



Biotechnology Industry Research Assistance Council

(A Government of India Enterprise)

To,

Date: 18th August, 2020

Dr. Tessa Iype
Principal Scientist
MagGenome Technologies Pvt. Ltd.,
E-mail: tessa.m@maggenome.com
Mob.: 09946042179

And

Dr Padma Srikanth
Professor
Dept of Microbiology
Sri Ramachandra Institute of Higher Education and
E-mail: Padmasrikanth@sriramachandra.edu.in
Mob.: -9884389682

And

Rajendra Pilankatta
Associate Professor & HOD
Dept. of Biochemistry and Molecular Biology
Central University of Kerala
Email: praj74@gmail.com
Mob.: 9061877113

Ref: Project Title " Development of a diagnostic kit comprising sample collection buffer and RNA extraction kit for real time RT PCR based detection of SARS CoV-2." under strategic funding for Covid-19 Consortium.

Dear Dr. Iype, Dr. Srikanth and Dr. Pilankatta,

With reference to your above, mentioned proposal, we are pleased to inform that your proposal has been approved by BIRAC at a total cost of **Rs. 91.00 Lakhs (Rupees ninety one Lakhs only)** under strategic funding for Covid-19 Consortium with support of **Rs. 47.00 Lakhs (Rupees forty seven Lakhs only)** as Grant-in-aid to MagGenome Technologies Pvt. Ltd., support of **Rs. 15.00 lakhs (Rupees fifteen lakhs only)** as Grant-in-aid to Sri Ramachandra Institute of Higher Education and Research and support of **Rs. 19.00 lakhs (Rupees nineteen lakhs only)** as Grant-in-aid to Central University of Kerala. The amount put in by MagGenome Technologies Pvt. Ltd. is **Rs. 10.00 Lakhs (Rupees ten Lakhs only)** towards the Project for **8 months** as per the terms of the Grant in Aid Letter Agreement (GLA) enclosed.

If you are in acceptance with the terms of funding support as mentioned in the GLA, the following documents should be executed within a time period of **TWO WEEKS** from the date of issue of this communication.

- **Grant-in-aid Letter Agreement (GLA)** including all the Schedules: All pages to be clearly initialled by the Fund Recipient and the Company should affix the organisation official seal with Director Signatures on the signature page to the GLA. *Considering the current lockdown situation, Signatures of Competent Authority may be done and the GLA executed. The official seal could be affixed after your office resumes.*

PKS

- **Board resolution of the Company** in the prescribed format of BIRAC.
- **No-lien account letter** to be submitted by the applicant with regard to specific project amount in the prescribed format of BIRAC.
- **Saving Bank Account** details to be submitted by the Institutes.
- **Letter of Authorisation:** LOA is required from institute in favour of person who is executing the GLA on behalf of the institute. This may kindly be provided as per the prescribed format of BIRAC.

Kindly take two colour printouts of this Grant-in-Aid Letter agreement (GLA) and the schedules (as many copies as the Parties- BIRAC and **MagGenome Technologies Pvt. Ltd., SRIHER and CUK**) and execute the same from your end. The scanned copy to be shared with BIRAC. The hard copy of the executed GLAs (after affixation of organization Official Seal) to be shared with BIRAC after the office resumes.

The first instalment of fund release will be made only after completion of all these formalities and upon submission of above-mentioned documents as per norms.

For Biotechnology Industry Research Assistance Council.


Dr. P.K.S. Sarma

(GM and Head-Technical, BIRAC)





जैव प्रौद्योगिकी उद्योग अनुसंधान सहायता परिषद
(भारत सरकार का उपक्रम)
Biotechnology Industry Research Assistance Council
(A Government of India Enterprise)

Ref. No. – BT/COVID0008/01/20

Dated: 19th June, 2020

Subject: Funding of Project entitled "Development of a diagnostic kit comprising sample collection buffer and RNA extraction kit for real time RT PCR based detection of SARS CoV-2" under strategic funding for Covid-19 Consortium.

GRANT-IN-AID LETTER AGREEMENT

This Grant-in-aid Letter Agreement (hereinafter called as "GLA") is between Biotechnology Industry Research Assistance Council, a Government of India enterprise, incorporated under the Companies Act, 2013 having its office at 1st Floor, MTNL Building, 9, CGO Complex, Lodhi Road, New Delhi-110003 (the "BIRAC") and the entities mentioned below for research proposal entitled "Development of a diagnostic kit comprising sample collection buffer and RNA extraction kit for real time RT PCR based detection of SARS CoV-2" under strategic funding for Covid-19 Consortium.

1. **Recipient(s) and Designated Project Investigator(s):**

S. No.	Recipient(s)	Designated Project Investigator
1	M/s Maggenome Technologies Private Limited , a Company incorporated under the Companies Act, 2013 having its registered office at VII 431-C1, Narayana Building, Thazhavaram Lane, Kakkanad Ernakulam, Ernakulam, Kerala-682030, India , hereinafter referred to as the "Company" (which expression shall wherever the context so admits include its successors in interest, liquidators, administrators and permitted assignees).	Dr. Tessa Iype Principal Scientist MagGenome Technologies Pvt. Ltd.. E-mail: tessa.m@maggenome.com Mob.: 09946042179
2	Central University of Kerala , an Institute having its office at Thejaswini Hills, PO Periyar, Kasaragod -671316, Kerala hereinafter referred to as the "Institute 1" (which expression shall wherever the context so admits include its successors in interest, liquidators, administrators and permitted assignees).	Rajendra Pilankatta Associate Professor & HOD, Dept. of Biochemistry and Molecular Biology Dean, School of Medicine and Public Health Central University of Kerala (CUK) Email: praj74@gmail.com Mob.: 09061877113
3	Sri Ramachandra Institute of Higher Education and Research , an Institute having its office at No.1 Ramachandra Nagar, Porur, Chennai - 600 116, Tamil Nadu , hereinafter referred to as the "Institute 2" (which expression shall wherever the context so admits include its successors in interest, liquidators, administrators and permitted assignees).	Dr Padma Srikanth Professor Dept of Microbiology Sri Ramachandra Institute of higher Education & Research E-mail: Padmasrikanth@sriramachandra.edu.in Mob.: -9884389682



2. **Aims & Objectives:**

The detailed aims and the objectives that are to be executed by the aforesaid are as per the detailed Project document, submitted including revisions / modifications incorporated therein (hereinafter called as "Project") and appended herein as **Schedule 3**.

