YENEPOYA
(DEEMED TO BE UNIVERSITY)
Recognized under Sec 3(A) of the UGC Act 1956
Accredited by NAAC with 'A' Grade

Details of the Collaborative Activity

2020-21

Name of the Collaborating Institute: Policy and Economic Research Department, International Vaccine Institute, Seoul, South Korea.

Name of the Collaborating Departments: Department of Paediatrics, Department of Microbiology & Yenepoya Research Centre

Activities:

A joint research Project and Publication

- Mogasale VV, Saldanha P, Pai V, Rekha PD. A descriptive analysis of antimicrobial resistance patterns of WHO priority pathogens isolated in children from a tertiary care hospital in India. *Scientific Reports*. 2021; 11(1):1-7.

Research Project:

Systematic Reviews & Drug Resistance Analysis. Sponsored by International Vaccine Institute, South Korea. PI. Dr. Vijayalaxmi Mogasale PI.

ATTESTED

Dr. Gangadhara Somayaji K S
Registrar
Yenepoya (Deemed to be University)
University Road, Deralakatte
Mangalore 575 018, Karnataka.

YENEPOYA

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Accredited by NAAC with 'A' Grade

Project Title: Systematic reviews and drug resistance analysis

Amount Received: Rs. 5.59 lakhs

Documents in Support:

1. Research Agreement with budget
2. Fund Received details

ATTESTED

Dr.Gangadhara Somayaji K.S.
Registrar
Yenepoya(Deemed to be University)
University Road, Deralakatte
Mangalore- 575 018, Karnataka

Duration of the Project: 3 Years

RESEARCH AGREEMENT

This Research Agreement (this "**Agreement**") is made between Yenepoya (Deemed to be University), having its principal place of business at University Road, Deralakatte, Mangalore, Karnataka, India, 575018 ("**Grantee**"), and the International Vaccine Institute, having a place of business at SNU Research Park, 1, Gwanak-ro, Gwanak-gu, Seoul, Korea 151-742 ("**IVI**"), for performance of a research entitled, Systematic reviews and drug resistance analysis (the "**Research**").

The parties hereto agree that the Research shall be conducted in accordance with the following terms and conditions.

1. Scope of Work; Principal Investigator; Consultations.

(A) Scope of Work and Purpose. Grantee will conduct the research as described in the scope of work attached hereto as Appendix A (the "**Scope of Work**") and in accordance with the terms of this Agreement. The purpose of the Research is to conduct systematic reviews in the areas of cholera and typhoid fever with particular focus on outbreaks, clinical complications, anti-microbial resistance (AMR) and costs and other outcomes related to the disease (the "**Research Purpose**").

(B) Principal Investigator. The Scope of Work will be conducted under the supervision of Dr. Vijayalaxmi Mogasale ("**Principal Investigator**"), who shall be responsible for the direction and activities of the Research. If, for any reason, the Principal Investigator is unable or becomes unavailable to continue on the Research, or if such inability or unavailability is anticipated by or is otherwise made aware to Grantee, Grantee shall immediately notify IVI thereof and shall nominate a replacement for IVI's confirmation within [30] days of notice to IVI. If IVI does not find the nominee acceptable, IVI may, in its sole discretion, terminate this Agreement upon [30] days written notice to Grantee.

(C) Subcontractors. Where deemed reasonably necessary, Grantee may delegate any portion of the Research to subcontractors, subject to IVI's prior written consent with respect to the engagement of each such subcontractor. All subcontractors shall be bound by the terms of this Agreement, and Grantee shall remain primarily liable for subcontractors' performance under this Agreement.

(D) Consultations; Site Visits. During the term of this Agreement, IVI shall be entitled to reasonable access for consultation with Principal Investigator and, upon reasonable notice, may visit Grantee's premises to review the progress of the Research.

2. Human Subjects; Vertebrate Animal Subjects; Bio-hazardous Materials; Documentation.

(A) Human Subjects. If the Research involves human subjects, by signing this Agreement, Grantee warrants that it is and will continue to be in compliance with all applicable laws, regulations, and guidelines of the country where the Research is being conducted and other countries and applicable international standards, including the ICH-GCP guidelines, the Declaration of Helsinki and the Nuremburg Code.

(i) Confidentiality of Data involving Human Subjects. Grantee shall safeguard the privacy and confidentiality of data concerning any human subjects as required by applicable laws and regulations of the country where the Research is being conducted and other countries, and all internationally accepted standards. This confidentiality obligation survives the termination or expiration of this Agreement.

(ii) Written Approval by Local Institutional Review Boards. When applicable, Grantee is responsible for obtaining prior written approval of the research protocol as may be required by the applicable local institutional review board or its equivalent. Whenever local board approval is required, Grantee must send to IVI copies of written approvals from the local institutional review board or its equivalent before the commencement of the Research.

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(iii) Written Approval by IVI Institutional Review Board. All research protocols must be approved in writing by the IVI Institutional Review Board prior to the commencement of the Research. Grantee must comply with all applicable procedures of IVI's Institutional Review Board in conducting the Research.

(B) Vertebrate Animal Subjects. If the Research involves vertebrate animal subjects, by signing this Agreement, Grantee warrants that it is and will continue to be in compliance with all applicable laws, regulations, and guidelines of the country where the Research is being conducted and other countries, as well as all applicable international standards, including the Animal Protection Act, the Laboratory Animals Act, and the Ministry of Agriculture, Food and Rural Affairs' Guideline for the Animal Tests.

(C) Bio-hazardous Materials. If the Research involves bio-hazardous materials, by signing this Agreement, Grantee warrants that it is and will continue to be in compliance with all applicable laws, regulations and guidelines of the country where the Research is being conducted and other countries.

