than 5 years ago (*Report under review*).

A scoping review of MPDSR implementation shows that a culture of learning, continuous improvement and accountability is critical.<sup>53</sup> WHO (linked through AI Portela) has a new, extensive suite of MPDSR implementation tools.<sup>54</sup> These tools provide a roadmap for conducting effective MPDSR involving clinicians, policymakers and healthcare managers. In 2023-2024, UNFPA (AI Breen Kamkong) will support at least 4 countries, including Indonesia and PNG, with MPDSR system support and targeted capacity development through subnational and national committees using the new WHO MPDSR<sup>54</sup> implementation tools. Implementing these new tools will be undoubtedly challenging and require ongoing mentoring and support, but also presents a critical opportunity to generate new knowledge on their effective implementation.

This project leverages the expertise and experience of teams from India (CI Goudar, AIs Pujar, Somannavar), Australia (CI's Gordon, Bradford) and PNG (CIs Vallely, Pomat, Homer and AI Bolnga) in conducting effective MPDSR. We will utilise a similar conceptual framework applied in the PURPOSe study (Project to Understand and Research Preterm pregnancy Outcomes and Stillbirths in South Asia) in India and Pakistan CI Goudar, AIs Somannavar, Pujar).<sup>14,15</sup> This work draws upon our existing partnership with the Minimally Invasive Tissue Sampling (MITS) Alliance (CI Goudar, AI Somannavar).

**OBJECTIVE**: To implement the new MPDSR tools<sup>54</sup> in three countries (PNG, Thailand and one other Pacific Island country) and undertake a process and impact evaluation to develop an implementation framework.

**APPROACH**: We will implement the new MPDSR tools in collaboration with Ministries of Health, UNFPA and WHO in these 3 countries. We will use implementation research to understand the barriers, enables and essential elements for success through collecting qualitative and quantitative data at selected sites in the three countries. We will take a health policy and systems approach, examining people, their relationships and communication channels with a strong focus on how data drives response. We will be able to augment this study with data generated by provider-and facility-level data from the Global Platform related to maternal and perinatal death audit and reporting practices (*Project 1.1*). The analysis will support countries to implement the new MPDSR tools as part of an accountability system for every death and ensure that the results are able to be translated into local quality improvement measures.

**OUTPUT**: A framework will be developed to support implementation and sustainability of the new WHO MPDSR tools that can be used in other countries across the region.

# (2.3) Regional scale up of key elements of WHO recommendations on antenatal, intrapartum and postnatal care.

*Project Steering Group:* CIs Vogel, Bohren, Lumbiganon, Homer, Vallely, and AIs Bolnga, Portela, Pattanittum, Kongwattanakul, Pujar, Somannavar, Scoullar, Breen Kamkong. Supported by a **Consumer Reference Group**. *Collaborators*: WHO, UNFPA



The suite of WHO guidelines for maternal and newborn care (see Figure, left) was completed in 2022 with the release of the WHO recommendations on women and newborn care after birth for a positive postnatal experience.<sup>30</sup> These join WHO's antenatal,<sup>32</sup> intrapartum,<sup>55</sup> and postpartum haemorrhage prevention guidelines.<sup>56</sup> These have all been developed through WHO expert panels (CI Homer, CI Lumbiganon were members) with significant leadership from AI Portela, CI Vogel and CI Bohren. WHO has developed an implementation toolkit for antenatal care<sup>57</sup> and are currently developing toolkits for intrapartum and postnatal care. It is not known to what extent the WHO recommendations have been implemented across the Asia-Pacific region, and the specific barriers and enablers to implementation. We will use the WHO Toolkits as part of exploring the barriers and enablers to successful translation.

**OBJECTIVE**: Explore barriers, facilitators and strategies

for implementing WHO maternal health guidelines in three LMICs in the Asia-Pacific region.

**APPROACH**: This project will be conducted in India, PNG and Thailand, and adapted from our previous work in Myanmar, Uganda, Tanzania and Ethiopia, based on the KTA framework.<sup>58</sup> We will first engage senior Ministry of Health, WHO and UNFPA staff via our existing linkages and ensure country engagement and ownership. We will use first use stakeholder surveys and focus group discussions to understand current barriers and enablers to guideline implementation. This will be combined with real-world data derived from our Global Platform study (see *Project 1.1*) that will reflect current implementation gaps in facilities providing intrapartum and postnatal care. We will then hold in-person workshops with multiple stakeholder groups (administrators, policymakers, professional associations, healthcare providers and consumer representatives) to review these data, deliberate on local barriers and facilitators to WHO guideline uptake, and identify potential solutions. Prioritisation exercises and nominal group techniques will be used to reach consensus.

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The Consumer Reference Group (4-5 individuals from across the 3 countries) will be involved in engaging consumers in data collection, ensuring diverse consumer perspectives are heard, and ensuring implementation strategies address the real-world needs of communities.

**OUTPUTS**: Development of context-specific implementation strategies for successful translation of key WHO recommendations into clinical practice and policy in three countries, with applicability to other LMICs countries in the region.

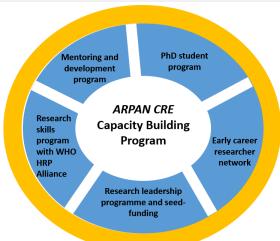
# (2.4) Dissemination and communication of ARPAN CRE findings and products

In the first 6 months, *ARPAN CRE* will establish a detailed research translation and communication strategy to ensure that evidence products are widely disseminated across the region. This strategy will include:

- *ARPAN CRE* Website will be developed a launched in Year 1. This will showcase our activities, investigators, early-career researchers and students, promote funding opportunities and provide a central resource for knowledge outputs. We will establish social media channels (Facebook is most popular in the region), in consultation with our Consumer Reference Group.
- **Peer-review publications in high-impact journals.** Our publication plan will leverage our CI team's extensive Editorial experience (CI's Homer, Vogel, Bohren, Lumbiganon). Burnet Institute will fund author-processing charges to ensure generated knowledge are open-access.
- Annual ARPAN CRE Scientific Meetings: ARPAN CRE Investigators hold leadership roles in key regional conferences Asia and Oceania Federation of Obstetrics and Gynaecology biennial Congress (CI Lumbiganon is President), the biennial International Conference on Maternal, Newborn and Child Health (Hosted by JNMC-India, CI Goudar, AI's Somannavar and Pujar are Lead Organising Committee), the biennial Pacific Society for Reproductive Health (CI Homer is on Scientific Committee), and the annual Perinatal Society of Australia and New Zealand (CI Homer is President). Annual ARPAN CRE Scientific Meetings will be organized alongside these conferences, ensuring we reach a wider international and multidisciplinary audience. We will also organize satellite sessions/symposia within high-profile international conferences such as the International Federation of Gynecology and Obstetrics (FIGO) World Congress, the International Conference (IMNHC).
- Quarterly **CRE Webinars** led by Australia, India, PNG and Thailand investigators will be used disseminate outputs across the region, leveraging our existing linkages with professional societies.

# **CRITERION 3: DEVELOPING THE HEALTH & MEDICAL RESEARCH WORKFORCE**

ARPAN CRE is committed to delivering training and support to future leaders in research in maternal and newborn health in the Asia-Pacific Region. We will provide **education and development opportunities** to boost capability of the health and medical research workforce at all levels. This includes all disciplines involved in maternal and newborn health including medical doctors, midwives, nurses, epidemiologists, social scientists and knowledge translation experts. We aim to especially support PhD students, early to mid career investigators and clinician researchers through five key areas (see Figure right).



Our activities to develop the health and medical workforce will be integrated with the Global Platform *(see 1.1)* which will link researchers and

GRANT PROPOSAL – 2023 Centres of Research

Application ID: 2024658 Excellence funding commencing 2023 CIA Surname: HOMER produce novel epidemiological data from ~120 facilities in 10 countries. The previous WHO multicountry near-miss study (CI's Vogel and Lumbiganon were investigators) resulted in 41 peerreview articles and >15 higher-degree student projects, as well as embedding LMIC research capacity strengthening throughout the study implementation, analysis and write up phases. We aim to emulate this level of success.

(3.1) Research training and education, staff development, and other collaborative activities to strengthen maternal and newborn research capability across the Asia-Pacific Project Steering Group: All CIs and AIs Collaborator: WHO HRP Alliance

We will establish a **Research Development Committee** with representation from CRE CIs to oversee development and training of PhD students, early-mid career academics, clinicians and consumers.

**PhD student program:** We will attract and support at least three PhD scholars from across the region. These will be based in overseas institution (India, Thailand and PNG). Students will be recruited from a range of relevant disciplines including obstetrics and gynaecology, midwifery, sexual and reproductive health, social science, epidemiology and paediatrics. PhD students will be embedded in the ARPAN CRE program of work, augmenting the cross-country linkages within the network. We will provide top-up scholarships and annual competitive funding to support student attendance at relevant regional and global conferences.

Network for supporting early career researchers (ECRs): We will also develop an ECR network (research assistants, PhD students, recent PhD graduates) which will be led by CI Vogel with involvement of other CIs and AIs on a rotational basis. the ECR network will meet monthly (online) for mentoring, support, practical advice and to foster a peer-to-peer research support culture. This network will be open to researchers from across the region, including those from other institutes and other Australian CREs (Stillbirth, Health in Preconception and Pregnancy). These relationships will be augmented through Australia Awards Fellowships for ARPAN CRE ECRs.<sup>59</sup>

**Research leadership programme and seed-funding:** Ensuring that promising ECRs can continue to develop into research leaders is critical to progress on maternal and newborn health in the Asia-Pacific. We will support 6-12 month Research Fellowships that will provide project seed funding to enable ECRs to lead a project within the ARPAN CRE network.

Research skills programme as part of the WHO's HRP Alliance: The HRP Alliance is part of the UNDP/UNFPA/UNICEF/WHO/World Bank Special Programme of Research, Development and Research Training in Human Reproduction (HRP)<sup>60</sup>. The HRP Alliance provides opportunities for developing local research capacity through a network of HRP Alliance Hubs and research partner institutions, WHO country and regional offices, WHO special programmes, and WHO Collaborating Centres. We will partner with the WHO HRP Alliance to utilise and augment their successful approach, that has been shown to build the capacity of LMIC institutions to conduct their own research and promote use of evidence for better outcomes.<sup>60</sup> CIs Lumbiganon, Goudar and Bohren are Directors of WHO Collaborating Centres and are already working closely with the HRP Alliance to mainstream research capacity strengthening in existing projects. Using the HRP Alliance model, CIs Vogel and Bohren previously built capacity in research teams in Ghana, Guinea, Myanmar and Nigeria as part of a multicounty study. All four country teams led multiple peer-reviewed publications, developed through training workshops and mentorship on research methods, data analysis, and scientific writing.

The HRP Alliance is operationalised through regional Hubs based in research institutions in Brazil, Burkina Faso, Ghana, Kenya, Pakistan, Thailand and Viet Nam. CI Lumbiganon and Khon Kaen

- Workshops and trainings on research methodologies and biostatistics, systematic review and meta-analysis, qualitative research methods, implementation research, monitoring and evaluation, protocol development and manuscript writing
- Post-graduate education (through masters and doctoral degrees)
- Tailored support to national research institutions for development and implementation of research studies and producing scientific publications
- Leadership in knowledge transfer activities that ensure implementation of WHO recommendations for policy and practice
- Cross-institution grant proposal development, supported by senior HRP Alliance researchers
- New collaborations among HRP Alliance fellows for specific research projects
- Research mentoring programmes, including specific mentoring for female ECRs.

The *ARPAN CRE* will extend HRP Alliance work by undertaking these activities with researchers across the Asia-Pacific region. HRP Alliance has prioritised this region for expansion.

# (3.2) Establish a mentoring and development program between India, Thailand, PNG and Pacific Island researchers

Project Steering Group: All CIs and AIs. Collaborators: WHO HRP Alliance

We will establish a formal research mentorship program between India, Thailand, PNG and Pacific Island researchers. This program aims to support high-potential health researchers to progress into leadership positions, retaining their skills in our sector. The program will pair ECRs/emerging leaders with more senior CRE investigators, advancing ECR skills and advancing their careers through international collaboration. Gender equity will be ensured by efforts to engage early and mid-career women and men equally. Our program will also provide current leaders the opportunity to develop ECR mentorship skills, as well as increasing awareness of the value of a diverse and inclusive workplace and the role they play in achieving this.

We will build on a model successfully implemented in Australia,<sup>36</sup> which is a structured program that combines informal mentoring sessions with formal sessions facilitated by experts in inclusive leadership. This will be supported by a specialist mentoring agency (eg. Serendis Leadership) to deliver the program. The CIs will work with this agency to develop and tailor a formal mentoring program to our contexts and needs. It will include a 12-month schedule for designated ECR/MCR team members from within the *ARPAN CRE* Network with formal group sessions (6 workshops) and one-to-one meetings between mentees and mentors. Another unique attribute of the mentoring program will be a considered matching process for the mentees and mentor pairs, which will take into account their career level, their aims are for the mentoring program each 12 months with up to 6 mentee-mentor pairs per year with ongoing support provided to the mentees.

# (3.3) Establishing a regional network of consumers and advocates

Consumer and advocacy representatives are key to ensuring *ARPAN CRE* meets the needs of diverse communities. This is currently no regional entity or organisation that links maternity-oriented consumer and advocacy groups across the Asia-Pacific, though several national and local groups do exist. *ARPAN CRE*, in partnership with ISA Western Pacific Regional Office and the Stillbirth CRE, will first create a register of these organisations in our priority countries.

JNMC-India team (CI Goudar, AIs Sommannavar, Pujar) have >20 years experience with community engagement in study design, implementation and dissemination. We shall adopt their successful approach in our study activities in other countries:

- Establishing a community engagement board at study sites to provide a forum for local input regarding research relevance, ensure we remain sensitive to community needs, and assisting with integrating research findings into local practice. The group usually comprises 10 to 12 individuals, including community leaders that are sought through local government, schools, religious organizations and local industries. The board meets with study investigators on a regular (quarterly) basis, or when new studies are proposed.
- Pre-study community sensitization meetings held in public venues to explain research purpose, relevance and processes, with community feedback obtained
- Early and continual engagement with Ministry of Health and local government officials, as well as community health workers and peer counsellors.
- Post-study dissemination meetings to share findings, discuss pathways to implementation

The aforementioned consumer/advocacy network, as well as community engagement boards, will be utilised to help identify appropriate individuals for **Consumer Reference Groups** within individual projects.

# **CRITERION 4: FACILITATING COLLABORATION**

Our governance model (Figure below) aims to facilitate collaboration both within *ARPAN CRE* stakeholders and more broadly across the Asia-Pacific region. A **Steering Committee** will have overarching responsibility, ensuring that all CRE activities are well-integrated. The Steering Committee, including all CIs and the CRE Manager, will meet every 2-3 months via videoconference.