The main objectives proposed to be achieved from the project are enumerated hereunder:

- Optimization of viral RNA extraction protocol using influenza virus followed by SARS CoV-2 and kit development.
- Optimization of sample collection solution
- Optimization and inclusion of a real time RT PCR detection kit in the final product (complete kit) and Validation of kit by ICMR approved institute and commercialization

Additional Objective may consist of effective management of health disasters or undertaking research connected therewith such as COVID-19 using the Project resources and through the implementing measures of the supported Project as may be identified in National interest and governed by a specific BIRAC Order

3. **Project Duration:** The Recipients shall complete the Project within the stipulated period of 8 months from the date of execution of the Royalty agreement ("**Effective Date**"). Project Duration is subject to the Change order(s) issued by the BIRAC from time to time under this provision.

4. **Project Implementation Site:**

MagGenome Technologies Pvt. Ltd.
First Floor, Plot 153, First Main Road,
Industrial Estate, Perungudi
Chennai - 600 096

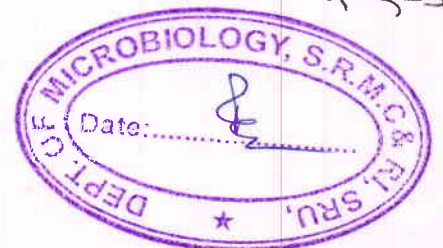
And

Molecular Biology and Clinical Virology Section,
Dept of Microbiology
Sri Ramachandra Institute of Higher Education and Research (SRIHER),
Porur, Chennai-600116

And

Dept of Biochemistry and Molecular Biology
Central University of Kerala (CUK)
Thejaswini Hills, PO Periy
Kasaragod -671316, Kerala

5. **Project Cost and Contribution:** The total estimated cost of the Project is **Rs. 91.00 Lakhs (Rupees ninety one Lakhs only)**. The contribution of BIRAC is **Rs. 47.00 Lakhs (Rupees forty seven Lakhs only)** as Grant-in-aid to MagGenome Technologies Pvt. Ltd., Contribution of BIRAC is **Rs. 15.00 lakhs (Rupees fifteen lakhs only)** as Grant-in-aid to Sri Ramachandra Institute of Higher Education and Research and Contribution of BIRAC is **Rs. 19.00 lakhs (Rupees nineteen lakhs only)** as Grant-in-aid to Central University of Kerala. The amount put in by the Company is **Rs. 10.00 Lakhs (Rupees ten Lakhs only)** on the terms and conditions detailed in this GLA.



6. BIRAC Budget break-up:

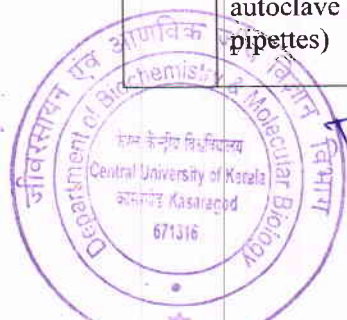
Budget- Head	Support under strategic funding for Covid-19 Consortium to the Company	Support under strategic funding for Covid-19 Consortium to Institute 2	Support under strategic funding for Covid-19 Consortium to Institute 1	Contribution by the Company	Grand Total (in Lakhs)
Non- Recurring	20.00	0.00	6.46	0.00	26.46
Recurring	27.00	15.00	12.54	10.00	64.54
Total	47.00	15.00	19.00	10.00	91.00

BUDGET Break-up Recurring (Rs In Lakhs)					
Heads	BIRAC Contribution			Contribution of the company	Total (Rs. in lakhs)
	To Company	To Institute 2	To Institute 1		
Recurring					
Manpower	1.80	2.25	4.80	7.50	16.35
Consumables	21.20	11.00	6.74	0	38.94
Outsourcing	2.00	0	0	0	2.00
Contingency	1.00	1.00	1.00	1.00	4.00
Travel	1.00	0.75	0	1.50	3.25
Total	27.00	15.00	12.54	10.00	64.54
BUDGET Break-up Non Recurring (Rs In Lakhs)					
Non-Recurring items	BIRAC Contribution			Contribution of the company	Total (Rs. in lakhs)
	To Company	To SRIHER	To CUK		
Equipment	17.00	0	6.46	0	23.46
Accessories	3.00	0	0	0	3.00
Total	20.00	0.00	6.46	0	26.46

Details of Equipment Proposed to be Acquired through Company's Contribution: NA

Details of Equipment to be acquired by the Company through BIRAC Contribution

S. No	Infrastructure/ Equipment	Specific Requirement In The Project	Capacity	Quantity	Estimated Value (Rs. In Lakhs)
1.	Real time PCR machine	RT-PCR detection of RNA. In order to develop independent capacity of doing the assays in future	Standard	1	11.21
2.	Agarose gel electrophoresis unit with Powerpack	In order to dedicate one unit specifically for RNA work	Large	1	0.89
3.	BSL-2 facility (3 components-cabinet, autoclave and pipettes)	To become independent in performing RNA extraction from samples collected in our collection buffer and for having a	Standard	1	4.78



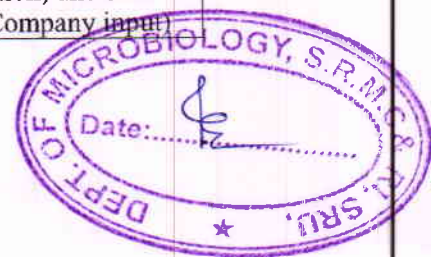
		dedicated space for continuing QC evaluation of the developed kit.			
		Total			16.88
		Accessories to be Acquired (Rs. in lakhs)			3.00
		Grant Total			19.88

Details of Equipment Proposed To Be Acquired Through BIRAC Contribution for Applicant Institute

S. No	Infrastructure/ Equipment	Specific Requirement In The Project	Capacity	Quantity	Estimated Value (Rs. In Lakhs)
For Institute 2					
NA					
For Institute 1					
1.	Microcentrifuge	Required for sample processing and nucleic acid isolation	Standard	1	2.85
2.	BSL-2 facility and work area	A separate BSL2 facility is required for handling the samples for diagnostic work. Existing BSL2 facility is meant for research purpose and temporarily adapted for COVID-19 test. This includes BSL2 cabinet and PCR work station along with aluminum fabrication to separate the area.	Standard	1	3.61
		Total			6.46
		Accessories to be Acquired for Institute 2 (Rs. in lakhs)			0
		Accessories to be Acquired for Institute 1 (Rs. in lakhs)			0
		Grant Total			6.46