(D) Approvals; Documentation. Before IVI releases any funds to Grantee, Grantee shall provide IVI with documentation of all approvals required under this Agreement and with evidence that it is otherwise in compliance with the requirements of this Section, including, if applicable, the Certification for the Designation of Institution for Conducting Clinical Study or its equivalents in the relevant jurisdictions.

3. Funding; Reporting; Deviation from Purpose.

(A) Funding. In consideration of Grantee's conduct of the research described in the Scope of Work and subject to the terms of this Agreement, IVI will make funds available to Grantee in accordance with the approved budget (the "**Budget**") and milestones described in the payment schedule (the "**Payment Schedule**"), the details of both of which are attached hereto as Appendix B (Budget, Milestones and Payment Schedule). Funds awarded under this Agreement may only be used for the Research Purpose. Grantee may not use the funds to reimburse any expenses incurred prior to the start of the Research. Any change in the Budget line item of more than 10% must be approved in writing by IVI in advance. Further, IVI's payment of the funds may be withheld, if IVI determines that any scientific progress report required under Section 3(C) is not satisfactory or if the financial report required under Section 3(C) shows sufficient cash balance to carry on the research activities. At the completion of the Research, any funds not spent, including any interest accrued thereon, shall be immediately returned to IVI with the final financial report.

(B) Payments. Payment will be sent as follows

NAME OF THE BANK	- VIJAYA BANK FOUNDERS BRANCH, LIGHT HOUSE HILL ROAD MANGALORE
ACCOUNT NO	- 113200301000289
IFSC CODE	- VIJB 0001132
SWIFT CODE	- VIJBINBBMLR

(C) Reports. During the term of this Agreement, Grantee shall provide IVI with (i) interim financial reports (each substantially in the form of Appendix C) and (ii) interim scientific progress reports on the Research as described in the payment schedule attached hereto as Appendix B. The financial reports must show use of funds provided by IVI in accordance with the Budget and must be certified as accurate by Grantee. Scientific progress reports will be in narrative form and must describe in detail the status and progress of the Research. In addition, Grantee will provide a final financial report accounting for all funds received and costs incurred and a final comprehensive scientific progress report on the results of the Scope of Work and the Research (each marked "**Final**") within [45] days following the completion of the Research. All financial reports and scientific progress reports required under this Agreement shall be referred to collectively as "Financial Reports" and "Narrative Reports,"

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respectively. Grantee shall draft the interim and final financial reports in English. Grantee shall promptly provide any further information that IVI requests following its review of any report. Two copies of all reports must be submitted to:

Florian Marks
International Vaccine Institute
SNU Research Park
1 Gwanak-ro, Gwanak-gu, Seoul, Korea 151-742
Tel: 82-2-881-1133
E-mail: fmarks@ivi.int

with a copy to

Hyonjin Jeon

E-mail: hyonjin,jeon@ivi.int

(D) Deviation from Research Purpose. If Grantee deviates from the Scope of Work or the Research Purpose without IVI's prior written consent, IVI may withhold future funding and require Grantee to return funds already granted that were not used in accordance with the Scope of Work or the Research Purpose.

(E) Taxes. Grantee acknowledges that it shall be solely responsible for paying the appropriate amount of all federal, state, governmental and local taxes with respect to all funding paid to Grantee pursuant to this Agreement, and that IVI shall have no responsibility whatsoever for withholding or paying any such taxes for or on behalf of Grantee.

4. Period of Performance; Termination; Final Reports and Accounting.

(A) Period of Performance. This Agreement shall take effect upon signing by both parties (the "**Effective Date**") and shall continue through Grantee's completion of the Scope of Work and IVI's acceptance of all required reports, unless sooner terminated under Section 4(B). Notwithstanding the foregoing, the licenses granted under this Agreement shall survive in accordance with their terms.

(B) Termination

(i) For Convenience. IVI may terminate this Agreement at any time for any reason by giving Grantee [90] days written notice.

(ii) For Breach. Either party may terminate this Agreement upon written notice if the other party has breached any term of this Agreement but fails to cure the breach within [30] days after it receives written notice specifying the breach from the non-breaching party.

By IVI with Immediate Effect. IVI may immediately terminate this Agreement in whole or in part if: (i) Grantee or its creditors or any other eligible party files for Grantee's dissolution, liquidation, bankruptcy, reorganization, rehabilitation or compulsory composition; or (ii) Grantee undergoes a change of control by way of merger, consolidation, share exchange or other business combination or a similar transaction, as a result of which the direct or indirect beneficial ownership of 50 percent or more of Grantee's voting stock or the power to direct the management of Grantee, whether through the ownership or voting securities, by contract or otherwise, is transferred to a third party.

(C) Final Reports; Accounting. Upon any termination of this Agreement under Section 4(B)(i), IVI will reimburse Grantee for costs incurred in accordance with the Budget and non-cancelable commitments incurred in accordance with the Budget as of the effective date of the

termination, as well for any costs that IVI approves for expenditure after that date, provided that IVI receives satisfactory final reports in accordance with Section 3. If IVI has already made funds available to Grantee to cover such costs, Grantee will refund any excess amounts within [45] days following termination. If IVI terminates this Agreement because of Grantee's breach, IVI reserves the right not to provide additional funds and to require the return of funds not expended as of the effective date of the termination.