The Steering Committee will have a rotating chair between CIs Homer, Goudar, Lumbiganon, Vogel and Pomat (one-year term per person). A detailed strategic plan with Key Performance Indicators will be drawn up in the first 3 months and reviewed annually. Project management support will be provided across the CRE program through the **Operational group**, consisting of CI Homer, the CRE Manager and Research Support Officer and key CIs or AIs depending on the projects underway at the time. The **Consumer Advisory Committee** will be co-chaired by a

consumer advocate and CI Leisher, provide advice across all key activities, and administer the register of consumer/advocacy groups across the region (*see 3.3*). Membership will be nominated consumers/consumer advocates across the region. The **Consumer Reference Groups** engaged with specific projects will be sourced and co-ordinated via this Committee.

A Research and Evidence Translation Committee will be established with representation from the CI and AI teams, Partnership Advisory Committee and the Research Career Development Committee. This Committee will meet every 3 months to monitor project implementation and ensure performance indicators are met. It will also oversee the dissemination and communication strategy (see 2.4). The Partnership Advisory Committee will be chaired by one of the CIs and will include the key partners as well as our AIs from WHO and UNFPA. The membership will vary

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over the 5-year period depending on the key activities underway at the time. Similarly, the Committee will meet every 3 months monitor progress, troubleshoot problems and support new and ongoing partnerships. The **Research Career Development Committee** will be chaired by one of the CIs and will have representation from all *ARPAN* countries. This committee will include representatives from the CI and AI groups and will meet every 3 months to develop and oversee the mentoring program, drive researcher development, and monitor, promote and support publications and funding opportunities.

**WHO Collaborating Centres (WHO CC):** The ARPAN CRE will also build a regional collaboration between the three WHO Collaborating Centres:

- WHO CC for Women's Health in the Western Pacific Region, University of Melbourne (CI Bohren is the Co-Director)
- WHO CC for Research Synthesis in Reproductive Health based in Thailand (CI Lumbiganon is the Director)
- WHO CC for Maternal and Perinatal Health Research based in India (CI Goudar is the Director).

**Key partners:** Our CI/AI team are well connected and will utilise our wide networks to strengthen collaborations with partners regionally and globally. The names in **bold** have agreed to support the work. For example:

- Asia Oceania Federation of Obstetrics and Gynecology (AOFOG): CI Lumbiganon is the President and CI Black is on the SRH Committee.
- International Stillbirth Alliance (ISA): CI Leisher is the ex officio Chair as well as current chair of ISA's Stillbirth Advocacy Working Group, **Professor Vicki Flenady** from the Australian Stillbirth CRE is a former ISA Chair and CI Gordon is a board member.
- Pacific Society for Reproductive Health: **Dr Kara Okesene-Gafa** is the President, **Dr Amanda Noovao-Hill** (close collaborator <sup>26</sup>) is the Secretariat and CI Homer is a Life Member
- RANZCOG global health committee: CI Black is a member and chairs the Sexual and Reproductive Health Special Interest Group
- WHO's HRP Alliance for Research Capacity Strengthening: **Professor Anna Thorson** is a specialist in infectious disease epidemiology who co-ordinates the WHO HRP Alliance. The Alliance brings together institutions conducting research in sexual and reproductive health and rights (SRHR) and CI Lumbiganon represents the South-East Asian Hub.<sup>61</sup>
- International Confederation of Midwives (ICM): **Ann Kinnear** is the ICM Board member for the Western Pacific region and will provide key links to midwifery associations

# (4.1) Establish a Pacific Perinatal Health Research Community of Practice with the Pacific Society for Reproductive Health

**Project Steering Group:** CIs Homer, Vogel, Vallely, Black. AIs Bolnga, Bradford. **Collaborators**: Pacific Society for Reproductive Health, WHO CC for Women's Health in the Western Pacific Region

The Pacific Society for Reproductive Health (PSRH) is a multidisciplinary society open to all those involved in reproductive, maternal and newborn health care in the Pacific. It was formed >20 years ago to foster education and assistance between members in Pacific Island countries through educational workshops and development of distance education for continuing professional development. It is an active network of professionals in reproductive, maternal and newborn health across 14 Pacific Island nations and neighbouring countries. For the past 10 years, CI Homer has delivered 2-3 day intensive research and audit workshops prior to biennial PSRH Conferences. Moving training online due to COVID-19 led to the creation of the Pacific Perinatal Health Research Community of Practice in 2021, which >30 clinicians from across the region have joined.

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Support from the *ARPAN CRE* will enable this Community of Practice to be formalised, strengthened and expanded. Pacific clinicians need access to online training on research methodologies, workshops to assist with grant writing and developing papers for publication and opportunities to present their work. This Community of Practice will directly link with the research development opportunities and networks described in **Criterion 3**. The Community of Practice will use a structured online program to engage the skills and expertise of our teams in India, Thailand and PNG to support research capacity strengthening across Pacific Islands nations. We plan to link mid-career researchers in our three countries with Pacific colleagues through the PSRH via a mentoring program.

(4.2) Establishing a Regional Stillbirth Alliance to identify stillbirth prevention and care research priorities in the region

*Project Steering Group:* CIs Homer, Vogel, Goudar, Vallely, Leisher, Gordon and AIs Bolnga, Duro-Aina, Bradford. *Collaborators:* Stillbirth CRE and ISA

The Australian Stillbirth CRE is the Western Pacific Regional Office of the International Stillbirth Alliance, with a focus on expanding activities regionally through the Burnet Institute (CIs Leisher, Homer, Vogel, Gordon). As described in **Criterion 1**, we have undertaken studies on stillbirths and newborn deaths in PNG (CIs Vallely, Pomat, Homer, Vogel and AI Bolnga) and the potential application of elements of a stillbirth prevention bundle into LMICs in the region. Members of our team (CI Goudar, AI Somannavar) have led a large prospective, observational cohort study in India and Pakistan examining the pathways to fetal and neonatal deaths with the Child Health and Mortality Prevention Surveillance (CHAMPS) network.<sup>15 38</sup>

The next step is to formally link the Pacific Society for Reproductive Health with the ISA Western Pacific Regional Office and the Stillbirth CRE to establish the Regional Stillbirth Alliance as part of the Global Monitoring Platform (*Project 1.1*). We will have a specific page for this Alliance on the *ARPAN CRE* Website that will enable cross country collaboration, networking and sharing of knowledge and experiences. We will draw on the Alliance to develop and identify stillbirth research priorities in the region, and examine feasibility of projects, such as developing a regional classification system to improve quality of data on causes of perinatal deaths. The Alliance will also provide education and training to clinicians and researchers from the countries in the region through a series of Webinars.

(4.3) Regional collaborations to enhance training, guidelines and access to contraception. Project Steering Group: CIs Homer, Black, Lumbiganon, AI's Breen Kamkong, Duro-Aina. Collaborators: UNFPA, WHO

In 2018 the Australian Government committed \$30 million to the UNFPA Transformative Agenda Program in six Pacific countries (Fiji, Kiribati, Samoa, Solomon Islands, Tonga, Vanuatu). The objectives of the Transformative Agenda program are to increase supply and improve client demand for integrated sexual and reproductive health information and services, in particular family planning, and promoting a more conducive and supportive environment for people to access goodquality services. Burnet Institute (CI Homer) is one of seven regional implementing partners for the Transformative Agenda with AIs Breen Kamkong and Duro-Aina.

A key area of the Transformative Agenda is improving access to modern methods of contraception. *ARPAN CRE* will link researchers with clinicians, regional development partners (UNFPA, WHO) and policymakers in the Pacific to improve contraception programs, but also utilise the expertise of India and Thailand research teams that have successfully addressed these issues in their own contexts. UNFPA team members will also facilitate sharing of research and translation into policy level action with parliamentarians through their regional network on sexual and reproductive health

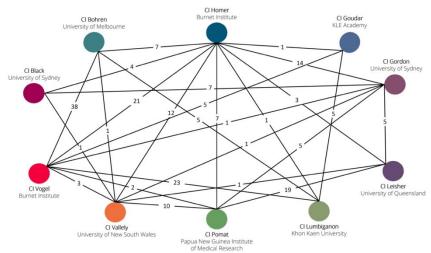
GRANT PROPOSAL – 2023 Centres of ResearchApplication ID:2024658Excellence funding commencing 2023CIA Surname: HOMERand rights. UNFPA's Asia Pacific Office (through AI Breen Kamkong) will raise issues with the<br/>Association of Southeast Asian Nations (ASEAN) through formal channels.2024658

#### **CRITERION 5: RECORD OF RESEARCH AND TRANSLATION ACHIEVEMENT**

#### (5.1) Team expertise, research record, reputation, and discipline contribution

The project builds upon strong, proven collaboration between CIs, AIs and our partner organisations. The team comprises internationally recognised experts in midwifery, obstetrics, newborn health, reproductive health, public health, epidemiology, infectious diseases, social science, knowledge synthesis and research translation. The team includes researchers with exceptional track records relative to opportunity at various career stages, including early (CI Leisher) and mid-career (CIs Vogel, Bohren, Vallely) researchers, who are supported by global leaders. The team's high international standing is evidenced by high publication output, grant success, leadership in professional organisations and frequent invitations for presentations and addresses at international fora. The team have demonstrated capability to advance research and

translation in maternal and newborn health through collaboration across borders and through key global organisations for advancing health (e.g. WHO, UNFPA, Cochrane and the Bill and Melinda Gates Foundation). Many of our team have worked together (see Figure above); this CRE provides opportunities to expand into new collaborative areas.



The reputation of our team is further evidenced by our leadership within national, regional and global professional organisations and contribution to major journals as editors and peer-reviewers. Notably, CI Homer is the top-rated expert in Midwifery in the world during the years 2011-2021 (according to Expertscape); Editor-in-Chief of *Women and Birth* (highest ranked global midwifery journal) and President of the Perinatal Society of Australia and New Zealand (PSANZ); AI Bradford is a board member. CI Lumbiganon is Convenor of Cochrane Thailand and President-Elect of the Asia Oceania Federation of Obstetrics and Gynaecology. CI Pomat is Director of the PNG Institute of Medical Research and Editor of the PNG Medical Journal. CI Goudar is Director of WHO Collaborating Centre for Research in Maternal and Perinatal Health and Senior Foreign Investigator, Global Network for Women's and Children's Health Research. CI Leisher is Chair of the International Stillbirth Alliance and CI Gordon is a board member.

**Our international research groups**: We bring together three outstanding Asia-Pacific research groups (from India, Thailand and Papua New Guinea), leaders from five Australian institutions with expertise in research and implementation, and a global organisation, the International Stillbirth Alliance (ISA).

*Jawaharlal Nehru Medical College (JNMC)* is a constituent medical school of KLE Academy of Higher Education and Research (Deemed-to-be University) located in Belgaum, Karnataka State in India. The JNMC Women's and Children's Health Research Unit is a member of the Eunice Kennedy Shriver National Institute of Child Health and Human Development-funded Global Network for Women's and Children's Health Research since 2001. The Unit is a WHO

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Excellence funding commencing 2023 CIA Surname: HOMER Collaborating Centre for Research in Maternal and Perinatal Health and has collaborations with international institutions from UK, USA and Canada, all aimed at reducing maternal and neonatal mortality. The Unit's 22-year research program has been funded by the Medical Research Council (UK), Government of India, National Institutes of Health (US), WHO and the Gates Foundation.

*Khon Kaen University* is a public research university in Thailand that offers 105 undergraduate majors, along with 129 master's degree programs, and 59 doctoral programs. The Faculty of Medicine is a WHO Collaborating Centre for Research Synthesis in Reproductive Health, the host institution of Cochrane Thailand, and is the Southeast Asia Regional Hub for Research Capacity Strengthening for the WHO-HRP Alliance. The Faculty has collaborations with academic institutions in Argentina, Burkina Faso, France, Kenya, WHO, UK, USA, and Australia, and has received research funding from NHMRC, European Commission, WHO, United States Agency for International Development, and Wellcome Trust (UK).

**PNG Institute for Medical Research** *is* PNG's primary medical research institution with a 50-year history of research into causes and solutions to PNG's major medical issues. PNGIMR conducts research in close collaboration with many Australian and international medical research organisations. The Institute was established in 1968 as a statutory body and is the research arm of the PNG Department of Health. One of the key programs in the PNGIMR is sexual and reproductive health. With its headquarters in Goroka, PNGIMR has more than 500 staff and has research sites, facilities and laboratories in Madang, Maprik, Alotau, Kokopo and Port Moresby.

*International Stillbirth Alliance (ISA)* is a global membership organization uniting bereaved parents and other family members, health professionals and researchers. ISA's mission is to raise awareness and promote global collaboration for the prevention of stillbirth and newborn death and provision of appropriate respectful care for all those affected. The ISA was established in 2003 and is an alliance of over 50 member organisations and individual supporters on every continent. The Stillbirth Centre for Research Excellence and the Burnet Institute host the ISA office of the Western Pacific region. ISA leads the Parent Voices Initiative with projects in India (through our partner organizations in Delhi and Chandigarh) and Kenya; manages the Global Stillbirth Support Registry of parent support organizations, which identified over 100 support organizations in Asia and the Pacific region; and leads the Global Scorecard work which recently included adaptation for the Western Pacific region.<sup>26</sup>

## (5.2) Research Translation

The *ARPAN CRE* team have an exceptional record of scientific excellence and research translation. Our team has particular strengths in affecting research translation in LMIC country contexts, driven by a collective commitment to advancing equity in maternal and newborn health. Critical elements in our team's success in health research and translation are wide-ranging involvement in international and regional bodies advancing maternal and newborn health, multi-disciplinary collaboration and significant experience in clinical practice/public health guideline development and communication.

CIs Homer, Vogel, Goudar, Lumbiganon and Bohren and AI Portela have all made significant contributions to WHO guidelines or standards for maternal and newborn care. CI Lumbiganon, AI Pattanittum, CI Vogel and CI Bohren have played a key role in Cochrane activities in the Asia Pacific Region. AI Duro-Aina and AI Breen Kamkong are technical advisors with UNFPA and have extensive experience implementing evidence-based policy on maternal and reproductive health, including in low resource settings and during humanitarian crises.

