

Ref. No. BT/AIR0775/PACE-18/19

Dated : 26.2.2020

Sub: Funding of Project entitled "**Menstruation Prediction Kit during luteal phase of menstrual cycle**" for funding under AIR-(PACE)

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 "Menstruation Prediction Kit during luteal phase of menstrual cycle"**

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

S. No.	Recipient(s)	Designated Project Investigator
1	B.K.L. Walawalkar Hospital, Diagnostic & Research Centre, under the Trust named Shri Vithalrao Joshi Charities Trust having its office at C-28, 'Suyash' Apartment, Gokhale Road, (North), Dadar ('N), Mumbai - 400028 , hereinafter referred to as the "Trust" (which expression shall wherever the context so admits include its successors in interest, liquidators, administrators and permitted assignees).	Dr. Suvarna Netaji Patil Medical Director, Associate Professor, General Medicine B.K.L. Walawalkar Hospital, Diagnostic & Research Centre At & Post: Sawarde, Kasarwadi, Taluka: Chiplun, District: Ratnagiri, Maharashtra State, PIN- 415606 Email- director.bklwrmc@gmail.com

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:

1. Levels of Serum, urinary and Salivary progesterone will be measured early morning of all women participants during 4 consecutive premenstrual days.
2. Prototype development of a kit using lateral flow technology for quantitative estimation of Salivary progesterone.
3. Kit will be used for prediction of onset of menstrual cycle in all women.

3. **Project Duration:** The Recipients shall complete the Project within the stipulated period of **18** months from the date of acceptance of the GLA by all the recipients. In the event the Parties affix their signatures to this GLA on separate dates, the GLA shall be effective from the date on which the last set of signature is affixed thereto "**Effective Date**". Project Duration is subject to the Change order(s) issued by the BIRAC from time to time.

Sajay Saxena



4. **Project Implementation Site:**

B.K.L. Walawalkar Hospital, Diagnostic & Research Centre
At & Post: Sawarde, Kasarwadi,
Taluka: Chiplun, District: Ratnagiri,
Maharashtra State - 415606

5. **Project Cost and Contribution:** The total estimated cost of the Project is **Rs. 50.00** Lakhs (Rupees Fifty Lakhs only). The contribution of BIRAC is **Rs. 50.00** Lakhs (Rupees Fifty Lakhs only) as Grant-in-aid to the **BKL Walawalkar Hospital Diagnostic Research**. on the terms and conditions detailed in this GLA.

6. **BIRAC Budget break-up : (Rs.in Lakhs)**

Details	Support under PACE to	Total
	BKL Walawalkar Hospital Diagnostic Research Centre	
Non-recurring	5.00	5.00
Recurring	45.00	45.00
Total	50.00	50.00

Budget Break-up Recurring(Rs In Lakhs)		
Recurring items	Contribution by BIRAC to BKL Walawalkar Hospital Diagnostic Research Centre	Total
Manpower	16.02	16.02
Consumables	18.43	18.43
Travel	1.00	1.00
Outsourcing	8.55	8.55
Contingency & Other Costs	1.00	1.00
Total	45.00	45.00

Details of equipment proposed to be acquired through BIRAC contribution for applicant Trust

S. No	Infrastructure/Equipment	Capacity	Quantity	Specific Requirement In The Project	Estimated Value (Rs. In Lakhs)
1	ELISA reader and washer	NA	1	To measure progesterone in blood, urine & saliva	5.00
Accessories To Be Acquired (Rs in Lakhs):					0.00
Total :					5.00