5. Confidential Information.

(A) Confidential Information. Each party acknowledges that in performing its obligations under this Agreement, it may have access to the other party's Confidential Information (as defined below) and agrees (i) to treat it as strictly confidential and not to disclose it to any third party without the prior written consent of the other party, (ii) to use it solely in performing its obligations under this Agreement and for no other purposes whatsoever, and (iii) to make it available only to its employees or independent contractors who require access to it for the sole purpose of performing this Agreement, but only after informing such persons of the obligations to keep it confidential. "**Confidential Information**" means any and all proprietary information of a party hereto which is intended by such party to remain confidential or is marked confidential or proprietary at the time of disclosure or, if disclosed visually or orally, is stated to be confidential at the time of disclosure and confirmed as confidential within [15] days after initial disclosure.

(B) Information Not Covered. The above confidentiality obligations will not attach to information that: (i) is publicly available as of the Effective Date or becomes publicly available thereafter through no wrongful act of the receiving party; (ii) was known to the receiving party before disclosure by the other party or becomes known to the receiving party thereafter on an unrestricted basis from a source unrelated to the disclosing party and not known by the receiving party to be under a duty of confidentiality to the disclosing party; (iii) is disclosed by the disclosing party without restriction on further disclosure; or (iv) is independently developed by the receiving party without resort to any Confidential Information of the disclosing party (as evidenced by the receiving party's contemporaneous written records).

(C) Disclosure in Response to Legal Process. The receiving party may produce the other party's Confidential Information if obligated to do so pursuant to an order of a court of competent jurisdiction, a valid administrative or governmental subpoena, or similar legal process, provided that the receiving party (i) promptly notifies the disclosing party in advance of such disclosure and (ii) limits the scope of disclosure only to the extent absolutely necessary to comply with any such order or subpoena based on prior consultation with the disclosing party.

6. Publication; Intellectual Property. To the extent any intellectual property is created under this Agreement, the following will apply:

(A) Publication. Each party has the right to publish and otherwise publicly disclose information it has gained from the Research. Grantee will provide IVI with copies of each article written by the Principal Investigator or other personnel reporting on the Research at least [30] days before submitting the article for publication. IVI will receive credit for its support of the Research in all publications about the Research.

(B) Inventions and other Technology. Title to any invention or discoveries conceived or first reduced to practice by Grantee in the course of the Research will be jointly owned by both parties. Both parties may file a patent application on such an invention based on mutual agreement. Title to any discovery, invention, technology (including biological materials) created by Grantee in the course of the Research for which the parties mutually decide not to seek patent protection will be jointly owned by both parties and considered Know-How under this Agreement.

(C) Copyrights. Title to any works of authorship, copyrights or other copyrightable material created by Grantee in the course of the Research will be jointly owned by both parties.

(D) Know-How. Title to any Know-How created by Grantee in the course of the Research will be jointly owned by both parties. "Know-How" includes proprietary data, instructions, processes, formulas, chemical or biological substances, information, unpatented inventions and discoveries, technologies, knowledge, experience, expertise or skill of a technical, commercial or other nature.

(E) Data. Title to any data generated in the course of the Research will be jointly owned by both parties.

(F) IVI's Charitable Purposes. "**Charitable Purposes**" means IVI's activities in furtherance of the IVI Mission, whether the activities are conducted in the endemic or other countries or through a not-for-profit organization or commercial entity so long as the activities further the mission to accelerate the development and introduction of a vaccine that is appropriate, safe and accessible to children in endemic countries. The parties expressly acknowledge and agree that IVI is entitled to fully exploit (either on its own or through any of its licensees) any of the intellectual properties which it jointly owns with Grantee pursuant to Article 6 for any Charitable Purpose without the need for a separate consent from Grantee.

(G) Background Intellectual Property. If Grantee owns or licenses rights to background intellectual property ("**Background IP**") that is not subject to this Agreement but which is essential or useful in exercising any of the intellectual properties jointly owned between Grantee and IVI under this Agreement, Grantee hereby grants to IVI an irrevocable, perpetual, worldwide, non-exclusive, fully paid-up, royalty-free license to use the Background IP to exploit any such jointly-owned intellectual properties.

(H) Subcontractors. If Grantee subcontracts any activities under the Research, it will obtain from the third party all rights that may be necessary for Grantee to grant the rights granted to IVI under this Agreement.

7. **Conflict of Interest**. Grantee, its investigators and participating organizations in this Research are required to adhere to applicable ethical, regulatory and professional standards in all matters related to the Research. Grantee is required to have a Conflict of Interest (COI) Policy in place which guides its staff, investigators and participating Organizations in matters related to activities and transactions. The COI policy should prohibit Grantee's employees or officers from participating in specific dealings when the individual knows that any of his/her immediate family, may pose a conflict of interest to a specific transaction. Such a transaction will require disclosure of the relationships known to the Research participants which are covered by the Grantee's COI policy and which may affect improperly the transaction. It is thus a requirement for this Research for the Declaration of Conflicts of Interest (COI) in Research Projects to be signed by Grantee (the "**Declaration**"). A form of the Declaration is provided in Appendix D, together with the explanatory notes.

8. **Tangible Research Results.** If the Research results in the creation of tangible research results (collectively, the "**TRR**"), Grantee shall, upon request by IVI, promptly sell any and all TRR to IVI at or below the production cost for use in connection with IVI's Charitable Purposes. Grantee hereby grant to IVI an irrevocable, perpetual, worldwide, non-exclusive, fully paid-up, and royalty-free license to exploit the TRR so purchased by IVI for IVI's Charitable Purposes.

9. **Title to Equipment.** "**Equipment**" means non-expendable, tangible, property that has an acquisition cost of $1,500 or more, is free standing, and has a normal life expectancy of one year or more. All Equipment purchased with funds under this Agreement will be identified as Equipment in the Budget or in Grantee's reports. IVI reserves the right to transfer title to Equipment to IVI or a third party designated by IVI upon termination or expiration of this Agreement. If IVI has not notified Grantee of its intention to transfer title within [120] days following termination or expiration, title will remain with Grantee.