Major achievements in research translation by our team members in maternal and newborn survival and health include the following. CI Lumbiganon and CI Goudar have conducted randomised

## $GRANT\ PROPOSAL-2023\ Centres\ of\ Research$

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Excellence funding commencing 2023 CIA Surname: HOMER controlled trials of heat-stable medicines for prevention and treatment of major obstetric haemorrhage in LMIC's where cold chain is difficult. For example, the *WHO CHAMPION Trial Heat-Stable Carbetocin versus Oxytocin to Prevent Haemorrhage after Vaginal Birth* (111 citations) led to Carbetocin being introduced at low cost in >90 countries advancing a significant fight to reduce maternal deaths due to haemorrhage. CI Lumbiganon and CI Bohren are implementing a 5-year multi-centre implementation research project to reduce caesarean section, supported by the WHO and the European Commission. CI Goudar's investigations into healthcare provider competence in newborn resuscitation led to development of nationwide Helping Babies Breathe curriculum in India.

CI Homer's research findings on midwifery continuity of care have been integrated into the recommendations in the 2021 State of the World's Midwifery Report<sup>4</sup> and informed the development of midwifery education standards of WHO.<sup>39</sup> Her research has informed international guidelines for the implementation of midwifery continuity of care by the WHO (Pregnancy 2016, Intrapartum 2018, Postpartum 2022); implementation toolkits from New South Wales, Queensland and Western Australia and the 2020 National Stillbirth Action Plan. The outcomes been implemented in more than 50 hospitals in Australia and 14 publicly funded homebirth programs.

CI Homer and CI Vogel lead the panel (CI Gordon is a member) developing the living guidelines for the clinical care of pregnant woman with COVID-19 in Australia.<sup>40</sup> CI Gordon and AI Bradford have led the development and update of the PSANZ clinical practice guideline for care of women with decreased fetal movements. CI Bohren's research findings<sup>62-65</sup> have led to significant changes in maternity service provision, and influenced policy and implementation guidance, including four WHO guidelines and standards, a World Health Assembly resolution 'Strengthening people-centred health services), a WHO position statement and used in the development of national maternal health indicators. CI Valley's community-based intervention to reduce postpartum haemorrhage (with CI Homer)<sup>41</sup> led to the design of a district-level evaluation of the intervention, supported by UNICEF PNG. CI Pomat led a series of clinical trials of pneumococcal vaccines that changed immunisation policy in PNG. CI Black's research has been cited in WHO guidance for Actions for scaling up long-acting reversible contraception in Papua New Guinea<sup>66</sup> and has informed the development and continuation of a contraception service in one hospital.<sup>67</sup>

## CONCLUSION

*ARPAN CRE* is a unique opportunity to bring researchers, clinicians and consumers together to build back better and fairer in the post-COVID-19 era. Our CRE responds to key challenges facing the Asia-Pacific region including an inability to monitor the quality of maternal and newborn care; a lack of capacity to reduce preventable stillbirth; a lack of access to postpartum contraception; poor implementation of WHO recommendations across many of the countries; and, limitations in reviewing and responding to maternal, newborn deaths and stillbirths. All these issues have been exacerbated by disruption due to the COVID-19 pandemic.

This is a significant opportunity to bring together stellar teams from Australia, India, Thailand and PNG to improve the quality of maternal and newborn care, reduce maternal and neonatal morbidity and mortality and stillbirths and strengthen the capacity of the workforce to ensure that women, babies and families have the best chance of improved health outcomes. Our program of work will support the countries to meet the important Sustainable Development targets in reproductive, maternal and neonatal health and make a considerable difference across the Asia-Pacific region.

#### GRANT PROPOSAL – 2023 Centres of Research Excellence funding commencing 2023 Consumer and Community Participation (1 page)

Working across several Asia-Pacific countries, *ARPAN CRE* will engage with multiple consumers and community representatives - primarily pregnant women, their families and representatives or leaders of their communities. This engagement builds on our CI's existing partnerships with their local and national community organisations. We will be guided by NHMRC's consumer and community involvement framework to ensure we deliver value to these communities.

The **Consumer Advisory Committee** will be the co-ordinating entity for our consumer and community engagement, and the main forum for ensuring relevancy of research, that we remain sensitive to community needs, and to assist with integrating research findings into local practice. The group will comprise 10-12 individuals including community leaders, women with lived experience of childbirth, and social activists. We will ensure equitable representation from key Thailand, PNG, India, Pacific Islands and Australia, with equal female-male proportions. The study CI/AIs and study Coordinators will convene quarterly meetings or as needed when a new protocol is being proposed for a community or country. Project-specific **Consumer Reference Groups** drawn from local consumer/advocacy networks in the participating countries or the Consumer Advisory Committee as needed. The level of consumer engagement will vary between projects, but includes priority-setting (see *1.1, 1.3, 3.3*), research design and development (see *1.2.1, 1.2.2, 2.1. 2.3 and 3.3*), co-design activities (see *1.2.2, 1.3, 2.4*).

We have a strong partnership with the **International Stillbirth Alliance** (ISA, represented by CI Leisher). ISA is a membership organization uniting bereaved parents and other family members, health professionals and researchers to drive global change for the prevention of stillbirth and neonatal death and bereavement support for all those affected. It is a non-profit global parent and advocacy organisation established in the USA in 2003. CI Leisher, as immediate past Chair of ISA, has strong relationships with community groups in India and across Asia and now into the Western Pacific through the Stillbirth CRE. CI Gordon is a Board member of ISA. The accomplishments and partnerships of ISA that we will draw upon include:

- creating the first-ever global registry of stillbirth parent support organizations, and participatory development of toolkits to support parent advocacy in India and Kenya
- Supporting the Lancet's landmark 2016 Ending Preventable Stillbirths series including producing a Laypersons' Summary with consumers and translating it into 11 languages
- co-hosting the launch of the first-ever regular country-specific UN stillbirth estimates in 2020 and making space for parent voices from Indonesia, Kenya, and Nigeria who spoke to >2000 global participants
- working in partnership with Save the Children's Healthy Newborn Network, to support a monthly stillbirth-focused blog series with posts by parents, researchers, clinicians and policy makers globally (from many settings, e.g. Uganda, Nigeria, Australia, USA, Haiti, Zambia, Ghana, Sweden).

Our teams in India and PNG have existing community engagement boards and committees, that we will engage in project-specific Consumer Reference Groups. Other countries and research institutions (Thailand, other Pacific Island nations) do not yet have such community partnerships. *ARPAN CRE* cross-country collaboration will help address this gap, with India and PNG-based investigators coaching international colleagues on establishing similar relationships.

## CI Track Record (1 pages per CI)

**CIA PROFESSOR CAROLINE HOMER** AO RM MN (UTS) MMedSc(Clin Epi) (USyd) PhD (UTS) FAAHMS

*Career summary:* 2017-current, CI Homer is a leading midwifery and maternal health researcher, globally and in Australia. She is the Co-Program Director for Maternal, Child and Adolescent Health at the Burnet Institute and has honorary academic appointments at UTS, University of Melbourne, Monash, Deakin, Cardiff Universities and Kings College London. She holds an NHMRC Investigator Grant (L3) 2023-2027), is a recipient of the Order of Australia, Fellow of the Australian Academy of Health and Medical Sciences, was named as one of the 2020 WHO 100+ Outstanding Women Nurses and Midwives, received the Women's Hospitals Australasia – Medal of Distinction (2019) and has twice been named by the Australian's Research magazine as the top researcher in the field of pregnancy and childbirth (2020 and 2022). In 2022, CI Homer was awarded an honorary Fellowship of the Australian and New Zealand College of Obstetricians and Gynaecologists in recognition of collaboration.

*International standing:* Inaugural Chair of WHO's Strategic and Technical Advisory Group of Experts (STAGE) for Maternal, Newborn, Child, Adolescent Health, and Nutrition (2020-current) and a member of WHO's Scientific and Technical Advisory Group (STAG) for the WHO's Special Programme of Research, Development and Research Training in Human Reproduction. *Research support:* Last 5 years 1). L3 NHMRC Investigator Grant (\$3.4M) "Reducing maternal and newborn deaths: Transforming midwifery in the Asia-Pacific region through research and innovation (2023-2027); 2) CI on NHMRC Stillbirth CRE (2021-25), NHMRC Ideas Grant (2020-2022) "An investment case to catalyse funding for maternal, newborn, and child health", NHMRC Partnership Grant (2021-2023) "Advancing women in healthcare leadership" and MRFF Grant (2020-2022) on "The impact of neonatal care on long-term healthcare needs and outcomes". *Collaborations:* Collaborations at a local, national and international level especially on global maternal health. CI Homer has led collaborations with policy/decision makers in government to translate evidence into practice and is currently working with WHO and the International Confederation of Midwives on research on midwife-led birth centres in 4 LMICs.

*Community engagement:* Significant contributions in midwifery, both in Australia and globally. CI Homer is the immediate Past President of the Australian College of Midwives and has undertaken volunteer work teaching maternity emergencies across Australia as well as in Samoa and Timor-Leste. Previous member of Boards (volunteer capacity) Australian College of Midwives; Advanced Life Support in Obstetrics (ALSO) Asia Pacific and a current member of the Board of the Catherine Hamlin Fistula Foundation and the Perinatal Society of Australia and New Zealand (President). *Professional involvement:* Chair of NHMRC Council, Deputy Chair, Australian Medical Research Advisory Board, Co-Chair of the COVID-19 Clinical Evidence Taskforce: Pregnancy and Perinatal Care Panel, Chair of the Steering Committee for the National Clinical Evidence Taskforce and Steering Committee member for the Australasian Nursing and Midwifery Clinical Trials Network.

*Contribution to field, including translation of research into health*: She has an outstanding research output –>140 publications since 2017. Career total >300 peer-reviewed journal articles, 4 books and 14 book chapters.

*Example of the impact of previous research in the last 5 years:* CI Homer's research has made a significant impact on midwifery education and development of maternal health services. The findings from the Lancet Series on Midwifery (2 papers) have been integrated in the Standards for improving quality of maternal and newborn care in health facilities from the World Health Organization (WHO) in 2016, as well as informing the development of midwifery education standards by WHO (2019). CI Homer's research on homebirth is cited in the Victorian Government's guidance on safe and sustainable homebirth (Safer Care Victoria 2021), has been used by the ACT Government and the Australian College of Midwives to support homebirth, and was showcased in the 2020 Birth Time documentary. The study attracted media from the ABC, Sydney Morning Herald and Brisbane Times.

#### GRANT PROPOSAL – 2023 Centres of Research Excellence funding commencing 2023 **CIB ASSOCIATE PROFESSOR VOGEL** BMedSc MBBS PhD

*Career summary:* CI Vogel is an internationally recognised perinatal epidemiologist and a Senior Principal Research Fellow in maternal and perinatal health at the Burnet Institute in Melbourne. He co-heads the Global Women's and Newborn's Health Group with Prof Homer. He is an NHMRC Emerging Leadership Fellow (EL2, 2021-2025) and as the highest ranked applicant he was recognised with the 2020 NHMRC Peter Doherty Investigator Grant Award and the Commonwealth Health Minister's Award for Excellence in Health and Medical Research. He has honorary appointments at the University of Melbourne, Monash University, Deakin University and the University of Birmingham. Prior to coming to Burnet, he held maternal health research and guideline development roles at WHO.

**International standing:** CI Vogel has strong international research collaborations with senior researchers in Kenya, India, Nigeria and the UK. He has produced 188 peer-reviewed publications (10726 citations), including 99 in the past 5 years. His research is published in high-impact general journals including NEJM (1), Lancet (5), Lancet Global Health (7), PLoS Medicine (2) and Cochrane (9). His scientific contributions have been recognised as the 2020 winner of the Nature Driving Global Impact Awards.

**Research support:** CI Vogel has been an investigator on >20 primary research studies recruiting women in 39 countries and has led, or co-led development of 18 WHO guidelines. His research has been supported by Gates Foundation, WHO, UNFPA, Wellcome Trust, USAID, Merck for Mothers, Gates Foundation and others. During the past five years, he has been a lead or co-lead investigator on projects with grants totalling >A\$86 mil. This includes >A\$76 mil for the WHO ACTION Trials Collaboration, which he co-established with WHO colleagues for research on antenatal corticosteroids for preterm birth in low-resource countries. This collaboration has completed two multicentre trials (ACTION-I and ACTION-II), with another ongoing (ACTION-III) and a new multicountry implementation research study (ACTION-IR) funded. In the last 3 years he has been awarded an Investigator Grant (\$1.6 mil), a multi-centre trial in India (CIA, A\$410,102) and establishing a maternal health drug development pipeline (CIB, A\$2.56 mil).

*Contribution to field of research:* CI Vogel has an international reputation in the field of preterm birth, evidenced by his leadership roles in WHO global estimates of preterm birth (Lancet Glob Health 2019), the WHO preterm birth guidelines (WHO 2015) and the WHO ACTION-I trial (NEJM 2020). He was a member of the leadership group that developed the 2018 WHO intrapartum care guidelines, the 2020 WHO Labour Care Guide and he led the evaluation of this new clinical tool in 6 countries (Vogel et al, Birth 2020). CI Vogel was a lead investigator on the Umbiflow International Study (recruiting 7,000 pregnant women in five countries), and from 2012 – 2015 he co-ordinated the WHO Multi-Country Survey on Maternal and Newborn Health Network (A\$3.7 mil survey across 29 countries) which produced 41 scientific papers.

**Community Engagement and participation:** CI Vogel has run training workshops on research methods in several African countries and facilitated workshops on guideline development and implementation for national ministries of health, UN agencies and development organizations in >10 countries. He is a grant reviewer for national (NHMRC, MRFF) and international (UK MRC, Swiss National Science Foundation, European Research Council) organisations. He has supervised 34 individuals (26 female, 8 male) in a research environment, including 6 PhD students (5 ongoing, 1 completed), 6 Masters, 6 Honours, 7 medical student research projects (all completed), and 13 people through WHO internships.

**Professional Involvement and International Standing:** CI Vogel has presented at 25 national and international scientific meetings across 17 countries in the past 8 years, including 12 as invited speaker on preterm birth. As a WHO Officer, he convened >20 technical consultations of international experts. He is an Editor for two Cochrane Groups, was a co-author on the landmark 2016 Lancet Maternal Health Series.