7. Milestones/Timelines

Installment	Milestones	Month end activity	of of	Required financial input (Rs. In Lakhs)
1 st	Acceptance of Undertaking under GLA And Fulfilment of fund release requirements	1		32.40 (40% of BIRAC contribution) and 4.00 (40% of Company input) Total: 36.40
2 nd	Status report on Comparability of extraction of RNA from clinical samples (sputum, and nasopharyngeal or oropharyngeal	4		40.50 (50% of BIRAC contribution) and 5.00 (50% of Company input)



		swabs) with commercial RNA extraction kit and evaluating compatibility of extracted RNA with commercial real time RT-PCR based SARS COV-2 kits And Submission of UC/SOE for the corresponding milestone certified by internal finance.		Total: 45.50
3 rd Final	and	Status report on Evaluation of complete kit at ICMR approved centre And Submission of final completion report, consolidated Utilization Certificate (UC) and Statement of Expenses (SOE) duly certified by Chartered Accountant (CA)/Auditor.	8	8.10 (10% of BIRAC contribution) and 1.00 (10% of Company input) Total: 9.10
Note:- Utilization Certificate (UC) and Statements of Expenses (SOE) duly audited by a chartered accountant for the expenditure incurred towards the Project every half yearly , ending 30th September and 31st March, to BIRAC, within a month of closure of the accounts for the respective half year should be submitted till completion of Project Duration.				
The Company shall submit audited Annual reports along with the audited balance sheets and profit & loss accounts to BIRAC within six months of the completion of the financial year ending 31st March till the Project duration and on initiation of commercialization of the Product till full and final settlement of Royalty in terms of the Royalty Agreement.				

***Regulatory Requirements :**

- Test License and Manufacturing License from CDSCO

8. Specific conditions of Implementation

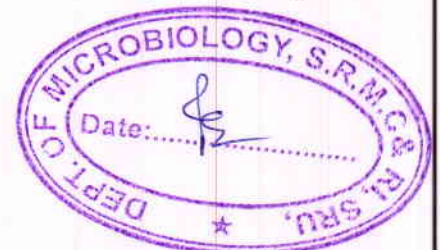
- Sale of products out of this project in India will be subjected to negotiation of pricing by BIRAC/Government of India to promote affordability on account of the grant-in-assistance under BIRAC.
- Government orders will be given preference over private orders for all products coming out of this project.

9. Periodic Payment/Release Arrangements of the project support based on milestones

(Rs. In lakhs)

Instalment	BIRAC Contribution			Company Contribution	Total (Rs. in Lakhs)
	To Company	To Institute 2	To Institute 1		
1 st	18.80	6.00	7.60	4.00	36.40
2 nd	23.50	7.50	9.50	5.00	45.50
Final	4.70	1.50	1.90	1.00	9.10
Total	47.00	15.00	19.00	10.00	91.00

10. The recipient of the fund should convey their acceptance to the terms and conditions of this GLA within four (4) weeks of the issue of GLA failing which the present offer of the funding support will be considered as infructuous and the project will be treated as withdrawn



11. Inclusion by Reference:

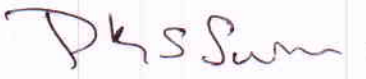

This GLA includes and incorporates by this reference:	<ul style="list-style-type: none">-Terms and Conditions (Schedule 1)- Acceptance and Undertaking (Schedule 2)- Project document (Schedule 3)- Intellectual Property Governing Framework (Schedule 4)- ROYALTY AGREEMENT: (Schedule 5)
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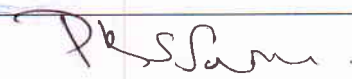
12. The Expenditure is debitable to **B.0.15(b)** – Head of Accounts for the financial year **2020-2021**.

13. This issue with the approval of competent authority vides BFD No **BFD/AO/B.15(b)/035/2020-2021** dated **19th June, 2020**.


14. The GLA has been noted at Serial No. **15** in the Register of Grant/Cost.


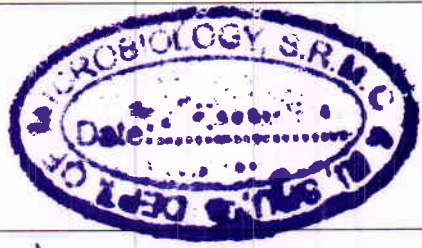

THIS GLA is between Biotechnology Industry Research Assistance Council ("BIRAC") and "MagGenome Technologies Pvt. Ltd.", "Sri Ramachandra Institute of Higher Education and Research" and "Central University of Kerala", and is effective as of the date of last signature. Each party to this GLA may be referred to individually as a "Party", "M/s MagGenome Technologies Pvt. Ltd." as "Company", "Sri Ramachandra Institute of Higher Education and Research" as "Institute 2", "Central University of Kerala" as "Institute 1", Institute 1 and Institute 2 as "Institutes", and Company and Institutes together as "Fund Recipient" and all Party together as the "Parties." As a condition of this grant, the Parties enter into this GLA by having their authorized representatives sign below:

I) For and on behalf of BIRAC	
Name	Dr. Kumara Savithru Sarma Pakala
Designation	GM and Head Technical
Signature	
Official Seal	






D)	For and on behalf of M/s “MagGenome Technologies Pvt. Ltd.” “the Company” duly authorized vide Resolution No 002/MGT/20-21.. dated 23-06-2020 of its Board of Directors.
Name	M R Balamani Amma For MagGenome Technologies Pvt Ltd.
Signature	 Director
Designation	Director
Company Common Seal or Signatures of Two Directors or One Director and Company Secretary	

2)	For and on behalf of “Sri Ramachandra Institute of Higher Education and Research” “Institute 2” duly authorized vide letter dated by its concerned authority.
Signature	
Name	DR. PADMA SRIKANTH
Designation	PROFESSOR
Institute Seal	 



2) For and on behalf of "Central University of Kerala" "Institute 1" duly authorized vide letter dated 29/06/20 by its concerned authority.

Signature 

Name Dr. Rajendra Pillankattu

Designation Associate Professor & Head



Dr. S. Sum.