10. **Warranties and Covenants; Indemnities; and Insurance.**

(A) Warranties and Covenants. Grantee warrants and covenants that: (i) it has the full right and authority to enter into this Agreement and to grant the licenses and rights granted hereunder; (ii) the intellectual property and other rights granted in this Agreement, either on their own or as used by IVI for its Charitable Purposes, do not and will not infringe or violate any third-party rights; (iii) the Principal Investigator possesses sufficient knowledge, skills, expertise, and experience to effectively oversee and manage the Research, (iv) all of its employees, subcontractors and agents who are assigned to perform services under this Agreement are properly supervised by the Principal Investigator, medically qualified, have sufficient expertise, training, and experience, and are made aware of and are bound by the obligations of Grantee under this Agreement; and (v) Grantee will perform the Services in a competent and professional manner and the results of the Research will not be fabricated or exaggerated.

(B) Indemnities. Grantee shall indemnify, defend and hold IVI, its officers, directors, employees, and agents harmless from and against any demands, claims, losses, damages, or cost of judgments (including reasonable legal expenses and attorney's fees; collectively, the "**Losses**") that may arise from any action, suit or other claim made or instituted against any of them arising from or related to: (i) any breach of the obligations, representations, or the warranties made by Grantee under this Agreement, including Grantee's breach of or non-compliance with any Research plans; (ii) the performance of the Research by Grantee or its employees, subcontractors, or agents; or (iii) the failure to comply with applicable laws, regulations, and guidelines by Grantee or its employees, subcontractors, or agents. Grantee shall defend against any and all Losses at Grantee's sole cost, and IVI shall have the right to participate in any such defense with its own counsel at its own expense. In the absence of IVI's prior written consent, Grantee may not settle any claim that could adversely affect the conduct of the Research or that which would otherwise bind IVI. For clarity, all references to Grantee's employees, subcontractors or agents in this Agreement shall be construed as to include the Principal Investigator.

(C) Insurance. Grantee represents that it carries sufficient insurance coverage to comply with the requirements of applicable laws as well as its obligations under this Agreement. In addition, IVI reserves the right to require Grantee to provide such additional insurance as IVI may from time to time specify in writing to Grantee, provided, however that such requirements shall not be unreasonable.

11. Audit. Grantee will maintain complete and accurate records and books, including all expenditures and costs incurred and supporting documentation, relating to the Research (the "**Records**"). Grantee will make its Records available to IVI and its designee during the term of this Agreement and for at least [three] years thereafter upon IVI's request during regular business hours and upon reasonable advance notice so that IVI or its donors can verify compliance with the terms of this Agreement.

12. Use Of Names. Grantee may use IVI's name in publications and similar materials solely to indicate IVI's support for the Research and IVI may use Grantee's name in publications and similar materials solely to indicate IVI's support of Grantee for the Research. A party may use the other party's name, trademarks, logos or other indicia of source for other purposes only if the other party has approved the use in writing in advance in each case, including, but not limited to, any use on a website, advertising, promotional or sales literature or other publicity. Prior written approval from IVI must be obtained from IVI's Director General.

13. General Provisions.

(A) Notices. Any notice under this Agreement must be in writing and be addressed to a party at the address below (or to another address designated by a party in accordance with this Section). Notices must be delivered by certified or registered first class mail (air mail if not domestic) or by commercial courier service, or may be delivered by facsimile or email. Notice under this Agreement shall be deemed given after five (5) days of dispatch in the case of notice by mail, or upon transmission in the case of any notice by facsimile or email.

If to Grantee: If to IVI:

Dr.Vijayalaxmi Mogasale
Department of Pediatrics,
Yenepoya Medical College, (A unit of Yenepoya Deemed to be University)
University Road, Deralakatte, Mangalore,
Karnataka State, India, 575018
Tel: +91-824-2206000
E-mail: vijayalaxmimogasale@gmail.com

With copy to Dr. Rekha PD
dydirectoryrc@yenepoya.edu.in

Florian Marks
International Vaccine Institute
SNU Research Park
1 Gwanak-ro, Gwanak-gu, Seoul,
Korea 151-742
Tel: 82-2-881-1133
E-mail: fmarks@ivi.int

with a copy to

Hyonjin Jeon

E-mail: hyonjin,jeon@ivi.int

(B) Further Assurances. If, at any time (whether during the term of this Agreement or the term of any license), a party requests the other party to execute and deliver additional documents to confirm (or to assist the requesting party in obtaining full benefit of) any license or other right granted under this Agreement, the other party will provide such additional documents reasonably requested.

(C) Relationship of the Parties. The parties are independent contractors and nothing in this Agreement may be construed to create an employment, partnership, joint venture, agency or similar relationship between the parties. Neither party may bind or obligate the other in any way.

(D) Assignment. This Agreement is binding upon and shall inure to the benefit of the parties and each of their permitted successors or assigns. This Agreement may not be assigned by either party without the prior written consent of the other party. Any attempted assignment other than as specifically provided in this Section is void.

(E) Force Majeure. Neither party will be responsible to the other for failure to perform any of the obligations imposed by this Agreement, provided such failure is caused by acts of God (including fire, flood, explosion, earthquake), governmental interference, civil commotion, riot, terrorism, war, or a similar cause beyond the party's reasonable control. Notwithstanding the foregoing, if an act of force majeure causes a party to be unable to perform for more than 60 consecutive days, the other party may terminate this Agreement upon 10 days' written notice.

(F) Including. The word "including" as used in this Agreement means "including without being limited to."