#### GRANT PROPOSAL – 2023 Centres of Research Excellence funding commencing 2023

Application ID: 2024658

Excellence funding commencing 2023 CIA Surname: HOMER CIC: PROFESSOR PISAKE LUMBIGANON MD, Dip Thai Board of Ob & Gyn (Mahidol University), MS in Clinical Epidemiology, (University of Pennsylvania), Certificate in Strategic Leadership (Johns Hopkins University), FRCOG (ad eundem)

*Career Overview:* CI Lumbiganon is a prominent and highly-regarded researcher and administrator at regional, national and international levels. He is President of the Asia Oceania Federation of Obstetrics and Gynaecology. CI Lumbiganon was the President of the Royal Thai College of Obstetricians and Gynaecologists (2016-2018). He has been a professor of Obstetrics and Gynaecology since 1998 and was a dean of the medical faculty, Khon Kaen University (2009-2013). He has been a technical advisor for WHO since 1987. He was admitted as the Fellow ad eundem of the Royal College of Obstetricians and Gynaecologists (UK) in 2019 and was awarded the Prototype Doctor Award by the Thai Medical Council in 2018. He received Senior Researcher Awards and Distinguished Professor Award from Thailand Research Fund in 2004, 2007 and 2014 respectively. He has published > 200 papers with > 11,000 citations in the SCOPUS system. Research Support: CI Lumbiganon was the Co-PI of the South East Asia Optimising Reproductive and Child Health in Developing Countries (SEAORCHID) Project jointly funded by an International Collaborative Research Grant from the Australian NHMRC (No. 307703) and Wellcome Trust, United Kingdom (071672/Z/03/Z), a total budget of £1,037,641. He received two Senior Researcher Awards and one Distinguished Professor Award from Thailand Research Fund with a total budget of about US\$750,000. CI Lumbiganon was the PI (Thailand) for WHO CHAMPION Trial Group. Heat-Stable Carbetocin versus Oxytocin to Prevent Haemorrhage after Vaginal Birth financially supported by the Department of Sexual and Reproductive Health Research, WHO with a budget of US\$154,177. CI Lumbiganon is also a director of the WHO LID Regional Hub for the HRP Alliance of the Department of Sexual and Reproductive Health Research, WHO to do research capacity strengthening for WHO/SEARO region. This is an ongoing project, the budget up to this fourth year is US\$838,191. Most recently, CI Lumbiganon is the PI for a 5-year multi-country study on the Implementation and evaluation of nonclinical interventions for appropriate use of caesarean section in low- and middle-income countries jointly supported by WHO and European Commission (EUR 631,011).

**Research Translation and Impact:** CI Lumbiganon's publications have been cited as in *Williams Obstetrics* 24<sup>th</sup> and 25<sup>th</sup> Editions, WHO recommendations on interventions to improve preterm birth outcomes (2015), WHO recommendations for prevention and treatment of maternal peripartum infections (2015), WHO Guideline for protecting, promoting and supporting breastfeeding in facilities providing maternity and newborn services (2017), WHO recommendations: uterotonics for the prevention of postpartum haemorrhage (2018) and WHO recommendations non-clinical interventions to reduce unnecessary caesarean sections (2018).

**Community Engagement and Participation:** CI Lumbiganon has served as chair of the maternal and child health board of Khon Kaen Province in Thailand for more than 20 years. In 2017, when he was the president of the Royal Thai college of Obstetricians and Gynaecologists, he successfully convinced the Ministry of Public Health of Thailand to accept proposals to prioritise reducing unnecessary caesarean section and elimination of cervical cancer as national agendas. At the international level, CI Lumbiganon has served as the technical advisor for the department of sexual and reproductive health research (WHO HRP) for more than 30 years.

*Supervision and Mentoring:* CI Lumbiganon has been convenor of Cochrane Thailand since its inception in 2002. CI Lumbiganon has extensive experience in supervision and mentoring of faculty members and residents undertaking primary research and systematic reviews focusing on sexual and reproductive health. In 2017, he was appointed to be the director of the WHO/HRP Alliance LID HUB for research capacity strengthening in WHO SEARO.

#### GRANT PROPOSAL – 2023 Centres of Research Excellence funding commencing 2023

Application ID: 2024658

Excellence funding commencing 2023 CIA Surname: HOMER CID DR SHIVAPRASAD S GOUDAR MBBS (Medicine and Surgery) 1984 Karnataka University Dharwad, MD (Physiology) 1988 Karnataka University Dharwad, MHPE (Health Professions Education), 2001 University of Illinois at Chicago, USA

*Career summary:* CI Goudar is Director-Research, KLE Academy of Higher Education and Research, Belgaum (since 2020). Director, WHO Collaborating Centre for Research in Maternal and Perinatal Health (IND 156) (Since 2019). Senior Foreign Investigator, Global Network for Women's and Children's Health Research Site 8 (Since 2018), Research Coordinator, Global Network for Women's and Children's Health Research Site 8 (2001 - 2018), Professor of Physiology, J N Medical College, Belagavi (Since 2001).

*International standing:* CI Goudar as the former Research Coordinator and current Senior Foreign Investigator, has been responsible for implementation of all the research studies by the Belgaum site of the NICHD Global Network for Women's and Children's Health Research (GN) since 2001. CI Goudar also the Principal Investigator for a number of research protocols of the RHR and MNCAH Divisions of WHO and currently head the WHO Collaborating Center for Research in Maternal and Perinatal Health at J N Medical College as its Director.

**Research support:** Last 5 years 1). PI for Indian sites on; Multi-site Efficacy and Safety Trial of Intrapartum Azithromycin in LMICs (2019 to 2022); Low-birthweight Infant Feeding Exploration (2018-2022); Limiting Adverse Birth Outcomes in Resource -Limited Settings – The LABOR Study (2018-2023); WHO ACTION (Antenatal CorticosTeroids for Improving Outcomes in preterm Newborns) Trials (2017-2024); Aspirin Supplementation for Pregnancy Indicated Risk Reduction in Nulliparous Women (2015-2022)

*Collaborations:* Besides working with a number of international academic partners from the USA, Canada, UK, Africa and South Asia, CI Goudar has developed research collaborations with 25 academic research centres in different geographical regions of India. As Director-Research of KAHER, Belagavi, CI Dr Goudar is facilitating collaborative academic and research activities with Thomas Jefferson University, Philadelphia to address major global public health challenges, especially affecting mothers and children as well as mentoring junior investigators.

**Community engagement:** Evidence generated from studies Dr Goudar is involved has informed public health policy as well as leading to programmatically scale up for improving the health status of mothers and children globally. Notable being: the endorsement of oral misoprostol for prevention of PPH by the Govt. of India and FIGO-ICM, its registration in 26 countries for this indication, and its inclusion in the WHO List of EM and the UN Life Saving Commodities for Women and Children; revised 2015 WHO guidelines for the use of ACS in preterm births; refinement of the NRP and development of HBB newborn resuscitation training curriculum for birth attendants in community settings by the AAP and its subsequent incorporation in the Government of India guidelines of Newborn Resuscitation.

**Professional involvement:** Member of; Scientific Committee for Maternal Health Research and Emergencies Initiated by WHO & funded by BMGF; ICMR Expert Committee on Research Priorities in Stillbirth of ICMR, DHR, Ministry of Health and Family Welfare, Govt. of India; Technical Evaluation Committee for the Women and Child Health and Nutrition of DBT, Ministry of Science & Technology, Govt. of India.

*Contribution to field, including translation of research into health*: Dr Goudar has more than 200 peer reviewed publications and 7028 citations.

**Example of the impact of previous research in the last 5 years:** CI Goudar's research has made a significant impact; for example, the inclusion of heat-stable carbetocin in the WHO guidelines and FIGO-ICM recommendation for the use of uterotonics for the prevention of PPH, its inclusion in the 21st WHO model list of essential medicines and UNFPA product catalogue of quality assured products related to reproductive health.

# GRANT PROPOSAL - 2023 Centres of ResearchApplication ID:2024658Excellence funding commencing 2023CIA Surname: HOMERCIE PROFESSOR WILLIAM POMAT PhD MSc Post Graduate Diploma in Science BSc

*Career Overview*: CI Pomat is a public health researcher with a background in immunology, and expertise in neonatal pneumococcal infection and other respiratory pathogens. CI Pomat is the current Director of the PNG Institute of Medical Research, the country's leading academic research institute and an internationally recognised centre of excellence. CI Pomat's major research lies in the evaluation of new vaccines to prevent bacterial and viral infections and understanding protective immunity to infectious diseases among children, especially host-pathogen interactions at mucosal surfaces. Since 2016, he has jointly led a world-first cluster randomised trial that is evaluating point-of-care testing and treatment of sexually transmitted infections in pregnancy to improve birth outcomes in high-burden, low-resource settings. This trial is co-funded by the NHMRC and a Joint Global Health Trials award from DFID/MRC/Wellcome Trust UK, and is the largest clinical trial ever conducted in PNG. CI Pomat has 72 peer review publications; 52 in the past five years.

**Research Support:** In the past five years CI Pomat has secured >10 million USD in research funding. He is CIB of a co-funded NHMRC (APP1084429) and Welcome Trust (N006089) clinical trial in PNG (\$8.1 million; 2015-21); CIB of a World Health Organization funded study identifying the impacts and responses to COVID-19 in primary health care in PNG (\$219,406; 2021-2022); CIB of an NHMRC GACD grant of HPV-based testing and treatment for the elimination of cervical cancer in Papua New Guinea (\$1,590,166;2021-2025). CI Pomat is also co-investigator and incountry lead of a Gates Foundation award of pilot study to determine the feasibility, safety, and possible impact of probiotics to prevent early- life infections, early pneumococcal colonization and vaccine immunity in PNG infants (2019-21); and an NHMRC (APP1142715) project grant for control of endemic tuberculosis (2019-2021).

**Research Translation and Impact:** In the last decade, CI Pomat has led a series of clinical trials of pneumococcal vaccines that changed immunisation policy in PNG. Prof Pomat's specific skills in relation to this application relate to his in-depth understanding and experience in the conduct of clinical trials and interventions research in resource-limited settings; his extensive PNG field research experience; his proven track record in the establishment and leadership of robust collaborative research partnerships in PNG; and his leadership in the successful translation of research findings into public health policy and practice.

*Community Engagement and Participation*: CI Pomat is Deputy Chair and Secretary of the Institutional Review Board of the PNGIMR and committee member of the PNGIMR Biomedical and Social Science Society.

*Supervision and Mentoring:* Four Honours students completed in the last 5 years with ongoing mentoring of students on training programs through the Institute and from the University of Goroka.

*Peer Review and Discipline Involvement:* CI Pomat is Editor of the PNG Medical Journal and Editorial Board member of Pneumonia Journal. He has been an invited speaker at UNSW (2018, 2021) and recently presented at the Indo-Pacific Centre for Health Security on research activities through partnership.

CIF ASSOCIATE PROFESSOR MEGHAN A. BOHREN PhD, MSPH, BA (Psychology, African Studies)

*Employment history:* Associate Professor (since 2022), Senior Research Fellow (2019-2021), Lecturer (2018-2019), University of Melbourne. Previously a researcher with WHO in Geneva (2012-2017), Research Assistant, Johns Hopkins University (2010-2012), Research Ethics Board Coordinator, Population Services International (PSI) (2008-2010).

*Career summary*: CI Bohren is a leading social scientist and global health researcher specialising in gender and maternal health. CI Bohren's research is at the intersection of epidemiology and social sciences, using innovative approaches to understand complex healthcare and societal contexts to improve the quality of maternity care globally. CI Bohren has >100 research publications, including in high impact journals (Lancet, Lancet Global Health, PLOS Medicine), and >7500 citations. CI Bohren won the UniMelb Faculty of Medicine, Dentistry and Health Sciences 2020 research excellence award (early career).

**Research support:** Awarded >\$A34M in research funding from international and Australian funders, including >\$A2.7 million as CIA. CI Bohren has an Australian Research Council Discovery Early Career Award (2020-2023) and Dame Kate Campbell fellowship (UniMelb MDHS faculty). CI Bohren is a CI on 1 NHMRC Ideas grant, 2 Bill and Melinda Gates Foundation grants, 2 UK Medical Research Council grants, 1 EU-Horizon 2020 grant, and >\$2.5 million of research contract funding from national and international organizations.

**Contribution to field of research:** Mistreatment of women during childbirth (43 publications). The findings from this body of work have been applied globally, led to significant changes in maternity service provision, and influenced policy and implementation guidance, including 4 WHO guidelines and standards (2018 Intrapartum care guideline, 2016 Standards for improving quality of maternal and newborn care, 2016 Global Plan of Action to strengthen health systems to address interpersonal violence, World Health Assembly resolution 'Strengthening people-centred health services), a WHO position statement (2014), and used in the development of national maternal health indicators (Guinea, 2020).

*Community engagement and involvement:* Expert testimony at the United Nations Special Rapporteur on Violence Against Women's technical consultation on mistreatment during childbirth (2019, United Nations Office of the High Commissioner for Human Rights, Switzerland); Global Respectful Maternity Care Council (2013-), previously volunteer peer educator and HIV counsellor (Whitman Walker Clinic, Stellenbosch HIV Programme).

*Collaborations*: National and international collaborations including the WHO Collaborating Centre for the Western Pacific Region, Burnet Institute (honorary), Cochrane Effective Practice and Organisation of Care, GRADE-CERQual.

**Professional involvement:** WHO Guideline Methodology team (intrapartum care, preterm birth), GRADE-CERQual Methods Group Co-Convener (2018-) and Steering Group Member (2014-), Editor: *Cochrane Effective Practice & Organisation of Care* (2015-), Section Editor: *Reproductive Health* (2019-2021), Conference co-organiser (Fiocruz Brazil, Norwegian Institute of Public Health) "Using qualitative evidence to support decision-making in the SDG era" (2019), Human Ethics Advisory Group/Advisor University of Melbourne (2019-).

*Peer review:* Australian Research Council (2020-), European Science Foundation (2019-), WHO guidelines, clinical guidance, and technical documents (2017-)

*Supervision and mentoring*: Since 2018, CI Bohren has supervised 2 PhD students and 14 Masters research students to completion, and is currently supervising 9 PhD students.

#### GRANT PROPOSAL – 2023 Centres of Research Excellence funding commencing 2023 CIG: DR LISA M VALLELY PhD, MSc MCH

*Career summary:* Aug 2020-current Senior Research Fellow; Aug 2015-Jul 2020, Research Fellow, Kirby Institute, UNSW, Sydney. CI Vallely is an early-mid research fellow with the Global Health Program, Kirby Institute. She recently co-led a world-first cluster randomised trial of antenatal point-of-care testing and treatment for sexually transmitted infections to improve birth outcomes in high-burden, low-resource settings (2016-22). She was CIC of a study identifying the impacts and responses to Covid 19 in primary health care in PNG (2021-22). She is CIC of an adolescent sexual health study in PNG (2018-22). She is leading community and facility-based research to improve birth outcomes in rural settings in PNG (2022-)

*Academic Qualifications:* PhD, University of Queensland (2015); MSc MCH, University of London, UK (2000); Registered Midwife, Dip midwifery, UK (1994); Registered General Nurse, UK (1990).

**Research Support:** In the past five years CI Vallely has secured >\$A14 million in research funding. In 2018 she was awarded an NHMRC Early Career Fellowship (CIA; \$319K). She is CIH of a cofunded NHMRC (APP1084429) and Welcome Trust (N006089) clinical trial in PNG (WANTAIM trial \$A9.1 million; 2016-22), a world-first cluster randomised trial among antenatal women and their newborns; and CIC of an NHMRC project grant (APP1144424) on adolescent sexual, reproductive and maternal health in PNG (\$A702,234; 2018-21); and CIC of a WHO-funded study identifying the impacts and responses to Covid 19 in primary health care in PNG (\$A219,406; 2021-2022).