Schedule 1

The terms and conditions for Project support under Grant-in-aid Letter Agreement (hereinafter called as "GLA") are as follows;

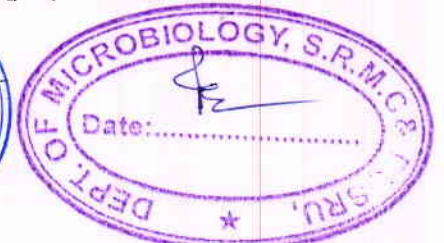
1. FUND DISBURSEMENT

- i. First installment of the Grant-in-aid will be released after issue of the GLA subject to fulfillment of the terms and conditions for such release (and after execution of Royalty Agreement) by the relevant Parties. Further release of funds shall be subject to satisfactory progress against the objectives, outputs, milestones and targets specified in the Project which progress shall be determined by BIRAC and on submission of audited/certified statements of accounts and utilization certificates as provided for in Point 2 (a).

2. FUND UTILISATION AND ACCOUNTING

- a. The Fund Recipient shall submit the Utilization Certificate (UC) and Statements of Expenses (SoE) duly audited by a Chartered Accountant (CA) as required for the project under the GLA.
- b. The Fund Recipient shall submit final consolidated UC and SoE duly certified by a CA/Auditor to BIRAC in the format provided on the completion of the project.
- c. The input credit for the expenditures incurred under the project out of Grant-in-aid shall be reported to BIRAC as a part of utilization certificate against the corresponding entry- "Amount of GST Input credit". Such amount, if any, will be considered accordingly at the time of the release of the next installment.
- d. The Fund Recipient shall submit audited Annual reports along with the audited balance sheets and profit & loss accounts to BIRAC within six months of the completion of the financial year ending 31st March till the completion of the Project Duration.
- e. The Institute shall duly submit the periodic Progress Report for the Project to BIRAC.
- f. The Company shall keep the Grant-in-aid assistance and their project contribution in a separate no-lien account in the name of the Company with a Scheduled Bank (as defined under the RBI Act, 1934), the withdrawals and payments from which account shall be subject to verification by BIRAC. It shall also obtain and furnish to BIRAC a letter from the concerned bank foregoing the right of set off or lien in respect of such account. Further, the interest earned on the Grant-in-aid if any should be reported to BIRAC. The interest thus earned will be adjusted towards further installment of the fund.
Institutes collaborator shall keep the Grant-in-aid assistance in an interest bearing account with a Scheduled Bank (as defined under the RBI Act, 1934), the withdrawals and payments from which account shall be subject to verification by BIRAC. The interest earned on the Grant-in-aid should be reported to BIRAC. The interest thus earned on the grant in aid will be adjusted towards further installment of the fund.

- g. The Fund Recipient shall ensure that the funds released for the Project are actually utilized only for the purposes of the Project and as expressly provided for in this GLA. Re-



appropriation of BIRAC funds from one budget head to another shall not be effected without the specific written approval of BIRAC;

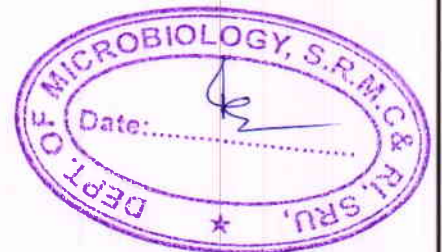
- h. The Fund Recipient shall refund such part of Grant-in-aid funds disbursed to it that remains unutilized with it upon completion of all the responsibilities, duties and functions specified in connection with the Project, within one month of such completion, to BIRAC along with consolidated accounts of the funds received and utilized and of the unutilized balance returned (UC &SOE);
- i. The Fund Recipient at their own cost shall take adequate care to maintain the capital assets acquired for the Project through BIRAC's Grant-in-aid. The capital assets acquired through BIRAC's Grant-in-aid shall not be disposed of or hypothecated without the specific approval of BIRAC till full and final settlement of all dues to the satisfaction of BIRAC.
- j. The Procurements for the Project shall be in accordance with the best commercial practices if the fund recipient is a Company/LLP and shall be in accordance with the procurement framework prescribed by BIRAC if the fund recipient is a Government/ public Institution.
- k. **The Fund Recipient shall give prior information to BIRAC about additional funding from any other government/ private source (National/ International) for the same project objectives availed at any time before the project completion.**

3. NATIONALLY IMPORTANT PROJECTS:

If certain projects are determined as Nationally important Projects, then BIRAC will issue a specific "Order" to make the following provisions applicable;

- A. In such cases of national importance BIRAC shall retain a royalty-free, non-exclusive, irrevocable license to the Product developed with the funding support of BIRAC with right to sub-license for the purposes of public interest/Government of India and/or as decided by the committee. The licensor of such Product will ensure that where the Product has been produced in collaboration with entities not in receipt of BIRAC's Grant-in-aid, such collaborators will also grant license to BIRAC in the same way.
- B. Nationally Important Projects shall mean such Projects that will serve specific purposes notified by Government of India in public interest.
- C. In cases of national importance, if BIRAC determines that such –
 - a) Action is necessary because the Fund Recipient or licensee/s has not taken, within the period of four (4) years from the date of completion of the Project, effective steps to commercialize the Product in such field of use;
 - b) Action is necessary to meet requirements for public use or national interest and such requirements are not reasonably satisfied by the Fund Recipient or licensee/s;

Then, March-in-rights are applicable whereby;



- i. BIRAC along with retainment of royalty-free, non-exclusive, irrevocable license to the Product, after taking into consideration the fund recipient's requirement for reasonable expansion and the demand supply gap at the appropriate time, shall have the right to require the Fund Recipient to transfer the technical know-how of the Product developed under the Project to other entrepreneur(s) and train them, on such terms and conditions as may be mutually agreed among BIRAC, the fund recipient and such other entrepreneur(s). Provided, BIRAC shall reserve its right to require that the Product must be manufactured and sold in India.
- ii. If the fund recipient (s) does not agree with the terms of above sub section (i), then BIRAC shall require that all rights and interests associated with the Product including Intellectual Property (IP) Rights to be assigned to BIRAC. The Fund Recipient(s) and co-owners of the IP shall undertake all necessary actions to affect the assignment.

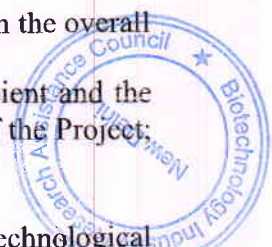
DISCLOSURE OBLIGATIONS FOR INSTITUTES AND NOT FOR PROFIT ENTITIES:

- a. The institute shall promptly disclose the commencement of commercialization of products through spinoffs, licensee, sub-licensee, assignee or other third parties.
- b. The institute shall submit the true copy of the contractual arrangement related to any interests of the Product including licensing agreement, technology transfer agreement, assignment deed etc.
- c. The Institute shall intimate the receipt of technology transfer fee, licensing fee, royalty, or revenue in any form resulting due to product commercialization, within sixty days from the closure of the corresponding half yearly accounts.