(G) Compliance with Laws. Each party agrees to comply with all laws, rules, regulations and guidelines and to obtain all necessary approvals applicable to its activities under this Agreement, including those described in Section 2 and those concerning the transfer or export of technical data, technology, computer software, laboratory prototypes and other commodities, and all applicable data protection and privacy laws.

(H) Governing Law; Dispute Resolution. This Agreement shall be governed by the laws of Switzerland. Any controversy arising from this Agreement shall be finally settled by a binding arbitration under the arbitration procedures stated in Section below:

(i) Any dispute, controversy, or claim arising under, out of, or in connection with this Agreement, including, without limitation, its formation, validity, binding effect, interpretation, performance, breach, or termination, as well as non-contractual claims shall first be subjected to negotiation between the parties to reach an amicable settlement. If an amicable settlement cannot be reached within [30] days for any reason, the dispute shall be referred to and finally settled by arbitration in accordance with the UNCITRAL Arbitration Rules then in effect. The number of arbitrators shall

ATTACHED

Dr.Gangadhara Somayaji K.S.
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be three, with one appointed by each party and the third selected by the two appointed arbitrators, and the language to be used in the arbitral proceedings shall be English. The place of arbitration shall be determined by mutual agreement, but if agreement cannot be reached the proceedings shall take place in Geneva, Switzerland.

(ii) Either party to this Agreement may request any court of competent jurisdiction to order any interim measures of protection for the preservation of its rights and interests to the extent permitted by law, including, without limitation, injunctions and measures for the preservation of such property and information that form part of the subject matter in dispute. Such requests shall not be deemed incompatible with, or as a waiver of, this agreement to arbitrate.

(iii) In the event a party fails to proceed with arbitration, unsuccessfully challenges the arbitrator's award, fails to comply with the arbitrator's award, or fails to comply with any interim measure of protection issued by any competent authority, the other party shall be entitled to costs of suit, including reasonable attorney's fees, for having to compel arbitration or defend or enforce the award or interim measure.

(I) Survival. Sections 5, 6, 7, 8, 9, 10, 11, 12 and 13 will survive any termination or expiration of this Agreement.

(J) Entire Agreement. This Agreement, together with all Appendices, (i) embodies the entire agreement between the parties and supersedes any prior or contemporaneous agreements, oral or written, regarding its subject matter and (ii) may be modified only by a writing signed by authorized representatives of both parties.

(K) Severability. If any term of this Agreement is found by a court of competent jurisdiction to be invalid or unenforceable, the remainder of the Agreement will remain in full force and effect.

(L) Waiver. The waiver of any term or breach of this Agreement must be in writing and a waiver of a particular term or breach will not be deemed a waiver of any other term or breach, whether similar or different.

(M) Headings. The descriptive headings of the sections of this Agreement are inserted for convenience only and shall not control or affect the meaning or construction of any provision hereof.

(N) Counterparts; Facsimile Signatures. This Agreement may be signed in counterparts, each of which will be considered an original and all of which together will be considered one and the same instrument. Signatures sent by facsimile or e-mail will be valid and binding and should be followed up with the original signed Agreement.

IN WITNESS WHEREOF, each party has caused its authorized representative to sign this Agreement, effective as of the date of the last signature below.

ATTESTED

Dr.Gangadhara Somayaji K.S.
Registrar
Yenepoya(Deemed to be University)
University Road, Deralakatte
Mangalore- 575 018, Karnataka

Grantee: Yenepoya (Deemed to be University)

By: Dr. Gangadhar_Somayaji K.S.

Title: _Registrar

Date: 24/01/2019

Registrar
Yenepoya (Deemed to be University)
University Road, Deralakatte
Mangalore 575 018

International Vaccine Institute

By: ___Dr. Jerome Kim

Title: _____Director General

Date: 31 Jan 2019

ATTESTED

Dr.Gangadhara Somayaji K.S.
Registrar
Yenepoya(Deemed to be University)
University Road, Deralakatte
Mangalore- 575 018, Karnataka

APPENDIX A

Scope of Work

1. Purpose of the study

International Vaccine Institute (IVI) is managing several projects that estimate disease burden and economic burden of cholera, typhoid fever and other vaccine preventable diseases. Summarizing existing evidence is one of the key aspects of conducing analytical research such as extrapolation and modeling to generate new evidence under many projects. The evidence thus generated is used in policy and decision making at global, regional and country levels. As a part of ongoing IVI project we intend to conduct systematic reviews in the areas of cholera and typhoid fever with particular focus on outbreaks, clinical complications, anti-microbial resistance (AMR) and costs and other outcomes related to the disease. Collection and analysis of primary data when possible is helpful to support the work.

2. Objectives and methodology

The work has two components, systematic literature review and primary data collection

a. Conducting systematic literature reviews as well assisting ongoing systematic reviews to generate and synthesize new data and develop manuscripts in area of typhoid and cholera will be the primary task. The systematic reviews should follow PRISMA guidelines http://www.prisma-statement.org/ and follow well recognized practices acceptable to journals for publications. The following are list of topics which may be modified based the requirement and research need as the work progresses.
   - Incidence of typhoid fever AMR by time and space: worldwide systematic review
   - Clinical outcomes, duration of illness, duration of hospitalization, mortality and costs among typhoid fever AMR in comparison with non –AMR
   - Health care utilization among typhoid fever and febrile illness cases
   - Cholera outbreaks review worldwide
   - Any other systematic literature review arising from above four topics

Some of the systematic reviews will be performed in collaboration with IVI research team, others will be conducted independently depending upon what work is ongoing and what is needed for the projects. Support on at least three systematic reviews is expected of which at least one should be led by the Yenepoya team. The systematic review is expected to result in manuscript.

b. Estimation of incidence of antibiotic resistance among body fluids such as blood, urine, stool, and CSF. For this records review of existing data at your Research Institute (Yenepoya University) to be conducted. As much possible data should be linked to patient records to summarize epidemiology and clinical outcomes of infectious diseases. This may include AMR on bacterial pathogen, typhoid fever, and febrile, pneumonia or diarrhea causing pathogens. The review may need ethical approval at your institute. A manuscript is expected if sufficient data is available.