*Example of the impact of previous research in the last 5 years:* CI Vallely's research impact in the last 5 years has provided new knowledge to address a critical gap in determining whether STI testing and treatment in pregnancy leads to a reduction in adverse birth outcomes in LMIC. CI Vallely identified a high burden of STIs among pregnant women in PNG and demonstrated that WHO-endorsed strategies based on clinical diagnosis do not work. Her work went on to show the clinical performance, acceptability, and operational feasibility of point-of-care testing and treatment for the management of STI among women attending routine antenatal clinics in LMIC that drove the design and funding of the WANTAIM trial among 4600 women and newborns in PNG. CI Vallely's research on perinatal mortality in PNG has confirmed the high burden of avoidable perinatal deaths in PNG. These findings have highlighted the importance of stillbirth as a regional and global priority.

*Collaborations:* Honorary Senior Fellow, Burnet Institute (2021-current); Honorary Senior Research Fellow, PNGIMR (2015-date).

*Community engagement:* CI Vallely provides mentorship and support to the PNG Midwifery Society and provides technical guidance and support to government, non-government and development partner agencies at national and provincial level in PNG, including the National Department of Health, Susu Mamas, Care PNG, UPNG.

*Supervision and Mentoring:* CI Vallely supervises two PhD candidates at the Kirby Institute, UNSW. She recently supervised to completion a Papua New Guinean doctor undertaking her research-based MMedSci at the University of PNG. She provides mentorship and support to three Papua New Guinean PhD students, all of whom are conducting their research as part of studies on which she is a CI.

*Peer Review and Discipline Involvement:* CI Vallely regularly acts as peer reviewer for several journals in the field of midwifery, infectious diseases and public health. These include Repro Health J, Midwifery, PlosOne, ANZJOG, PNG Med J, BMJ Open, among others.

GRANT PROPOSAL – 2023 Centres of Research	Application ID:	2024658
Excellence funding commencing 2023	CIA Surname: H	OMER
CIH: PROFESSOR KIRSTEN BLACK MBBS, MMed, I	FRANZCOG, FFSRH, DLS	SHTM,
DDU, PhD		

*Career summary*: CI Black is Professor of Sexual and Reproductive Health at the University of Sydney, a Fellow of the Royal Australian and New Zealand College of Obstetricians' and Gynaecologists' (RANZCOG) and a Fellow of the Faculty of Sexual and Reproductive Health (FSRH) in the UK. She obtained a PhD from the London School of Hygiene and Tropical Medicine and works clinically as a gynaecologist in the areas of contraception, abortion and preconception care. At the University of Sydney CI Black leads the medical student teaching in Perinatal and Women's Health at her clinical school and is an academic leader in the Masters of Sexual and Reproductive Health Program. In 2018 CI Black received the Professor JA Young Medal, awarded by the Faculty of Medicine for excellence in research coupled with exemplary service to Sydney Medical School, the University and the community at large.

*Contribution to field of research*: CI Black undertakes epidemiological and clinical studies in obstetrics and gynaecology and in the last five years has published 90 peer reviewed publications and been named investigator on 9 successful grants totalling more than \$8 million, including 4 NHMRC grants and a national Department of Health Grant.

*Collaborations*: CI Black has established collaborations with CI Homer, CI Vallely, and CI Gordon. She is a member of the Sydney Health Partners Clinical Academic Group on Reproductive, Maternal and Newborn Health along with CI Gordon.

*Community engagement and participation*: CI Black chairs Family Planning NSW's clinical Advisory Committee and previously chaired the Heavy Menstrual Bleeding Clinical Care Standard Topic Working Group for the Australian Commission on Safety and Quality in Healthcare. She is a member of NSW Health's advisory group on abortion access. She regularly appears on national radio and television; in 2022 on SBS News, ABC News, ABC Health Report and Radio National's Background briefing.

**Professional involvement**: CI Black is a member of RANZCOG Women's Health Committee, the Global Health committee and chairs the special interest group in Sexual and Reproductive Health, a role which has seen her lead RANZCOG's development of training pathways in abortion and contraception. She is currently the deputy chair of the abortion guideline development group for Australia and New Zealand.

*International standing:* CI Black was a member of the FSRH International Affairs Committee between 2019 and 2021 and in 2021 was appointed to the Sexual and Reproductive Health Committee of the Asia Oceania Federation of Obstetricians and Gynaecologists (AOFOG). CI Black is regularly invited to speak at international meetings; in the last three years has presented at the RCOG World Congress in London, the Hong Kong Society of Obstetrics and Gynaecology and conducted webinars for AOFOG. Her research has been cited in a World Health Organization Action Plan, the National Clinical Care Standard for Heavy Menstrual Bleeding, the Faculty of Sexual and Reproductive Health Guidelines and RANZCOG clinical statements.

*Supervision and mentoring*: CI Black has had 9 PhD and 5 MPhil completions. She currently supports 6 PhD students, a post-doctoral midwife, as well as MD and Masters' student projects. She has been an academic career mentor through the Franklin Women's Program.

*Peer review involvement*: CI Black has been a panel member for the MRFF International Clinical Trial Collaborations 2021 and the 2022 EMCR Grant Opportunity Assessment Committee, the Medical Research Council (United Kingdom), the National Institute for Health Research (UK) and the Irish Medical Council. CI Black is a scientific editor on BMJ Sexual and Reproductive Health and until recently a scientific editor of BJOG.

# GRANT PROPOSAL – 2023 Centres of ResearchApplication ID:2024658Excellence funding commencing 2023CIA Surname: HOMERCII PROFESSOR ADRIENNE GORDON MBChB, MRCP (UK), FRACP, MPH (Hons), PhD

Career summary: CI Gordon is a Senior Neonatal Staff Specialist in the Royal Prince Alfred Hospital (RPAH) centre for newborn care and a Clinical Professor with the Discipline of Obstetrics, Gynaecology and Neonatology at the University of Sydney. CI Gordon is known nationally and internationally as an academic clinician whose research career has focused on prevention of adverse pregnancy outcome, and improving care, in particular stillbirth. CI Gordon is a chief investigator on the NHMRC Stillbirth CRE and leads a collaborative intervention enabled cohort called BABY1000 at the University of Sydney's Charles Perkins Centre, which is focused on the impact of intergenerational obesity, and includes the recently MRFF funded PRE-BABE trial. CI Gordon has been a plenary or invited speaker Nationally on > 60 occasions and invited speaker internationally 4 times including the World Obesity Congress 2016. CI Gordon is regularly asked to present at relevant National Annual Congresses including the Perinatal Society of Australia and New Zealand, RANZCOG, the Global Obstetric Update and the Sydney Innovation Symposium. CI Gordon represented both the Royal Australian College of Physicians and the Stillbirth CRE at public hearings for the recent Australian Senate Enquiry into Stillbirth Research and Education. CI Gordon has received several awards in the last 5 years including: NSW Health Harry Collins Award (2016), Sydney Local Health District Patients as Partners Award (2016), Sydney Local Health District Innovation Symposium "the Pitch" (2016). CI Gordon has 62 original and review peerreviewed publications in the last 5 years (total pubs 90; 4528 citations).

*Research Support*: CI Gordon has been a CI on grants totalling more than \$13 million in the last 5 years and AI for grants of > \$2 million. CI Gordon is CIA for three currently recruiting RCTs - PRE-BABE Trial (2020-2025 – MRFF \$1,920,566), the SLiPP Trial (2018 – 2021 – RedNose/Cure Kids \$182,917 and the Gloves On Trial (2019 – 2022 NSW Health TRGS \$442,262).

Research Translation and Impact: CI Gordon is a chief investigator on the "Safer Baby Bundle" NHMRC partnership grant; aiming to reduce stillbirth rates by 20% in 5 years. CI Gordon has also been a key member of the development of significant maternity clinical practice guidelines over the past 5 years, including the Perinatal Society of Australia and New Zealand (PSANZ) Care after stillbirth or neonatal death guidelines (March 2018), Care of women with decreased fetal movements (August 2019), and evidence based position statements on fetal growth restriction, maternal sleep position and smoking cessation in pregnancy (2019). CI Gordon is National Coordinator for the IMPROVE program focused on implementation of the PSANZ perinatal death guideline, which has been run internationally and nationally and has recently been developed into an eLearning program. CI Gordon is CIA for a recently funded translational cluster randomised trial to reduce late onset infection in preterm infants using non-sterile gloves, which 8 health districts have committed to introducing into practice if effective (Gloves On Trial NSW TRGS). CI Gordon contributed to the Lancet Stillbirth Series in 2016 and led the Sydney Stillbirth Study which contributed to an international collaborative IPD meta-analysis published in 2019 synthesising the best available evidence on sleep position and stillbirth. This evidence has informed 2 public health campaigns in the UK and NZ, and sleep position is included as an element in the Australian Safer Baby Bundle (and part of this CRE). CI Gordon leads the Public Awareness work of the Stillbirth CRE and led the design, development of evaluation of the Movements Matter Campaign run in Victoria in 2018.

*Community Engagement and Participation*: CI Gordon has significant involvement with Stillbirth Foundation Australia, RedNose and Still Aware. CI Gordon also has collaborations with Miracle Babies Foundation, Raising Children Network and Best Beginnings.

*Supervision and Mentoring:* CI Gordon is currently primary supervisor for five PhD students and associate supervisor for a further 2 PhD students. CI Gordon has supervised 3 completed PhDs as associate supervisor (2 awarded 2019, 1 awarded 2020) CI Gordon is also primary supervisor for two post-doctoral project officers, two research midwives and a trial dietitian. CI Gordon has mentored many advanced trainees in Neonatal/Perinatal Medicine and also supported 2 MFM advanced trainee projects.

GRANT PROPOSAL – 2023 Centres of ResearchApplication ID:2024658Excellence funding commencing 2023CIA Surname: HOMERCIJ ASSISTANT PROFESSOR SUSANNAH LEISHER BA MA (Hons) MSc (Hons) (PhDEpidemiology to be awarded December 2022)

*Career summary:* CI Leisher is a stillbirth epidemiologist and global stillbirth advocate. She came to epidemiology from a 25-year prior career in global poverty alleviation, including 10 years living and working in Vietnam and 5 years working in Africa, Central America and South Asia. CI Leisher was motivated in her career direction by the unexplained stillbirth at term of her first child. She is honorary research fellow at the Stillbirth CRE, and ex officio chair of the International Stillbirth Alliance for which she has served since 2012. CI Leisher is co-chair of the Stillbirth Advocacy Working Group (founded by WHO's PMNCH) since 2016.

*International standing:* CI Leisher is a member of the WHO/UNICEF Every Newborn Action Plan (ENAP) management team since 2019 and co-chair of the ENAP/EPMM Advocacy and Accountability Working Group. She has represented parent voices in various other global platforms eg presented at India's 'National Data Quality Forum Webinar Series on parents' role in improving stillbirth data'; moderated a panel on parent voices for the global launch of AlignMNH, funded by the Gates Foundation, JHPIEGO and USAID; invited to make a statement of support at global launch of the new ENAP targets and milestones for 2025; member of the International Advisory Board, Stillbirth Society of India (since 2021); invited panelist for WHO's Patient Safety Day 2021 global event together with the presidents-elect of FIGO, IPA, etc on "the role of partners in advancing the safety and respectful care agenda in maternal and newborn health".

**Research support:** CI Leisher was PI, F31 Ruth L. Kirschstein National Research Service Award, National Institute of Child Health and Human Development, U.S. National Institutes of Health, 2020-2022 (US \$83,280), for her doctoral research; signatory and co-manager on behalf of International Stillbirth Alliance for grants from WHO Geneva (Parent Voices Initiative including first global registry for stillbirth support organizations; advocacy toolkits for parents and clinicians in India and Kenya to support respectful stillbirth care and parent advocacy, US\$38,873), WHO SEARO (incorporating parent voices into India stillbirth advocacy toolkit, US24,940), Gates Foundation (for creation of global stillbirth advocacy and prevention guide, \$99,900).

**Collaborations:** CI Leisher collaborated with UNICEF to co-host the global launch of the UN-IGME stillbirth estimates in 2020, including managing the placement of parent and midwife spokespersons from Kenya, Nigeria and Indonesia, and co-created the Global Scorecard for Ending Preventable Stillbirths which has most recently been updated by UNICEF, published in UNICEF's Every Newborn Action Plan Progress Report 2020, and was integrated into Australia's National Stillbirth Action Plan. CI Leisher is a member of core management team for COCOON, a global survey of pregnancy and birth challenges during COVID-19; an international initiative working on the development of a new classification system for causes of stillbirth and newborn death for use in high-resource settings, being piloted in Australia and the Netherlands; a group revising RESPECT global principles for respectful bereavement care to ensure inclusion of voices from parents/clinicians in LMIC; and groups adapting Global Scorecard.

**Community engagement:** CI Leisher designed, secured WHO funding for, and co-managed the Parent Voices Initiative which includes the first-ever global registry of stillbirth parent support organizations (identifying over 600 organizations in 75 countries) as well as projects with partner agencies in India and Kenya to develop advocacy toolkits to support clinicians and bereaved parents for respectful care. Her work creating and leading the Parent Voices Initiative funded by WHO and the Gates-funded Global Guide for Stillbirth Advocacy and Prevention, to be launched in May 2023, contributes to raising global awareness of stillbirth and ensuring it is not left out of action for maternal and newborn health. The Stillbirth Scorecard she co-created highlights progress and gaps within countries and regions as well as globally on stillbirth prevention and support.

*Contribution to field, including translation of research into health*: As a member of the Lancet's Stillbirth series study group, CI Leisher analysed the extent of inclusion of stillbirth in global health initiatives for the 2016 series "Ending Preventable Stillbirths". The series led to inclusion of the global stillbirth rate as an indicator within the monitoring and evaluation framework for the SDGs.

#### GRANT PROPOSAL – 2023 Centres of Research Excellence funding commencing 2023

Application ID: 2024658 CIA Surname: HOMER

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#### GRANT PROPOSAL – 2023 Centres of Research

- Excellence funding commencing 2023
- CIA Surname: HOMER
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# Fwd: Recognition of your Institute as Adverse Drug Reactions Monitoring Centre (AMC) under PvPI.