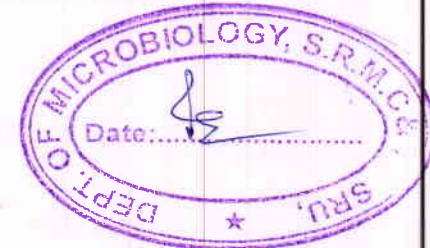
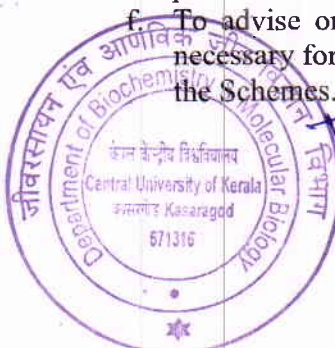
5. PROJECT MONITORING

A Project Monitoring Committee (PMC) comprising of eminent experts from the respective field(s)/Internal BIRAC and NBM members will be constituted to monitor the progress of the objective(s) of the Project. The functions of the PMC shall be as follows:

- a. To monitor the progress of the Project in conformity with the outputs, milestones, targets objectives and other terms and conditions as contained in the GLA
- b. To keep track of funding from any other source for the Project.
- c. To assess the global developments impacting the domain of the Project.
- d. Based on the foregoing, to assess and recommend:
 - i. the release of next installment or part release thereof by the BIRAC.
 - ii. revision of Project Duration
 - iii. closing, dropping or modifying any of the components of the Project, within the overall approved objectives, budget and time-frame,
 - iv. inclusion of additional industrial/institutional partner(s), if the Fund Recipient and the Institutes requests involvement of such partner(s), in the overall interest of the Project; and
 - v. revision of the financial assistance.
- e. To advise on issues related to securing of IPR and mentor to overcome any technological problem faced in the Project implementation; and
- f. To advise on any other matter as referred to it by BIRAC and/or otherwise reasonably necessary for effective discharge of its duties and/or achievement of aims and objectives of the Schemes.



Dksun



6. INDEMNIFICATION

- a. The Fund Recipient shall, at all times, indemnify and keep indemnified BIRAC against any claims or suits in respect of any losses, damages or compensation payable in consequences of any accident, death or injury sustained by their employees or by any other third party resulting from or by any act, omission or operation conducted by or on their behalf;
- b. The Fund Recipient shall, at all times, indemnify and keep indemnified BIRAC against all claims/damages etc. by any infringement of any Intellectual Property Rights (IPR) while carrying out their responsibilities/work under the Project and this GLA.
- c. The provision of Grant-in-aid funds by BIRAC does not create any liability, explicit or implicit, on BIRAC in respect of the manpower engaged in the Project.
- d. The Parties shall not be held responsible for non-fulfillment of their respective obligations in successful completion of the Project under this GLA due to the exigency of one or more force majeure events such as but not limited to acts of God, war, flood, earthquakes etc.
- e. BIRAC through the Project funding shall not be held as a "Sponsor" in terms of the Clinical Trial statutes and the Fund Recipient are entirely responsible for abiding by the relevant laws, Rules and Regulations of the land if any Phase of the Clinical Trial is a Project Component.

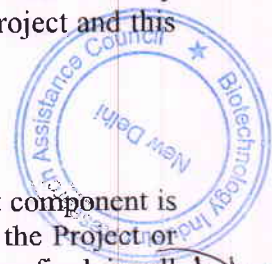
7. CHANGE OF CONTROL:

BIRAC shall reserve the right to reconsider further funding assistance, governance of the New Intellectual Property and consider refund of the amount of Grant-in-aid in such circumstances of change of control as mentioned the following paragraphs;

- a. The Fund Recipient shall inform BIRAC if it proposes to undertake or permit any merger, consolidation, reorganization scheme of arrangement or compromise with its creditors or shareholders or effect any scheme of amalgamation or reconstitution or substantial expansion. The word 'substantial expansion' shall have the same meaning as under the Industries (development and Regulation) Act, 1951.
- b. The Fund Recipient shall inform BIRAC within 30 (thirty) days, if it has notice of any application for winding up having been made or any statutory notice of winding up under the provisions of the Companies Act, 2013, or any other notice under any other Act or otherwise of any suit or other legal process intended to be filed or initiated against the Fund Recipient and affecting the title to the properties of the Fund Recipient or if a receiver is appointed of any of its properties or business or undertaking.
- c. The Fund Recipient shall notify BIRAC of any material change in its shareholding pattern, entity status, entity name, Project Coordinator, implementation site, registered office or any such change that would impact on performance of its obligations under the Project and this GLA.

8. FORECLOSURE AND TERMINATION

- a. In case, during the Project Duration, it is found that the Project or any Project component is not likely to lead to successful completion, BIRAC may decide to foreclose the Project or the Project component as warranted. The decision of the BIRAC shall be final in all respects. The Fund Recipient shall immediately refund any Grant-in-aid unutilized out of BIRAC's disbursements to BIRAC. BIRAC, at its discretion can allow deduction of the future committed expenses to third party vendors on pro-rata basis according to the



quantum of BIRAC's funding. The Fund Recipient shall submit consolidated accounts of funds received, utilized and unutilized (UC&SOE). If the Fund Recipient likes to continue the Project at its own cost, it would be able to do so without restrictions from BIRAC after complying with these provisions.

- b. The Fund Recipient may, before the completion of the Project, terminate this GLA by giving three months' notice in writing to BIRAC. BIRAC may also terminate this GLA by written notice in the event of committing breach of any term of this GLA and either not rectifying it to the satisfaction of BIRAC or not satisfying BIRAC about its inevitability within a specified period. In the event of termination of the GLA, no further disbursement shall be made by BIRAC. The Company shall be liable to return immediately the amount of Grant-in-aid already availed of from BIRAC with additional simple interest at the rate of 12 (twelve) per cent per annum within 30 (thirty) days of termination of the GLA. Interest on the quantum of funding assistance shall accrue from the date of release of the grant in aid assistance. The Collaborators Institutes shall immediately refund any funds unutilized out of BIRAC's disbursements, to BIRAC, along with consolidated accounts of funds received, utilized and unutilized (UC&SOE). In case of failure to repay, without prejudice to any other rights under this GLA, the amount can be recovered by initiating any procedure available in Law.