The work is expected to start from early February 2019.

ATTESTED

Dr.Gangadhara Somayaji K.S.
Registrar
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APPENDIX B

Budget, Milestones and Payment Schedule

Budget

Budget item	No. of Months	FTE	Unit costs (INR)	Total costs (1USD=70 INR)	
				INR	USD
1. Personnel					
Dr. Vijayalaxmi Mogasale (PI)	12	0.5	In kind	0	0
Research Assistant	12	1	25,000 per month	300,000	$4286
Biostatistician/Research Assistant	06	0.5	12,500 per month	150,000	$2143
Administrative Assistant	06	0.5			
Research Advisors Dr. Prakash Saldanha (Professor and Head, Department of Pediatrics)	12	0.1	In Kind	0	0
Dr. Rekha (Professor and Deputy Director, Yenepoya Research Center)	12	0.1	In Kind	0	0
2. Computer and software					
Desktop computer and accessories		1	50,000	50,000	$714
Endnote 9		1 Unit	49,500(3 licenses)	49,500	$707
3. Supplies & communication	12		1500	18,000	$257
Total				**567,500**	**$8,107**

Milestones

The work should start from early February 2019

Milestone	Activities	Outputs	Timeline
Systematic review	Conduct /support systematic reviews on above listed topics	Data on review 1 shared with IVI Data on review 2 shared with IVI Data on review 3 shared with IVI One draft manuscript is shared with IVI and provided inputs to others	April 2019 June 2019 Nov 2019 Dec 2019
Primary data collection	Collect primary data, analyze and write on above listed topics	Draft manuscript is shared with IVI (subject to data availability)	Jan 2020

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Registrar
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Mangalore- 575 018, Karnataka

Payment Schedule

Payment schedule[1]	Payments (USD)	Milestones[1]	Deliverables[1]
Payment 1 Jan 2019	$5,000	Contract signed	Signed contract
Payment 2 Jun 2019	$2,000	Two reviews completed	Final data on two reviews are shared with IVI
Payment 3 Dec 2019	$1,107	3rd review completed, prepared /contributed manuscripts.	Final data on 3rd review is shared with IVI Developed/contributed to 3 manuscripts [2]Final financial report
TOTAL	$8,107		

[1]Timely and successful achievement of milestones and timely receipt of acceptable deliverables at IVI or facilities designated by IVI will lead to the remittance of payment of amount listed in the same row.
[2]The Financial Report should be in the specified format

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APPENDIX C

Financial Report

Organization: _____

Agreement/Project Number: _____ **Period of Agreement:** _____

Period of this Report: From _____ to _____ **Date Submitted:** _____

	I	II	III	IV	V
Expense Categories	**Budget (in US dollars)**	**Expenses this Report**	**Total Expenses Previous Reports**	**Total Expenses (II + III)**	**Budget Balance (I - IV)**
TOTAL EXPENSES (US$)					

Status of Cash on Hand	**This Report**
Payments Received to Date	
Interest Earned	
Expenses Paid to Date (IV)	
Balance Cash on Hand	

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CERTIFICATION

I, the undersigned, who is the duly authorized officer, hereby certify that:

a. Information in the Financial Report is correct and such detailed supporting information as IVI may require will be furnished to IVI upon request; and,
b. All requirements in the Agreement have been met.

I also certify that payment of the amounts claimed under this Agreement is proper and due and that appropriate refund to IVI will be made upon request by IVI in the event of misrepresentation and/or non-performance in whole or in part under this Agreement or for any breach of this Agreement.

Name: _____

Signature:_____
Title: _____
Date: _____

<Instructions for Completion of Financial Report>

1. Top

   - Organization – Name of your institute (It is given by IVI)
   - Period of Agreement –
   - Period of this report – Study period that you are reporting
   - Date submitted – Date you are submitting this report

2. Middle

   - Expense categories (first column) – These could be personnel salary, equipment, supplies, shipping, communication, travel, education/training, workshops, study incentives, patient cost, lab cost, expenses etc. Please see the 'Payment schedule and deliverables' attached to Research Agreement.
   - Budget (second column) – Write down the budget on each blank according to the research agreement
   - Expenses this report (third column) – Write down how much money you have spent while conducting this study at each category
   - Total expenses previous report (fourth column) – Total amount of expenses until the last report except this report
   - Total expenses (fifth column) – Just add up together column II and column III
   - Budget balance (sixth column)– Deduct column IV from Column I. You can see how much money is left to keep conducting this Research.

3. Third box (Status of cash on hand) in the middle

   - Payments received to date – Total money you have received from IVI until the present
   - Interest earned – Interest you gained (from bank)
   - Expenses paid to date (IV) – The money you have paid for expenses up to date of this report. It should be the same as column IV, 2nd box.
   - Balance cash on hand – Actual money you have now. This should be equal to the money you have received from IVI to date, plus the interest earned from the bank (if any), less the expenses paid to date.