From: IQAC Cordinator (iqac@klepharm.edu)

To: preeti.salve@gmail.com; preetisalve@klepharm.edu; rohinikavalapure@yahoo.com; rohinikavalapure@klepharm.edu

Date: Saturday, 8 July, 2023 at 01:40 pm IST

------ Forwarded message ------From: **Dept.Pharmacy Practice KLECOP, Belagavi** <<u>klebgmpharmacypractice2016@gmail.com</u>> Date: Sat, Jul 8, 2023 at 1:30 PM Subject: Fwd: Recognition of your Institute as Adverse Drug Reactions Monitoring Centre (AMC) under PvPI. To: IQAC Cordinator <<u>iqac@klepharm.edu</u>>, <<u>klecopnaac@gmail.com</u>>

------ Forwarded message -------From: **Dr. Ramesh Bhandari** <<u>rameshbhandari@klepharm.edu</u>> Date: Wed, Jan 4, 2023 at 2:11 AM Subject: Fwd: Recognition of your Institute as Adverse Drug Reactions Monitoring Centre (AMC) under PvPI. To: <<u>klebgmpharmacypractice2016@gmail.com</u>>

------ Forwarded message ------From: **NCC PvPI** <<u>pvpi.ipc@gov.in</u>> Date: Mon, 23 Aug 2021, 11:31 am Subject: Re: Recognition of your Institute as Adverse Drug Reactions Monitoring Centre (AMC) under PvPI. To: <<u>msganachari@gmail.com</u>> Cc: JAIPRAKASH JAIPRAKASH <<u>jaiprakash.ipc@gov.in</u>>, SHASHI BHUSHAN <<u>bshashi.ipc@gov.in</u>>, <<u>rameshbhandari@klepharm.edu</u>>, <<u>principal@klepharm.edu</u>>

Sir/Madam,

Greeting from NCC-PvPI !!!

This is with reference to your letter of intent to participate in a nationwide programme to monitor the safety of drugs. It is a matter of great pleasure to bring in your kind notice that the Indian Pharmacopoeia Commission (IPC), National Coordination Centre (NCC) - **Pharmacovigilance Programme of India (PvPI)**, Ghaziabad has approved your institution as an Adverse Drug Reactions Monitoring Centre under PvPI.

The detailed roles, responsibilities of Coordinator and Deputy Coordinator of AMC are attached herewith.



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Roles & Responsibilities of AMC Coordinator (1) (1).doc 72kB



INDIAN PHARMACOPOEIA COMMISSION National Coordination Centre- Pharmacovigilance Programme of India (PvPI)

# *Roles & Responsibilities of Coordinator and Deputy Coordinator Of*

## Adverse Drug Reaction Monitoring Centres (AMCs):

With the aim to fulfil the overall quality objectives of Pharmacovigilance Programme of India (PvPI), the following guideline has been designed for all structures, process as well as the conduct of all tasks and responsibilities. If performance of the ADR Monitoring Centre (AMC) is found unsatisfactory, the Competent Authority reserves the right to derecognise the AMC, and no further correspondence in this regard will be entertained.

The Coordinators and Deputy Coordinators of the Adverse Drug Reaction Monitoring Centres (AMCs) have been assigned the following Roles & Responsibilities in order to ensure the smooth functioning of the AMCs.

#### **Role of the AMC Coordinator:**

- 1) Establishment and capacity building of AMC and assuring the logistics & infrastructural facilities for smooth functioning of the PvPI activities.
- 2) Ensure adherence to the defined core principles and quality policy of the PvPI.
- 3) Ensure a systematic approach towards quality management system, its implementation and maintenance.
- 4) Meeting commitments and responding to the requests from competent authorities/NCC for correct and complete information.
- 5) Ensure the timely and effective communication with NCC-PvPI.
- 6) Communicating information to healthcare professionals and patients about Drug safety alerts and signals issued from NCC-PvPI to promote patient safety.
- 7) Ensure the adequate compliance management (if any) when asked from NCC-PvPI.
- Coordination with the auditors appointed by NCC-PvPI/CDSCO in order to ensure the smooth functioning of AMC.
- 9) Good cooperation should be fostered between Pharmacovigilance Associate (PvA) competent authorities, patients, healthcare professionals and other relevant bodies in

#### INDIAN PHARMACOPOEIA COMMISSION



National Coordination Centre- Pharmacovigilance Programme of India (PvPI) accordance with the provisions for the conduct of Pharmacovigilance processes at AMC.

## **Responsibilities of the Coordinator:**

- 1) Responsible for the overall performance of Pharmacovigilance activities and progress of AMC.
- 2) To ensure the formation of Causality Assessment Committee (CAC) and timely conductance of meetings as per SOP.
- 3) Ensure the availability of all the documents at AMC as per SOP.
- 4) Monitor and guide the Pharmacovigilance Associate (if appointed) to perform the assigned duties of PvPI.
- Maintain the confidentiality of the Vigiflow login details and ensure timely electronic transmission of Individual Case Safety Reports (ICSRs) to NCC-PvPI through software.
- 6) Ensure the quality of Pharmacovigilance data submitted to the NCC-PvPI.
- 7) Establish mechanisms enabling the traceability and follow-up of ADR reports and ensure that it is handled and stored in a way to allow accurate reporting, interpretation and verification of that information whenever queried from NCC/Competent authorities.
- 8) Ensure the availability of the archiving arrangements for the electronic and/or hardcopies of the ADR reports (Source documents) at AMC and the retention of the documents as per the Pharmacovigilance norms.
- Ensure availability of the summary / description of the training / CME / awareness / sensitization programmes on Pharmacovigilance etc. conducted at AMC including the records and certificates.
- 10) Ensure good Coordination/communication between the appointed PvA and various departments of the college/hospital.

## **Role of the Deputy Coordinator:**

#### INDIAN PHARMACOPOEIA COMMISSION



National Coordination Centre- Pharmacovigilance Programme of India (PvPI)

- 1) Assisting and coordinating with the Coordinator of the AMC for PvPI activities and smooth functioning of the AMC.
- Assist in ensuring the adherence to the defined core principles and quality policy of PvPI.
- Ensure the timely and effective communication with NCC-PvPI in absence of the AMC Coordinator and vice versa.
- Handling of overall activities of AMC in case of Superannuation/transfer of the Coordinator till further appointment of the Coordinator at the centre and intimation to NCC-PvPI immediately.
- 5) Coordination with the AMC coordinator for awareness among healthcare professionals and patient for ADR reporting and drug safety.
- 6) Assisting coordinator to provide the information for adequate compliance management.
- 7) Foster good cooperation between Pharmacovigilance Associate, competent authorities, patients, healthcare professionals and other relevant bodies (if any) in accordance with the provisions for the conduct of Pharmacovigilance processes at AMC.

#### **Responsibilities of the Deputy Coordinator:**

- Responsible for the conductance of the Pharmacovigilance activities and progress of AMCs.
- 2) Verifying the availability of all the documents at AMC as per SOP.
- 3) Ensure the quality of Pharmacovigilance data including the correctness and completeness submitted to the NCC-PvPI.
- 4) Ensure the traceability and follow-up of ADR reports and providing the information when queried from NCC/Competent authorities through the coordinator of AMC.

#### ALL INDIA COUNCIL FOR TECHNICAL EDUCATION Nelson Mandela Marg, Vasant Kunj, New Delhi-110070

#### **RPS** - Sanction Letter

File No. 8-89/FDC/RPS (POLICY-1) /2019-20

Date: 14 Aug 2020

The Drawing and Disbursing Officer All India Council for Technical Education Nelson Mandela Marg, Vasant Kunj, New Delhi-110070,

Release of a sum of Rs.1264663/- being the 1st installment of the total grant of Rs.1283922/- for conduct of Project Sub: under Research Promotion Scheme (RPS) during the financial year 2020-21.

Sir.

With reference to the proposal submitted by the institute, this is to convey the sanction of the Council for payment of Rs.1264663/- (Rupees Twelve Lakh Sixty Four Thousand Six Hundred Sixty Three Only) as 1st installment out of a total approved grant-in-aid of Rs.1283922/- for conduct of a Project under the Research Promotion Scheme (RPS), as per details given below:-

l.	Name and address of the Beneficiary Institution (University / College / Institution)	*	Registrar / Director / Principal, KLES College of Pharmacy,Hubli, Hubli, Dharwad, Karnataka-580031
11.	Principal Investigator's Name & Dept./Course	:	Dr. Fatima Sanjeri Dasankoppa (Pharmacy)
, III. ·	Grant-in-aid Sanctioned	:	Rs.1283922 /- (Rs. 1091334/- for non-recurring and Rs.192588 /- for recurring expenditure)
1V.	Amount to be Released during the year 2019-20 (as 1 <sup>st</sup> installment)	•	Rs.1264663 /- (Rs. 1091334/ Full amount of non-recurring & Rs.173329/ 90 % of recurring sanctioned)
V.	Project Duration	:	3 Years
VI.	Title of the Project	:	"Febrication of Halloysite polymer doped nano composite scaffolds for Tissue Engineering"

#### I. Release of funds:

- 1. The amount of the grant shall be drawn by the Drawing and Disbursing Officer (DDO), All India Council for Technical Education, New Delhi on the Grants-in-aid bill and shall be disbursed to and credited to the account of KLES College of Pharmacy, Hubli, Hubli, Dharwad, Karnataka-580031 through RTGS/PMFS.
- 2. The sanctioned grant-in-aid is debitable to the Major Head "601.12.a (RPS Plan)" Gen. and is valid for payment during the financial year 2020-21.
- 3. The sanction issues in exercise of the powers delegated to the Council. It is also certified that grant-in-aid is being released in conformity with the rules and principles of the Scheme.
- 4. The grant-in-aid is being released in conformity with the Terms & Conditions as well as norms of the scheme as already communicated and also being communicated in this letter.
- II. Maintenance of account by the Institute/PI:
- 1. Funds covered by this grant shall be kept separately and would not be mixed up with other funds so as to know the amount of interest accrued on the grant.
- 2. The grant is intended to cover items of expenditure/equipment approved by AICTE.
- 3. Acknowledgement of receipt of grant and letter of acceptance of terms and conditions is to be submitted to AICTE within 15 days from the receipt of the grant to the following address:

Director (Faculty Development Cell), AICTE, Nelson Mandela Marg, Vasant Kunj, New Delhi-110070

Contd..



- 4. The accounts of the grantee will be opened for test check by the Council or Comptroller & Auditor General of India or by any officer designated by them
- 5. The Principal and PI of the institute are requested to verify the correctness of the undermentioned bank account/RTGS/PENAS doubt in the institute are requested to verify the correctness of the undermentioned bank

account/RTGS/PFMS details submitted by them alongwith the Proposal, in which the grant is being released. In case of any omission, the same characteristic submitted by them alongwith the Proposal, in which the grant is being released. omission, the same should be reported to AICTE immediately along with refund of entire grant: -Institute

Pan No. AABTK088	Bank Name	Branch	Bank Branch Add.	Account Holder Name	Account	Account Number	IFSC Code
16	Syndicate Bank	KLE Campus	Vidyanagar, Hubli- 580031	Principal	Saving Account	12402010014413	SYNB0001240

- 6. The grantee Institution shall observe all financial norms and guidelines as prescribed by the AICTE/Government of India from time to the second se time to time. Grantee institution must follow GFR guidelines in procuring the sanctioned items and maintain an audited record of assets acquired wholly or substantially out of the grant-in-aid and a register for assets shall be maintained by the Institute in the prescribed form i.e. GFR-19.
- 7. Interest accrued on the sanctioned grant-in-aid will be reported and refunded to AICTE and not adjusted against the subsequent installment.

#### III. General Instructions:

- 1. It should be ensured that no RPS project in favour of the same P.I. has been sanctioned during the last 03 years before utilizing this amount and the matter be brought to the notice of this Council immediately in case a faculty is sanctioned multiple RPS Projects.
- 2. The duration of Project is 03 years and the date of release of the grant by AICTE shall be taken as the date of commencement of the project. The Registrar/Director/Principal shall intimate about the receipt of the grant to AICTE. Any Expenditure, incurred prior to issuance of this Sanction Order, would not allowed to be adjusted in the grant and if the University/Institution do not take-up the project work within 6 months of the receipt of the grant, approval shall ipso facto lapse and the Institute has to necessarily refund the entire grant to AICTE along with interest within a month. In case the grant is not refunded within said duration 18% interest will be levied on it. The grant has to be refunded to AICTE, through RTGS as per details given below:

Account Number	55113199952
Name of the Account Holder	Member Secretary, AICTE, New Delhi
Bank Name	State Bank of India
Branch Name	Shashtri Bhawan, New Delhi
IFSC Code	SBIN0050203

3. The Institute may constitute a Project Monitoring Committee (PMC). The composition of the PMC shall be as under:

- Principal/Director of the institution (Chairperson) i
- Two HODs from institute (Members) ii.
- In case of private institute one subject expert from government institute, not below the rank of Associate Professor iii. (Member)
- Coordinator of the project (Member Secretary) iv.
- 4. The grant shall be utilized strictly for the purpose as specified in the sanction letter. Re-appropriation of funds from one Head to another is strictly not permitted viz. Recurring and non-recurring Heads. Further, the equipment(s)/item(s) purchased should be as per the specifications and individual item-wise costs sanctioned by AICTE, and not taking the total grant sanctioned as one entity. Item-wise purchase cost shall be matched with the sanctioned cost, and the cost of item purchased below the sanction cost shall be restricted as actual cost. If the item purchase cost is higher than its sanctioned cost, the cost shall be restricted to the sanctioned cost and the additional amount shall be met by the Institute from its own resources.
- 5. Similarly, the recurring grant shall be used for the items sanctioned by the AICTE. No money be used for going abroad to attend Conference / seminars. However, for presenting a Paper in a Seminar / Conference within the country, the travel expenses may be met from the recurring grant.