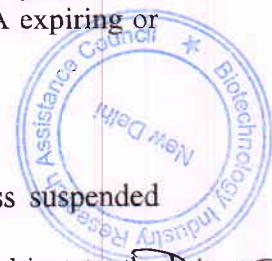
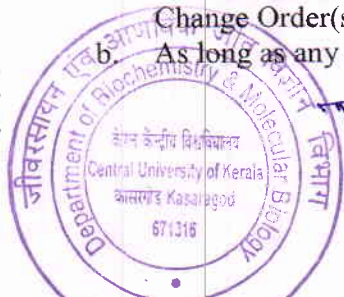
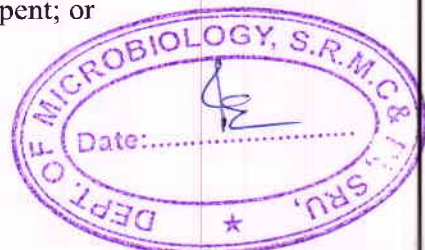
9. DISPUTE RESOLUTION AND ARBITRATION

In the event of any dispute or difference between the Parties hereto upon or in relation to or in connection with this GLA, such dispute or difference, shall be resolved amicably and in good faith by mutual consultation.

If such resolution is not possible, then the unresolved dispute or difference whatsoever arising between the Parties out of or relation to the construction, meaning, scope, operation or effect of this GLA or the validity the breach thereof or in respect of any defined legal relationship associated therewith or derived there from dispute shall be submitted for arbitration to International Center for Alternate Dispute Resolution (ICADR), an autonomous organization working under the aegis of the Ministry of Law & Justice, Department of Legal Affairs, Government of India. The Authority to appoint the arbitrator(s) shall be the ICADR. The Arbitration under this Clause and provision of administrative services by ICADR shall be in accordance with the ICADR Arbitration Rules, 1996 read with The New Delhi International Arbitration Centre Act 2019. The award made in pursuance thereof shall be binding on the Parties. The venue of arbitration shall be New Delhi and the arbitration proceedings shall be conducted in English Language. The provision of this Clause shall not become inoperative notwithstanding the GLA expiring or ceasing to exist or being terminated or foreclosed.

10. EFFECT AND AMENDMENTS TO THE GLA

- a. GLA shall remain in force for whichever of these is the longest time unless suspended sooner:
- a. For **08 Months** (Project duration) months from the above Effective Date subject to the Change Order(s) issued by the BIRAC from time to time
- b. As long as any part of the amount disbursed for the Project remains unspent; or



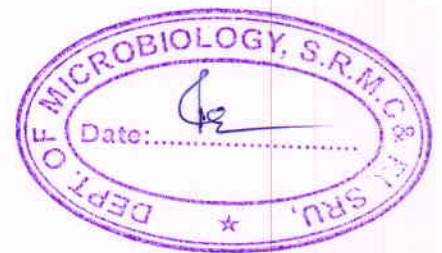
- c. For as long as any monitoring or recording or IP governance is required under any relevant laws and regulations.
- b. No amendment or modification of this GLA shall be valid unless the same is made in writing by the Parties or their authorized representatives specifically stating the same to be an amendment of this GLA. The modifications / changes shall be effective from the date on which they are made / executed unless otherwise agreed to.

11. SEVERABILITY

In case any one or more of the provisions or parts of a provision contained in this GLA shall, for any reason, be held to be invalid, illegal or unenforceable in any respect, such invalidity, illegality or unenforceability shall not affect any other provision or part of a provision of this GLA; and this GLA shall, to the fullest extent lawful, be construed as if such invalid or illegal or unenforceable provision, or part of a provision, had never been contained herein.

12. GOVERNING LAW

This GLA and the associated undertaking shall be governed and interpreted in accordance with the laws of India subject to the exclusive jurisdiction of the Courts at New Delhi.



Acceptance & Undertaking

In consideration of the foregoing, the Company, intending to be admittedly bound by the terms set forth above, undertake as stated below;

The Fund Recipient shall;

1. Execute the activities as set out in the Project document and shall conform to the specified objectives, outputs, milestones, and targets therein at **Schedule 3**.
2. Submit periodic Progress report to BIRAC as per the Project milestones, details of activities involved in performing the Project activities
3. Submit Utilization Certificate (UC) and Statements of Accounts Expenses (SOE) as per **Schedule 1**.
4. Comply with the fund utilization and accounting requirements as per Schedule 1.
5. Obtain all the necessary requisite approvals, clearance certificates, permissions and licenses from the Government/local authorities for conducting its activities/operations in connection with the Project.
6. Abide by the decisions of BIRAC to modify the objectives, outputs, milestones, targets, Project Grant-in-aid as also the foreclosure of the Project or any of its components as may be arrived at after mutual discussion.
7. Subject itself to Project monitoring of the Project Monitoring Committee (PMC).
8. Maintain strict confidentiality and refrain from disclosure thereof, of all or any part of such information and data exchanged/generated from the Project which is not in the public domain by use and/or publication at the time of its disclosure except for purposes in accordance with this Project or is required by public authority, by law or decree.
9. Complete the Project within the stipulated period subject to the Change Order(s) issued by the BIRAC from time to time.
10. Not sub-delegate or outsource the obligations under this GLA without express permission of BIRAC except as provided for in the Project Document
11. Manage the Intellectual Property developed through the funding Assistance of BIRAC in a manner that ascertains Global Access, regardless of whether this GLA expires, foreclosed or terminated.
12. Adhere to this GLA and the Conditions of Grant, as, violation of any provision of which shall be the reason for suspension of the Grant.
13. Consider any changes to the provisions of this GLA when made in writing only and shall consider any notice duly served if the same shall have been delivered electronically through the official mail of the Project Coordinator or delivered by post at the addresses mentioned in the GLA.
14. **The Company shall** abide by the conditions related to Royalty Payment as per the terms of the corresponding "Royalty Agreement".
15. **The Institute shall** abide by the specific Institute disclosure obligations as per Schedule 1.
16. Acknowledge the assistance of BIRAC while publishing or presenting in any manner the details of the Project, its progress or its success or commercialization/licensing of the Project.