4. Fourth box (certification) in the bottom
   Please write down PI's name, title and date with signature.

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APPENDIX D

Declaration of Conflicts of Interest (COI) in Research Projects

It is a requirement by IVI donors that all investigators and participating organizations adhere to the applicable ethical, regulatory and professional standards in all matters related to researches supported in part or in whole by their grants. Consistent with requirements of applicable regulatory agencies, donors prohibit employees or officers of Grantees from participating in specific dealings when the individual knows that any of his/her immediate family, may pose a conflict of interest to a specific transaction; and requires disclosure of any relationships known to the research participants which are covered by the COI policy and which may affect improperly the transaction.

In order to meet this requirement it is necessary that you confirm the following:

1. You have a Financial Conflict of Interest (FCOI) guideline in place in your organization.
2. Your organization will maintain objectivity in research by ensuring that the design, conduct, or reporting of research will not be biased by any conflicting financial interest of investigators responsible for the research.
3. Safeguards are in place to prevent employees, consultants, or members of governing bodies from using their positions for purposes that are, or give the appearance of being, motivated by a desire for private financial gain for themselves or others such as those with whom they have family, business, or other ties.
4. Your conflicts of interest guidelines reflect state and local laws and cover financial interests, gifts, gratuities and favors, nepotism, and other areas such as political participation and bribery.
5. If any of the above representations is found to be inaccurate in a material respect or any financial conflicts of interest is identified, you agree to promptly take appropriate measures to cure such inaccuracies or to resolve such conflicts of interest, in consultation with IVI.
6. And in the event that research investigator(s) are identified with financial conflicts of interest you agree to report the conflicts to the Director, IVI within 60 days of identifying them. These reports should indicate whether and how the FCOI has been managed, reduced, or eliminated.

I confirm:

Dr. Gangadhar_Somayaji K.S Registrar Yenepoya (Deemed to be University) Deralakatte Mangalore 575 018

Name of Head of Institution and Signature

24/01/2019
Date

Research title Systematic reviews and drug resistance analysis

Investigator: Dr. Vijayalaxmi Mogasale

Duration of Research: 1st February 2019 — 31st January 2020
Start Date of Research — End Date of Research

Budget: _____

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Explanatory Notes for your guidance:

Definition of Conflict of Interest
A conflict of interest may take many forms, but arises when a staff member, in relationship to an outside organization, is in a position to influence the institute's business, research, or other decisions in ways that could lead directly or indirectly to financial gain for the staff member or his or her family, or give improper advantage to others to the detriment of the Institute.

Examples of Possible Conflicts of Interest involving investigators:

Clinical Investigators should consider the potential effect that having a financial relationship of any kind with a commercial sponsor of a study might have on his or her conduct of a clinical trial or interactions with research subjects. Relationships that lead an investigator to prefer one outcome to another may influence an investigator's judgment and behavior.

1. An investigator may be influenced by a financial incentive, even if unwittingly, which could color the consent discussion in a manner that encourages participation by subtly minimizing the presentation of risks or overstating the benefits.
2. Additionally, the above and so-called "recruitment bonuses" paid per participant, or for reaching an accrual goal within a specific time-frame, and being paid or paying a "finders fee" for referral of potential participants, might affect one's judgment, or willingness to report adverse reactions possibly related to the study article, or the analysis and interpretation of data.

Some related matters include, but not limited to the following that need to be addressed are:

i. Any compensation that is affected by the study outcome?
ii. Whether the Investigator has any proprietary interests in the product including patents, trademarks, copyrights, and licensing agreements?
iii. Whether the Investigator has equity interest in the company-- publicly held company or non-publicly held company?
iv. Whether the Investigator receives significant payments of other sorts? (e.g. grants, compensation in the form of equipment, retainers for ongoing consultation, and honoraria)
v. What are the specific arrangements for payment?
vi. Where does the payment go? To the Institution? To the Investigator?
vii. What is the payment per participant? Are there other arrangements?
viii. What are the financial relationships between the Clinical Investigator and the commercial sponsor?

3. All aspects and types of relationships need to be carefully considered, including such clear-cut issues as commitments of financial support unrelated to the study in question, financial incentives, serving as a paid consultant or speaker on behalf of a commercial sponsor, to less obvious ones such as non-monetary inducements or rewards to investigators or their family members.

Other Considerations:

4. Key investigators for the Research: A key investigator is defined as:

   (a) The Research Director/Principal Investigator;
   (b) Co-Principal Investigators
   (c) Any other person who is responsible for the design, conduct, or reporting of the research; and
   (d) It is important to recognize that those individuals covered by the term "key investigator" are not strictly limited to individuals identified within the Institute. An external consultant or scientist associated with a subcontractor, sub-grantee, or cooperating institution may also qualify as a "key investigator" if he or she can reasonably be construed as being responsible for the "design, conduct, or reporting of the research.

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5. The spouse and dependent children of anyone who qualifies as a key investigator under (a), (b) (c) or (d) must also be considered in determining if a disclosure should be made.

These individuals must be queried about the existence of "**significant financial interests**" in the proposed sponsored research.

Definition: The term **significant financial interest** means anything of monetary value, including, but not limited to:

(a) Salary or other payments for services (e.g., consulting fees or honoraria);
(b) Equity interests (e.g., stocks, stock options, or other ownership interests); and
(c) Intellectual property rights (e.g., patents, copyrights, and royalties form such rights).

The term does not include:

(a) Salary, royalties or other remuneration from the Institute;
(b) Income from seminars, lectures, or teaching engagements sponsored by public or nonprofit entities;
(c) Income from service on advisory committees or review panels for public or nonprofit entities;
(d) An equity interest that, when aggregated for the investigator and the investigators spouse and dependent children, meets both of the following tests; does not exceed $10,000 in value as determined through reference to public prices or other reasonable measures of fair market value, and does not represent more than a 5% ownership interest in any single entity; or
(e) Salary, royalties or other payments that, when aggregated for the investigator and the investigator's spouse and dependent children, are not expected to exceed $10,000 during the next twelve month period.