Contd...3/-



#### :: 3 ::

- 6. No request for additional grant over and above the sanctioned grant shall be considered by the AICTE. The additional amount, if any, expended beyond the sanctioned grant shall be met by the Institute from its own resources.
- 7. The institute/University shall not charge any overheads on this Project and will provide all the administrative support and timely release of grant to PI for completion of the Project.
- 8. The grantee shall utilize grants only on approved items as per list of equipment attached. However, if the grantee wishes to recast the Project, approval of Council must be obtained for the revised item of expenditure and they will maintain proper accounts of the expenditure as per the norms/procedures of AICTE/Government of India. The revised proposal should be within the total grant sanctioned and duly supported with reasons and recommendations of the Project Monitoring Committee (PMC).
- 9. The assets acquired wholly or substantially out of All India Council for Technical Education's grant shall not be disposed or encumbered or utilized for the purpose other than those for which the Grant was given without proper sanction of the All India Council for Technical Education.
- 10. Each project sanctioned by AICTE is assigned a specific Reference Number, which is given on pre-page. All correspondence address to AICTE regarding the project must quote this number alongwith year of sanction of the project, otherwise correspondence may not be entertained.
- 11. The grantee shall follow the terms and conditions of Research Promotion Scheme (RPS) as laid down by the Council from time to time.
- IV. Submission of documents by the institute/PI to AICTE:
- A. Documents to be submitted within one month of completion of each financial year:
  - Annual Progress Report, indicating therein the number of patents, publications or any other achievement. i.
  - Utilization Certificate, Audited Utilization Certificate, Receipt & Payments, Statement of Expenditure. ii.
  - Audited record of assets acquired wholly or substantially out of the grant-in-aid and a register for assets in the iii. prescribed form i.e. GFR-19.
  - Separate Bills/vouchers related to Non-recurring and recurring expenditures duly signed & stamped by the PI & Head iv. of the institution.
  - Stock entry register duly verified by the Store-in-charge and PI & counter signed by Head of institution.
- Documents to be submitted within two month of completion of the Project:
  - The consolidated Utilization Certificate (UC) and Receipt & Payment Account for the Project duration, duly audited. i
  - Consolidated audited statement of expenditure, to the effect that the grant has been utilized for the purpose for which it has been sanctioned. It should contain the head-wise break up of expenditure made from the grant-in-aid provided ü. by the Council.
  - Project Completion Report duly signed & stamped by the PI & Head of the institution and Project Evaluation Committee iii. (PEC) Members.
- Principal Investigator/institute to submit the Feed Back Form in AICTE format. iv.
- The prescribed formats for submission of necessary mandatory documents and Terms & Conditions may please be V. downloaded from www.aicte-india.org/schemes/research-innovations-development-schemes.

Note: Any deviation from the above said time schedule will cause serious action against the institute.

Contd ..... 4/-



File No. 8-89/FDC/RPS (Policy-1)/2019-20

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#### Approved list of items under Non-recurring grant:

S. No.	Approved Item (As per proposal)	No. of Units	Amount recommended
A.	Non-recurring	1	Rs.1091334/-
i)	Differential Scanning Calorimetry- 60 Shimadzu	1	Rs.173329/
ii)	Freeze Dryer TFD- 8503 Labindia		KS.1133231
В.	Recurring (i.e. 90% of total approved recurring grant) for Contingencies & Consumables only		Rs.1264663,
	Grand Total (A)+(B)		

Registrar/Director/Principal, 1. KLES College of Pharmacy, Hubli, Hubli, Dharwad, Karnataka-580031

Name of Principal Investigator, 2. Dr. Fatima Sanjeri Dasankoppa, KLES College of Pharmacy, Hubli, Hubli, Dharwad, Karnataka-580031

Office of Director General of Audit 3. General Revenues, AGCR Building I.P. Estate, New Delhi-110002.

Guard File

4.

(Col. B. Venkat) Director (FDC) 21 106 2020





Karnataka Science and Technology Promotion Society Dept. of Information Technology, Bio Technology and Science & Technology, GoK "Vijnana Bhavan", 3<sup>rd</sup> Floor, #24/2, 21<sup>st</sup> Main Road, Banashankari 2<sup>nd</sup> Stage, Bangalore-70 Ph/fax: 080-26711166, E-mail: ksteps.dst@gmail.com

Dr. H. Honne Gowda Special Secretary (Technical), Dept. of IT, BT and S&T, Gok/ Managing Director, KSTePS

No. KSTePS/VGST-CISEE/2018-19/GRD No.747]315

Date: 17.07.2019

Dear Sir/Madam,

Sub: Intimation of selection of the project under the VGST scheme of CISEE – reg.

Greetings from the Department of Science and Technology, GoK & KSTePS. We are pleased to inform you that the project titled "Development of Bio adhesive nanoparticles for vaginal delivery of a selected antiretrovirals" submitted under the VGST scheme of CISEE for the financial year 2018-'19 has been approved by the Government based on the recommendations of Vision Group on Science and Technology under the Chairmanship of Bharat Ratna Prof. CNR Rao, Honorary President, JNCASR.

The total project grant award for a period of 3 years is Rs. 30.00 lakh, which will be released annually @ Rs. 10.00 lakh based on the progress of work. You are requested to take an immediate action to initiate the project at the earliest and to be completed within 3 years after receiving the grant of 1<sup>st</sup> installment from our office.

The grant will be paid to the Head of the institution, under whose supervision the Principal Investigator shall be responsible for completion of the stated objectives of the project. The Principal Investigator through the Institution Head shall have to submit the progress report in soft copy once in 6 months without fail. The grants shall be used only for the purposes described in the grant application by following due procedures of KTPP Act. Any deviation from the scheduled plan must have a prior approval from the VGST.

Future release of grants will be based on satisfactory project performance and review. The funding agency has the right to terminate the project, if it is found to be not satisfactorily pursuing and fulfilling the stated project goals and objectives. The whole amount sanctioned or any unspent balance must be returned back to the funding agency within 60 days following the final report of the project. Any publications or other dissemination arising from research supported by VGST grants should be acknowledged.

Dr. S. G. Sreekanteswara Swamy, Consultant, VGST will be the nodal officer for all future correspondences related to the project. His contact details are given below:



...2

Principal KLE College of Pharmacy Bengaluru-560 010

Scanned with CamScanner

Vision Group on Science and Technology, Department of IT, BT and S & T, Room No. 702, 7<sup>th</sup> Floor, 4<sup>th</sup> Gate, M.S. Building, Dr. Ambedkar Veedhi, Bengaluru – 560 001. Phone : 080-2203 2013 Email : <u>visiongroup.st@gmail.com</u> Website : <u>www.vgst.in</u>

The sanctioned grant will be sent through NEFT/RTGS to your institution. Hence, it is requested to send the following bank details on your intuitional letter head, sealed and signed by the head of the institution, by post. A scanned copy of the same may be sent through E-mail: <u>ksteps.dst@gmail.com</u> & <u>visiongroup.st@gmail.com</u> for swift process.

- 1. Account Name
- 2. Account Number
- 3. IFSC Number
- 4. Name of the Bank
- 5. Branch

After receiving the grant to the institute, you are suppose to open an new saving bank account in the name of VGST scheme & get the grant transferred from the institution's main account. I would like to personally thank and greet you for being selected as one of the VGST program members and we wish you a great success in the implementation of the project.

Thanking you,

Yours sincerely,

H. Honne Gowda)

#### To,

Dr. H.N Shivakumar, Professor & Head, Department of Pharmaceutics, KLE College of Pharmacy, 2nd Block, Rajajinagar, Bengaluru - 560 010.

CC:

- 1) The Principal, KLE College of Pharmacy, 2nd Block, Rajajinagar, Bengaluru 560 010.
- Deputy Secretary to Govt., Dept. of Science and Technology, Room No. 305, 5<sup>th</sup> Floor, 5<sup>th</sup> Stage, M.S. Building, Dr. Ambedkar Veedhi, Bengaluru -560 001.
- 3) Dr. S. G. Sreekanteswara Swamy, Consultant, Vision Group on Science and Technology, Department of IT, BT and S & T, Room No. 702, 7th Floor, 4th Gate, M.S. Building, Dr. Ambedkar Veedhi, Bengaluru -560 001.





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Vision Group on Science and Technology

Department of Information Technology, Biotechnology and Science & Technology 4th Gate, 7th Floor, M.S. Building, Dr. Ambedkar Veedhi, Bengaluru - 560 001 Phone : 080-2203 2013, E-mail : visiongroup.st@gmail.com, Website : www.vgst.in

Dr.S.G.Sreekanteshwara Swamy, Ph.D., Consultant

No /VGST/GRD -376/2014-15/2015-16/2020-21/ /66

Date: 05-10-2020

To, The Principal, KLE College of Pharmacy, 2<sup>nd</sup> Block, Rajajinagar, PB.No.1062, Bangalore-560 010.

Dear Sir.

Subject: Approval for the PART -A - (GRD No- 376) for the purchase of equipments under K-FIST(L1) scheme for 2nd Instalment.

With reference to the approval of GRD No- 376- Dr.Subhas.S.Karki, Department of Pharm.Chemistry, KLE college of Pharmacy,2<sup>nd</sup> block, Rajajinagar, Bengaluru, under the scheme, K-FIST (L1) was sanctioned the project entitled "Establishing the Facility for Design, Synthesis and Characterization of Silymarin Derivatives as Antioxidant & Anticancer Agents" and released the grant of Rs 10.00 lakh as 2<sup>nd</sup> Instalment for the FY:2015-16 through chq no:598766 Dt:28.01.2020).

The Review committee meeting held on 07/04/2018, approved for the purchase of equipments as submitted in the PART - A of GRD-376 by the Grantee Institution for the Second & Final Instalment. The details are as follows.

The 2<sup>nd</sup> Instalment – Non-Recurring Budget details under E-Tendering process (ETP) for the FY: 2015-16.

	SL. No	The PART – A under Non – Recurring (ETP) Budget as submitted by the Grantee Institution.	Unit Price x No.of units(in Rs)	Amount (Rs)
-	1	Iceflaker 50Kg/24hrs model:LMI-50 HSN	1,20,000.00 x 1	1,20,000.00
-	2	code:84186910 EQUITRON chilled water circulator	1,20,000.00 x 1	1,20,000.00
-	3	Chem office professional single user software	2,19,831.00 x1	2,19,831.00
Mint	40	Not a give water and the second and	KLE Colle	4,59,831.00 √→-\$ incipal ge of Pharmacy uru-560 010

The 2<sup>nd</sup> Instalment – Non-Recurring Budget details under M-Tendering process (MTP) for the FY: 2015-16.

SI. No	The PART –A under Non –Recurring (MTP) Budget as submitted by the Grantee Institution	Unit Price x No. of units(in Rs)	Amount (Rs)
1	Auto melting point apparatus 1934 (HSN code:90278090)	54,000 x 1	54,000.00
2	Advance make chrome view cabinet for easy viewing	16,000 x 1	16,000.00
3	Remi make laboratory refrigerator with stabilizer (HSN code8418)	99,000 x 1	99,000.00
4	Endnote x9 perpetual license	18,000 x 3	54,000.00
5	Equitron make concentric rings water baths	25,000 x 3	75,000.00
6	REMI make magnetic stirrer with hot plate	6,500 x 8	52,000.00
		Total Amount	3,50,000.00

The 2<sup>nd</sup> Instalment – Recurring Budget Details for the FY: 2015-16:

Sl	The PART –A under Recurring Budget as	Amount
.No	submitted by the Grantee Institution	(Rs)
1	Chemicals,	60,000.00
2	Glassware	
3	Plasticware	
4	Biological	
6	Mechanical Spare Parts	7,500.00
7	Contingency	20,000.00
8	Books and Journals	5,000.00
	Total	92,500.00

The PART – A details as submitted by the Grantee Institution are as follows.

Particulars	Amount (in Rs.)	
Previous year Balance according to the UC	48,688.00	
Grant Amount for the FY 2015-16	10,00,000.00	
TOTAL	10,48,688.00	
NON-RECURRING (A)		
E-Tendering (ETP)	4,59,831.00	
M-Tendering (MTP)	3,50,000.00	
EGEDQTAL (A)	8,09,831.00	
CU BORGELER TO HAND	KLE College of Bengaluru-	f Pharmacy

Recurring	
Contingency and consumables	92,500.00
TOTAL (B)	92,500.00
Approval by VGST (PART - A submitted	)= 0000
by $GI/PC$ ) TOTAL (A) + (B)	9,02,331.00
BALANCE AMOUNT NOT APPROVED	
DALINCE ANOUNT NOT AFPROVED	1,46,357.00

As mentioned in the procurement document (PART-A), the institution may purchase the equipments through E-Tendering and Manual Tendering Process. Please do not deviate from the KTPP Act for the procurement of equipments. Please submit the PART-B and Progress Report after the purchase is completed to the VGST office. The necessary formats are available in the VGST website following the

link : http://vgst.in/downloads.php

This is for your kind perusal.

With thanks and regards, Yours sincerely. 6 5/10/2020

Consultant

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QC : Dr.Subhas.S.Karki, Department of Pharm.Chemistry, KLE College of Pharmacy, 2<sup>nd</sup> Block,Rajajinagar,PB.No.1062, Bangalore-560 010.



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Frincipal KLE College of Pharmacy Bengaluru-560 010



# ಕರ್ನಾಟಕ ವಿಜ್ಞಾನ ಮತ್ತು ತಂತ್ರಜ್ಞಾನ ಪೋತನಾಹಕ ಸೊನೈಟಿ

ಮಾಹಿತಿ ತಂತ್ರಜ್ಞಾನ, ಜೈವಿಕ ತಂತ್ರಜ್ಞಾನ ಹಾಗೂ ನಿಜ್ಞಾನ ಮತ್ತು ತಂತ್ರಜ್ಞಾನ ಇಲಾಬೆ, ಕರ್ನಾಟಕ ಸರ್ಕಾರ 'ವಿಜ್ಞಾನ ಭವನ' ನಂ: 24/2, 3ನೇ ಮಹಡಿ, 21ನೇ ಮುಖ್ಯ ರಸ್ತೆ, ಬನಶಂಕರಿ 2ನೇ ಹಂತ, ಬೆಂಗಳೂರು–560 070 ದೂರವಾಣಿ/ಫ್ಯಾಕ್ಸ್: 080-26711166 /26711160 ಇ–ಮೇಲ್: ksteps.dst@gmail.com

ಡಾ. ಹೆಜ್. ಹೊನ್ನೇಗೌಡ ಸರ್ಕಾರದ ವಿಶೇಷ ಕಾರ್ಯದರ್ಶಿ (ತಾಂತ್ರಿಕ), ವಿತಂಇ/ ವ್ಯವಸ್ಥಾಪಕ ನಿರ್ದೇಶಕರು, ಕೆಸ್ಟೆಪ್ಸ್

ನಂ. KSTePS/VGST/K-FIST(L1)/2014-15/GRD-376/139/2019-20/383 ದಿನಾಂಕ: 28.01.2020

ವಿಷಯ: ವಿಜ್ಞಾನ ಮತ್ತು ತಂತ್ರಜ್ಞಾನ ದಾರ್ಶನಿಕ ಸಮೂಹದ K-FIST (L1) ಯೋಜನೆಯಡಿಯಲ್ಲ ಎರಡನೇ ಕಂತಿನ ಅನುದಾನ ಬಡುಗಡೆ ಮಾಡಿರುವ ಬಗ್ಗೆ.