IN ACCEPTANCE WHEREOF the fund recipients hereto through their duly authorized representatives have signed this undertaking as set below:

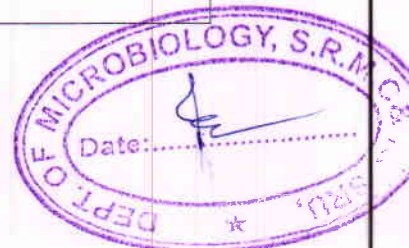
For and on behalf of M/s MagGenome Technologies Pvt. Ltd. "the Company"	
Date and Place: 23-06-2020, Kochi For MagGenome Technologies Pvt. Ltd.	
Signature	<u>Balamani Amma</u>
Name	M R Balamani Amma Director
Designation	Director
Company Common Seal or Signatures of Two Directors or One Director and Company Secretary	
Witnesses	
Signature	<u>Bibin Kumar M C</u>
Name	Mr. Bibin Kumar M C
Address	MagGenome Technologies Pvt.Ltd., Narayana Building, VII 431-C1, Thazhavaram Lane, Kakkanad, Ernakulam-682030


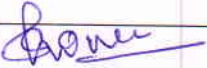
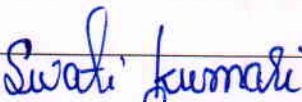
I) For and on behalf of "Sri Ramachandra Institute of Higher Education and Research", "Institute 2"

Date and Place: 29.07.2020; CHENNAI

Signature Dr. Padma Srikanth

Name DR. PADMA SRIKANTH



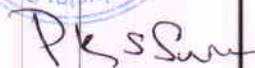
Designation	
Seal 	
Witnesses	
Signature 	Signature 
Name C. SIVASUBRAMANIAN.	Name Dr. Swati Kumari
Address MICROBIOLOGY DEPT. SRI RAMACHANDRA INSTITUTE OF HIGHER EDUCATION & RESEARCH	Address Dept. of Microbiology Sri Ramachandra Medical College Pondicherry, Chennai - 600116

I) For and on behalf of "Central University of Kerala", "Institute 1"	
Date and Place:	
Signature	
Name	
Designation	
Seal	
Witnesses	
Signature	Signature
Name	Name
Address	Address





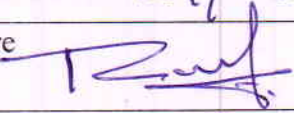




Designation	
Seal	
Witnesses	
Signature	Signature
Name	Name
Address	Address

I) For and on behalf of "Central University of Kerala", "Institute 1"



Date and Place: 29/06/2020 ; Ponje

Signature 


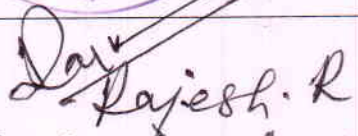
Name Dr. Rajendra Pilankatta

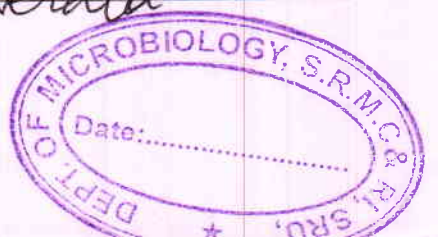
Designation Associate professor & Head

Seal
 डॉ. राजेन्द्र पिलांकट्टा / Dr. Rajendra Pilankatta
 आचार्य / Associate Professor
 जैवरसायन एवं आणविक जीवविज्ञान विभाग
 Department of Biochemistry & Molecular Biology
 केरल केंद्रीय विश्वविद्यालय / Central University of Kerala
 कासरगोड / Kasaragod-671 320

Witnesses

Signature 	Signature 
Name RETHEESH-U	Name Rajesh R
Address Lab Assistant Biochemistry & Mole. Biology Central University of Kerala	Address Technical Assistant Dept. of BEMB Central University of Kerala



Project Document:**PROPOSAL OBJECTIVES**

Objective1: Optimization of viral RNA extraction protocol using influenza virus followed by SARS CoV-2 and kit development

Methodology/Experimental Design To Accomplish The Stated Objective:

- Institutional ethics committee approval
- Preparation of the components of total RNA extraction kit and RNA extraction from normal saliva spiked with influenza viral particles.
- Optimization of the protocol to improve the quality and quantity of RNA
- RNA extraction from different amounts of influenza viral load per fixed volume of saliva and also from patient samples followed by Reverse Transcription, real time qPCR
- Extraction of SARS CoV-2 RNA from normal saliva spiked with CoV-2 virus with the optimized protocol. Establish Limit of detection.
- Extraction of SARS CoV-2 RNA from saliva, sputum, and nasopharyngeal or oropharyngeal swabs spiked with CoV-2 virus with the optimized protocol
- Establish stability of kit components

Comparability of extraction of RNA from clinical samples saliva, sputum, and nasopharyngeal or oropharyngeal swabs with commercial RNA extraction kit and evaluating compatibility of extracted RNA with commercial real time RT-PCR based SARS COV-2 kits

Alternate Strategies:

- The extraction protocol will be optimized at multiple steps before finalizing the optimum protocol.
- Spiked samples as well as patient samples saliva, sputum and swabs will be tested for influenza and SARS CoV 2.

Process Indicators for Measuring Success:

1. Expected yield and purity of RNA on Nanodrop
2. RIN value in the acceptable range
3. Intact RNA on gel
4. Ct value of Real time qPCR in acceptable range correlating to the viral concentration

Objective2: Optimization of sample collection solution**Methodology/Experimental Design To Accomplish The Stated Objective:**

- Preparation of different formulations of collection solution
- Determination of the stability of RNA from saliva, sputum and swabs in the best formulated buffer at 4^oC and at Room temperature, RNA extraction and RT and real time PCR
- Establish stability of sample collection solution
- Comparison of sample collection solution with existing viral transport medium for viral RNA stability and recovery. Establishing compatibility of the stored RNA samples with commercial real time RT-PCR based SARS COV-2 kits.

Alternate Strategies:

- Multiple formulations will be tested for several days and the one which provides the best integrity for RNA will be selected.
- The formulation will be tested for saliva, sputum and swabs.



P. S. Suresh

Process Indicators for Measuring Success:

- Expected yield and purity of RNA on Nanodrop
- RIN value in the acceptable range
- Intact RNA on gel
- Ct value of Real time qPCR in acceptable range correlating to the viral concentration

Objective3: Optimization and inclusion of a real time RT PCR detection kit in the final product (complete kit) and Validation of kit by ICMR approved institute and commercialization

Methodology/Experimental Design To Accomplish The Stated Objective:

- Assembly of kits
- Regulatory approvals for pilot manufacturing of kits for testing
- Evaluation of complete kit at ICMR approved centre
- Manufacturing License from CDSCO and kit commercialization

Alternate Strategies:

Multiple steps in Real time PCR will be optimized in an efficient and cost effective manner before compiling the final kit.