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View Wire-Transfer details

Basic Information

Utilization base	Internet		
Relationship	Principal Company	Company	국제백신연구소
Transaction	Wire-transfer to Overseas(Branch)	Executer	국제백신연구소 (OPIVI07)
Transfer-from bank	KEB HANA BANK	Transfer-from Account	(USD)
Fee Payment Account No.	(USD) 223-890034-80138		
Date	2019/02/28 15:34:56	Ref. No. of Wire Trans.	0109OTT190200136
Date & Time	2019/02/28 08:41:38	Seq. No.	190228AA013

View Wire-Transfer details

Registered

Transfer (scheduled) date.	2019/02/28	Processing Type	Offline
Remitt. Nation	Other(Overseas)	Information No.	
Amount	USD 5,000.00		
Relationship with Sender	INTERNATIONAL VACCINES INSTITUTE		
Address	SAN 4-8	A/C Holder	YENEPOYA UNIVERSITY
Receiver's A/C No.	113200301000289		
수취은행BIC코드	VIJBINBBMLR		
National Clearing Code			
Receiver's Bank			
Receiver's Address	MANGALORE		
Charge Payer	A/C Holder	Fee Payment Account	
Relation with Sender			
KRW Withdrawal Amount		Foreign Currency Withdrawal Amount	USD 5,020.00
Actual Exchange Rate			
Remt.Charge + Cable Charge(KRW)	0(USD 0.00)	Reimbursement Fee(Foreign Currency)	22,494(USD 20.00)
Processing Status	Completed		
Exec.Result	Completed.		

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Transfer amount exceeds the per-transfer transfer limit

Creator	국제백신연구소 (OPIVI07)	Approval request time	2019/02/26 08:41:38
Executer	국제백신연구소 (OPIVI07)	Date of execution	2019/02/28 15:34:58

Approval Stage	결재방식	Approver	필수	Approval or Not	Approval time
1	All	국제백신연구소 (OPIVI07)	Mandatory	Y	2019/02/28 09:01:41
2	All	국제백신연구소 (RUIVI02)	Mandatory	Y	2019/02/28 11:11:52

AP. Status	Approval Completed
Settlement Description	
Transaction Status	TRANSACTION COMPLETED
Transaction Description	

scientific reports

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OPEN

A descriptive analysis of antimicrobial resistance patterns of WHO priority pathogens isolated in children from a tertiary care hospital in India

Vijayalaxmi V. Mogasale[1], Prakash Saldanha[1], Vidya Pai[2], P. D. Rekha[3] & Vittal Mogasale[4]✉

The World Health Organization (WHO) has articulated a priority pathogens list (PPL) to provide strategic direction to research and develop new antimicrobials. Antimicrobial resistance (AMR) patterns of WHO PPL in a tertiary health care facility in Southern India were explored to understand the local priority pathogens. Culture reports of laboratory specimens collected between 1st January 2014 and 31st October 2019 from paediatric patients were extracted. The antimicrobial susceptibility patterns for selected antimicrobials on the WHO PPL were analysed and reported. Of 12,256 culture specimens screened, 2335 (19%) showed culture positivity, of which 1556 (66.6%) were organisms from the WHO-PPL. *E. coli* was the most common organism isolated (37%), followed by *Staphylococcus aureus* (16%). Total of 72% of *E. coli* were extended-spectrum beta-lactamases (ESBL) producers, 55% of *Enterobacteriaceae* were resistant to 3rd generation cephalosporins due to ESBL, and 53% of *Staph. aureus* were Methicillin-resistant. The analysis showed AMR trends and prevalence patterns in the study setting and the WHO-PPL document are not fully comparable. This kind of local priority difference needs to be recognised in local policies and practices.

Antimicrobial resistance (AMR) has been recognised as a major threat to global health[1]. According to the World Health Organization (WHO), mutations in microorganisms resulting in AMR, which consequently render medicines ineffective and infections persist in the body, increasing the risk of spread to others[1]. There are many reasons behind the development of AMR, ranging from microbial causes to human aspects such as overuse and over-prescription of antimicrobials, agricultural and commercial application of antimicrobials in the animal sector, and human behavioural factors[2]. Our ability to treat common pathogens becomes challenging because of AMR, resulting in increased duration of illness, costs, number of complications, and deaths. By 2050, an estimated 10 million deaths are projected to occur due to AMR[3], while another study projected AMR to cost the global economy US$100 trillion, in the same period[4].

In 2015, the 68th World Health Assembly endorsed the Global Action Plan on AMR to tackle this global challenge[5]. This action plan has five strategic actions, focusing on (1) improving awareness and understanding of AMR; (2) strengthening AMR surveillance; (3) reducing the incidence of infections; (4) optimizing antimicrobial use; and (5) developing the economic case for AMR control. To support the Global Action Plan, WHO has developed a priority pathogens list (PPL), through a consultative process[6]. The prioritization process involved multi-criteria decision analysis (MCDA) which used information from multiple sources, including disease mortality, transmissibility, treatability, health care burden, preventability in health care settings, and preventability in community settings, etc. Twelve families of drug-resistant bacteria, posing the greatest threat to human health, were categorized as critical, high, and medium priority organisms, in terms of their resistance to selected antimicrobials (Fig. 1). Although this categorization was intended to prioritize and stimulate research and develop new antimicrobials for specific drug resistance, it also makes a call for the prevention of infection and the rational use of antibiotics in both humans and animals[6].

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