ವಿಜ್ಞಾನ ಮತ್ತು ತಂತ್ರಜ್ಞಾನ ಇಲಾಖೆಯು, ಖ್ಯಾತ ವಿಜ್ಞಾನಿ ಭಾರತರತ್ನ ಪ್ರೊಫೆಸರ್ ಸಿ.ಎನ್.ಆರ್. ರಾವ್. F.R.S. ರವರ ಅಧ್ಯಕ್ಷತೆಯಲ್ಲ ವಿಜ್ಞಾನ ಮತ್ತು ತಂತ್ರಜ್ಞಾನ ದಾರ್ಶನಿಕ ಸಮೂಹ (ವಿತಂದಾಸ) ವನ್ನು 2008ರಲ್ಲ ಸ್ಥಾಪಿಸಿದ್ದು. ಈ ಯೋಜನೆಯಡಿ ಹಲವಾರು ವೈಜ್ಞಾನಿಕ ಕಾರ್ಯಕ್ರಮಗಳನ್ನು ಕಳೆದ 11 ವರ್ಷಗಳಂದ ರಾಜ್ಯಾದ್ಯಂತ ಯಶಸ್ವಿಯಾಗಿ ಅನುಷ್ಠಾನಗೊಳಸಿಕೊಂಡು ಬರುತ್ತಿರುವುದು ಸರಿಯಷ್ಠೆ. 2014–15ನೇ ಸಾಅನಲ್ಲ ತಮ್ಮ ಸಂಸ್ಥೆಯಿಂದ ಸಲ್ಲಸಿದ ಪ್ರಸ್ತಾವನೆಯಾದ "Establishing the Facility for Design, Synthesis and Characterization of Silymarin Derivatives as Antioxidant & Anticancer Agents" ನ್ನು ವಿತಂದಾಸದ ಪ್ರಮುಖ ಕಾರ್ಯಕ್ರಮವಾದ <u>Karnataka Fund for Infrastructure Strengthening in</u> <u>Science & Technology in Higher Education Institutions (KFIST L1)</u> ಅಡಿಯಲ್ಲ ದಾರ್ಶನಿಕ ಸಮೂಹವು ಆಯ್ಕೆ ಮಾಡಿ, ಸರ್ಕಾರ ಆದೇಶ ನೀಡಿರುವುದು ತಮಗೆ ತಿಳದ ವಿಷಯವಾಗಿದೆ.

ವಿಜ್ಞಾನ ಮತ್ತು ತಂತ್ರಜ್ಞಾನ ಇಲಾಖೆಯ ಅಂಗ ಸಂಸ್ಥೆಯಾದ ಕರ್ನಾಟಕ ವಿಜ್ಞಾನ ಮತ್ತು ತಂತ್ರಜ್ಞಾನ ಮ್ರೋತ್ಸಾಹಕ ಸೊಸೈಟಿ (ಕೆಸ್ಟೆಪ್ಸ್) ಯನ್ನು 2016–17ನೇ ಸಾಅನಿಂದ ದಾರ್ಶನಿಕ ಸಮೂಹದ ಕಾರ್ಯಕ್ರಮಗಳ ಉಸ್ತುವಾರಿ ಸಂಸ್ಥೆಯಾಗಿ ನೇಮಿಸಲಾಗಿದೆ. ಆದುದರಿಂದ. ತಮ್ಮ ಸಂಸ್ಥೆಯಿಂದ ಆಯ್ಕೆಗೊಂಡ ಪ್ರಸ್ತಾವನಗೆ ಎರಡನೇ ಕಂತಾಗಿ ರೂ. 10.00 ಲಕ್ಷಗಳ ಅನುದಾನವನ್ನು ಕೆಸ್ಟೆಪ್ಸ್ನನಿಂದ The Principal KLE University College of Pharmacy, Bangalore ಹೆಸರಿಗೆ ಚೆಕ್ ಮೂಲಕ (ಚೆಕ್ ಸಂಖ್ಯೆ: 598766 & ದಿ: 28.01.2020) ಅಡುಗಡೆ ಮಾಡಲಾಗುತ್ತಿದೆ. ಚೆಕ್ ಸ್ವೀಕರಿಸಿದ ನಂತರ, ಸ್ವೀಕೃತ ರಶೀದಿ (Acknowledgement) ಯನ್ನು ಕೆಸ್ಟೆಪ್ಸ್ ಸಂಸ್ಥೆಗೆ ಕಳುಹಿಸುವುದು.

ಈಗಾಗಲೇ ಜಡುಗಡೆ ಮಾಡಲಾಗಿರುವ ಮೊದಲನೇ ಕಂತಿನ ಅನುದಾನದಲ್ಲ ಉಳಕೆಯಾಗಿರುವ ಮೊತ್ತ ಹಾಗೂ ಬಡ್ಡಿಯ ಮೊತ್ತ ಸೇರಿ ಒಬ್ಬ ಉಳಕೆಯಾಗಿರುವ ರೂ. 48,688/–ಗಳನ್ನು ಮತ್ತು ಪ್ರಸ್ತುತ ಜಡುಗಡೆ ಮಾಡುತ್ತಿರುವ 2ನೇ ಕಂತಿನ ಅನುದಾನದ ಜೊತೆ ಸೇರಿಸಕೊಂಡು ಈ ಕೆಳಕಂಡ ಷರತ್ತು ಮತ್ತು ನಿಬಂಧನೆಗಳನ್ನಯ ಉದ್ದೇಶಿತ ಯೋಜನೆಗೆ ಮಾತ್ರ ಬಳಸಿಕೊಳ್ಳುವುದು.

ನಿಬಂಧನೆಗಳನ್ವಯ ಉದ್ದೇಶಿತ ಯೋಜನೆಗೆ ಮಾತ್ರ ಬಳಸಿಕೊಳ್ಳುವುದು.

KLE College of Pharmacy Bengaluru-560 010

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# ಷರತ್ತು ಮತ್ತು ನಿಬಂಧನೆಗಳು:

- ಸದರಿ ಪತ್ರದೊಂದಿಗೆ ಲಗತ್ತಿಸಿರುವ ನಮೂನೆಯಲ್ಲರುವಂತೆ ಪ್ರಾಯೋಕತ್ವದ ಸಂಸ್ಥೆ/ಇಲಾಬೆಯ ಹೆಸರನ್ನು ಕಡ್ಡಾಯವಾಗಿ ತಮ್ಮ ಸಂಸ್ಥೆಗಳಲ್ಲ ಸ್ಥಾಪಿಸಲಾಗಿರುವ ವಿತಂದಾಸದ ಸಂಶೋಧನಾ/ಬೋಧನಾ ಕೇಂದ್ರಗಳಲ್ಲ ಕಡ್ಡಾಯವಾಗಿ ಬ್ಯಾನರ್/ಬೋರ್ಡ್ ಅನ್ನು ಅಕವಡಿಸುವುದು.
- 2) ವಿಜ್ಞಾನ ಮತ್ತು ತಂತ್ರಜ್ಞಾನ ದಾರ್ಶನಿಕ ಸಮೂಹವು ವಿವಿಧ ಶೀರ್ಷಿಕೆಗಳಗೆ ಅನುಗುಣವಾಗಿ ಅನುಮೋದಿಸಿರುವಂತೆ ಕರ್ನಾಟಕ ಸಾರ್ವಜನಿಕ ಸಂಗ್ರಹಣೆಯಲ್ಲ ಪಾರದರ್ಶಕತೆ ಅಧಿನಿಯಮ 1999ರ (KTPP ACT) ನಿಯಮಾನುಸಾರ ವೆಚ್ಚ ಮಾಡುವುದು.
- 3) ಸದರಿ ಕಾರ್ಯಕ್ರಮದ ಅನುಷ್ಠಾನಕ್ಕೆ ಐಡುಗಡೆ ಮಾಡಲಾಗಿರುವ ಮೊದಲನೇ ಕಂತಿನ ಅನುದಾನದಲ್ಲ ಉಳಿಕೆಯಾಗಿರುವ ಮೊತ್ತ ಮತ್ತು ಅದಕ್ಕೆ ಬಂದಂತಹ ಬಡ್ಡಿ ಮೊತ್ತವನ್ನು ವಿತಂದಾಸದ ಕಾರ್ಯಕ್ರಮಗಳ ನಿಯಮಗಳನ್ವಯ ತಾವು Financial Status Proforma (FSP) ನಲ್ಲ ಸಲ್ಲಸಿ, ಕೆಸ್ಟೆಪ್ಸ್/ವಿತಂದಾಸದ ಪೂರ್ವ ಅನುಮತಿ ಪಡೆದು ಉದ್ದೇಶಿತ ಕಾರ್ಯಕ್ರಮಕ್ಕೆ ಐಡುಗಡೆ ಮಾಡಲಾಗುವ ಮುಂದಿನ ಕಂತುಗಳ ಅನುದಾನದ ಜೊತೆ ಸೇರಿಸಿಕೊಂಡು ಬಳಸಿಕೊಳ್ಳುವುದು.
- 4) ಅಲ್ಲದೆ, ಪ್ರಸ್ತುದಲ್ಲ ಬಡುಗಡೆ ಮಾಡುವ 2ನೇ ಕಂತಿನ ಅನುದಾನವನ್ನು ಬ್ಯಾಂಕಿನಲ್ಲ ಉಳತಾಯ ಖಾತೆಯಲ್ಲಲ್ಟು ಅಗತ್ಯಕ್ಕೆ ಅನುಗುಣವಾಗಿ ಅನುದಾನ ಬಳಸಿಕೊಳ್ಳುವುದು ಹಾಗೂ ಸದರಿ ಅನುದಾನದಲ್ಲ ಬಂದ ಬಡ್ಡಿ ಹಣವನ್ನು ಸಹ ನಿಗಧಿತ ನಮೂನೆಯಾದ FSP ನಲ್ಲ ಸಲ್ಲಸಿ ಕೆಸ್ಟೆಪ್ಸ್/ವಿತಂದಾಸದ ಅನುಮತಿ ಪಡೆದು ಉದ್ದೇಶಿತ ಕಾರ್ಯಕ್ರಮಕ್ಕೆ ಬಳಸಿಕೊಳ್ಳುವುದು.
- ಪ್ರತಿ 6 ತಿಂಗಳಗೊಮ್ಮೆ ಕಡ್ಡಾಯವಾಗಿ ಕಾರ್ಯಕ್ರಮದ ವರದಿಯನ್ನು ಸ್ಲeಸುವುದು.
- 6) ಸದರಿ ಅನುದಾನ ಚಿಡುಗಡೆಯಾದ ದಿನದಿಂದ ಒಂದು ವರ್ಷದ ಕಾಲಮಿತಿಯೊಳಗೆ ಅನುದಾನವನ್ನು ಬಳಸಿಕೊಂಡು ಉದ್ದೇಶಿತ ಕಾರ್ಯಕ್ರಮವನ್ನು ಧೇಯೋದ್ದೇಶಗಳನ್ವಯ ಅನುಷ್ಠಾನಗೊಳಸಿವುದು. 🤇
- 7) ಜಡುಗಡೆಯಾದ ಅನುದಾನವನ್ನು ಬಳಸಿಕೊಂಡ ನಂತರ ನೋಂದಾಯಿತ ಲೆಕ್ಕಪರಿಶೋಧಕರಿಂದ ಆಡಿಬ್ ಮಾಡಿಸಿ. ಸದರಿ ಪತ್ರದೊಂದಿಗೆ ಲಗತ್ತಿಸಿರುವ ನಮೂನೆ (Format) ಯಲ್ಲ ಉಪಯೋಗತಾ ಪ್ರಮಾಣಪತ್ರವನ್ನು (ದ್ವಿಪ್ರತಿಯಲ್ಲ) ಮತ್ತು ವರದಿಯನ್ನು ಕೆಸ್ಟೆಪ್ಸ್ ಸಂಸ್ಥೆಯ ವಿಜ್ಞಾನ ಮತ್ತು ತಂತ್ರಜ್ಞಾನ ದಾರ್ಶನಿಕ ಸಮೂಹ ವಿಭಾಗಕ್ಕೆ ನೀಡುವುದು.
- B) ಸಂಸ್ಥೆಯ ಮುಖ್ಯಸ್ಥರು ಮತ್ತು ಕಾರ್ಯಕ್ರಮ ಸಂಯೋಜಕರು ಯೋಜನೆಗೆ ಸಂಬಂಧಪಟ್ಟ ಎಲ್ಲಾ ಲೆಕ್ಕ ಪತ್ರಗಳನ್ನು ಸಂರಕ್ಷಿಸಿಡುವುದು ಹಾಗೂ ಸರ್ಕಾರದ ಮಹಾಲೇಖಪಾಲಕರು ಅಥವಾ ಕೆಸ್ಟೆಪ್ಸ್ ಸಂಸ್ಥೆಯು ತಪಾಸಣೆ ಹಾಗೂ ಮೌಲ್ಯಮಾಪನಕ್ಕಾಗಿ ಕೋರಿದಾಗ ದಾಖಲೆಗಳನ್ನು ಒದಗಿಸುವುದು.



علمی المح عند المح Son Principal KLE College of Pharmacy Bengaluru-560 010 ..З

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- 9) ಅಲ್ಲದೆ, ಈ ಯೋಜನೆಯ ಅನುಷ್ಠಾನಕ್ಕೆ ಸಂಬಂಧಿಸದಂತೆ ಪ್ರತ್ಯೇಕವಾದ ದಾಬಲೆ ಪುಸ್ತಕವನ್ನು ಸಹ ನಿರ್ವಹಿಸುವುದು.
- 10) ಕೆಸ್ಟೆಪ್ಸ್/ವಿತಂದಾಸದ ಅಧಿಕಾರಿಗಳಂದ ಕಾರ್ಯಕ್ರಮದ ಅನುಷ್ಠಾನ ಮತ್ತು ಪ್ರಗತಿಯ ಬಗ್ಗೆ ಭೇಟ ನೀಡಿ ಪರಿಶೀಅಸಲಾಗುವುದು.

ವಂದನೆಗಳೊಂದಿಗೆ.

ತಮ್ಮ ವಿಶ್ವಾಸಿ,

ವ್ಯವಸ್ಥಾಪಕ ನಿರ್ದೇಶಕರು

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- 2. ಡಾಗಿ ಎಸ್. ಜಿ. ಶ್ರೀಕಂಠೇಶ್ವರ ಸ್ವಾಮಿ, ಸಮಾಲೋಚಕರು, ವಿಜ್ಞಾನ ಮತ್ತು ತಂತ್ರಜ್ಞಾನ ದಾರ್ಶನಿಕ ಸಮೂಹ, 7ನೇ ಮಹಡಿ, 4ನೇ ಹಂತ, ಬಹುಮಹಡಿ ಕಟ್ಟಡ, ಬೆಂಗಳೂರು– 560 001 ಇವರ ಅವಗಾಹನೆಗೆ ಮತ್ತು ಸೂಕ್ತ ಕ್ರಮಕ್ಕಾಗಿ



And

For Principal KLE College of Pharmacy Bengaluru-560 010