Process Indicators for Measuring Success:

Best performance of the kit will be ensured before applying for regulatory approvals

OBJECTIVE WISE ACTIVITIES & TIMELINES

Objective 1: Optimization of viral RNA extraction protocol using influenza virus followed by SARS CoV-2 and kit development

Activities	Month Of Start Of Activity	Month Of End Of Activity	Deliverables	Role of collaborators
Institutional ethics committee approval	0	1	Receipt of approval	Institutional ethics committee approval for SRIHER and CUK
Preparation of the components of total RNA extraction kit and RNA extraction from normal saliva spiked with influenza viral particles.	0	2	Extraction of good quality and quantity of RNA	Sample collection and RNA extraction from normal saliva spiked with influenza viral particles SRIHER
Optimization of the protocol to improve the quality and quantity of RNA	1	2	Optimization of protocol	Sample collection and assisting in real time RT PCR SRIHER
RNA extraction from different amounts of influenza viral load per	2	3	Completion of protocol for Influenza	Sample collection and assisting in real time RT PCR

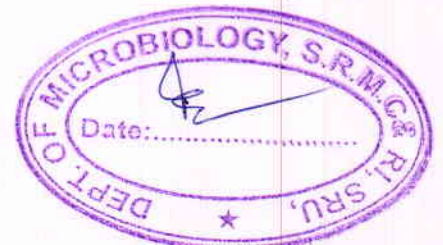


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fixed volume of saliva and also from patient samples followed by Reverse Transcription, real time qPCR					SRIHER
Extraction of SARS CoV-2 RNA from normal saliva spiked with CoV-2 virus with the optimized protocol. Establish Limit of detection.	1	2	Optimization of protocol	Sample collection and assisting in real time RT PCR CUK	
Extraction of SARS CoV-2 RNA from sputum, and nasopharyngeal or oropharyngeal swabs spiked with CoV-2 virus with the optimized protocol	2	3	Optimization of protocol	Sample collection and assisting in real time RT PCR CUK	
Establish stability of kit components	2	3			
Comparability of extraction of RNA from clinical samples (sputum, and nasopharyngeal or oropharyngeal swabs) with commercial RNA extraction kit and evaluating compatibility of extracted RNA with commercial real time RT-PCR based SARS COV-2 kits.	3	4	Completion of protocol for SARS CoV 2	Sample collection and assisting in real time RT PCR CUK	

Objective 2: Optimization of sample collection solution

Activities	Month Of Start Of Activity	Month Of End Of Activity	Deliverables	Role of collaborators
Preparation of different formulations of collection solution	5	6	Optimization of storage buffer	Sample collection and assisting in real time RT PCR SRIHER, CUK
Determination of the stability of RNA from sputum and swabs in the best formulated buffer at 4°C and at Room	5	6		Sample collection and assisting in real time RT PCR



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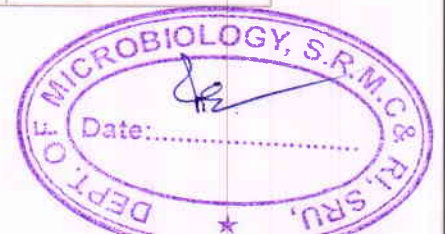
temperature, RNA extraction and RT and real time PCR				SRIHER, CUK
Establish stability of sample collection solution	5	6	Ensured stability	Sample collection and assisting in real time RT PCR SRIHER, CUK
Comparison of sample collection solution with existing viral transport medium for viral RNA stability and recovery. Establishing compatibility of the stored RNA samples with commercial real time RT-PCR based SARS COV-2 kits	6	7	Completion of sample collection kit	Sample collection and assisting in real time RT PCR CUK

Objective 3: Optimization and inclusion of a real time RT PCR detection kit in the final product (complete kit) and Validation of kit by ICMR approved institute and commercialization

Activities	Month Of Start Of Activity	Month Of End Of Activity	Deliverables	Role of collaborators
Assembly of kits	7	8	Complete kit as final product	NA
Regulatory approvals for pilot manufacturing of kits for testing	8	8	Receipt of approval	NA
Evaluation of complete kit at ICMR approved centre	8	8	Receipt of approval	NA
Manufacturing License from CDSCO and kit commercialization	8	8	Receipt of license	NA

Milestones and Timelines:

Milestones	Month of End of Activity
Signing of GLA	0
Comparability of extraction of RNA from clinical samples (sputum, and nasopharyngeal or oropharyngeal swabs) with commercial RNA extraction kit and evaluating compatibility of extracted RNA with commercial real time RT-PCR based SARS COV-2 kits.	4
Report of Evaluation of complete kit at ICMR approved centre	8



INTELLECTUAL PROPERTY GOVERNING FRAMEWORK**1. SCOPE OF IP GENERATED DURING THE CONDUCT OF THE PROJECT**

- a) The New Intellectual Property (IP) rights belong to fund recipients unless agreed otherwise.
 Provided, this Project is not determined as a "Nationally Important Project" to be governed through specific 'Order of BIRAC'. Such cases of "Nationally Important Project" shall have specific terms of licensing, pricing or March-in-rights for the purposes of public interest/ demand of Government of India.
- b) It is the responsibility of the Fund Recipients to protect the New Intellectual Property (New IP). They shall bear the expenditure involved in protecting the New IP.

2. GLOBAL ACCESS

The Fund Recipient agree to conduct and manage the Project and the resulting products, services, processes, technologies, materials, software, data or other innovations (collectively, "Product") and any IP that arises (New IP) in the manner that ensures "Global Access."

Global Access requires that

- a) The knowledge and information gained from the Project be promptly and broadly disseminated or published.
- b) Project Developments and/or New IP are made available and accessible at an affordable price to people most in need within developing countries.
- c) In this regard, ensure Global Access in all present and future research and development agreements in a suitable form.

NOTE: For the purpose of this GLA, New IP means intellectual property generated during the conduct of the Project by the fund recipients, but excluding the intellectual property generated by the Fund Recipient before execution of this GLA and any IP generated outside the scope of this GLA even during the term of this GLA.

1. The background Intellectual Property (IP) generated by the Fund Recipient(s) before execution of this GLA are as provided hereunder;

I.	Background IP of the Company
	Indian Patent: IN 244248; Indian Patent Application: 202041027858
II	Background IP of the Institutes (SRIHER and CUK)
	Nil