Saijag Saxena



7. Milestones/Timelines

S. No.	Milestones	Month of end of activity	Required financial input (Rs. In Lakhs)
1	Acceptance of Undertaking under GLA <i>And</i> Fulfilment of fund release requirements	0	15.00 (30% of BIRAC contribution)
2	Status report on Testing of blood, urinary and salivary progesterone by ELISA method in 100 participants. Selection of the sample and showing correlation of progesterone in salivary samples. Data analysis (TRL 3) <i>And</i> Submission of UC/SOE for the corresponding milestone certified by internal finance.	5	10.00 (20% of BIRAC contribution)
3	Status report on Prototype development of Kit. ELISA testing for saliva with Kit prototype, and initiation of study for prediction of onset of menstrual cycle in 100 women (TRL 4) <i>And</i> Submission of UC/SOE for the corresponding milestone certified by internal finance.	14	10.00 (20% of BIRAC contribution)
4	Status report on Validation of kit Sensitivity, Specificity In 100 women (TRL 5) <i>And</i> Submission of UC/SOE for the corresponding milestone certified by internal finance.	18	10.00 (20% of BIRAC contribution)
5	Submission of final completion report and consolidated Utilization Certificate (UC) and Statement of Expenses (SOE)	18	5.00 (10% of BIRAC contribution)
		Total	50.00

Note:- Utilization Certificate (UC) and Statements of Expenses (SOE) duly audited by a chartered accountant for the expenditure incurred towards the Project for every half year period, ending 30th September and 31st March, to BIRAC, within a month of closure of the accounts for the respective half year should be submitted by the Fund Recipient till completion of Project Duration.

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

Instalment	Contribution by BIRAC under PACE to BKL Walawalkar Hospital Diagnostic Research Centre	Total (Rs. in Lakhs)
First	15.00	15.00
Second	10.00	10.00
Third	10.00	10.00



Fourth	10.00	10.00
Fifth	5.00	5.00
Total	50.00	50.00

Regulatory Requirement : *Human Ethics Committee approval before start of the Project.*

9. 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.

10. 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)
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11. The Expenditure is debitable to B.04 - Head of Accounts for the financial year 2019-20.



12. This issue with the approval of competent authority vide BFD No. BFD/AD/B.04/0143/2019-20 dated 26/02/2020

13. The GLA has been noted at Serial No. 27 in the Register of Grant/Cost.

Sanjay Saxena



This GLA is between Biotechnology Industry Research Assistance Council ("BIRAC") and **B.K.L. Walawalkar Hospital, Diagnostic & Research Centre**, and is effective as of the date of last signature. Each party to this GLA may be referred to individually as a "Party", **B.K.L. Walawalkar Hospital, Diagnostic & Research Centre** 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	
Signature	
Name: Dr. Sanjay Saxena	
Designation : GM & Head – Investment	
Official Seal	
I) For and on behalf of B.K.L. Walawalkar Hospital, Diagnostic & Research Centre, the "fund recipient" duly authorized vide letter dated by its concerned authority.	
Signature	
Name	
Designation	
Trust Seal	

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

- a. First installment of the Grant-in-aid will be released after issue of the GLA subject to fulfilment of the terms and conditions for such release 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) for the expenditure incurred towards the Project for every half year period, ending 30th September and 31st March, to BIRAC, within a month of closure of the accounts for the respective half year, in the format provided by BIRAC.
- b. The Fund Recipient shall submit UC and SOE duly certified by Internal finance personnel to BIRAC in the format provided on the completion of the respective milestones.
- 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 instalment.
- d. The Fund Recipient shall submit audited Annual reports along with the audited balance sheets and profit & loss accounts to BIRAC within seven months of the completion of the financial year ending 31st March till the completion of the Project Duration.
- e. The Fund Recipient 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 instalment of the fund.
- f. 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;



- g. 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);
- h. 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.

3. PROJECT MONITORING

A Project Monitoring Committee (PMC) comprising of eminent experts from the relevant field(s) will be constituted by BIRAC to monitor the progress of the objective(s) of the Project. BIRAC shall have at least one representative in the PMC.

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 instalment 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 Trust 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.

4. 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-fulfilment 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.

5. 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 and the Trusts shall notify BIRAC of any material change in its 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.

6. FORECLOSURE AND TERMINATION

- i. In case, during the tenure of the Project, 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, along with detailed accounts of funds received, utilized and unutilized. If Fund Recipient like to continue the Project at its own cost, it would be able to do so without restrictions from BIRAC after complying with these provisions.
- ii. The Fund Recipient may, before the completion of the Project, terminate this Agreement by giving three months' notice in writing to BIRAC. BIRAC may also terminate this Agreement by written notice to "Fund Recipient" committing breach of any term of this Agreement 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 Agreement, no further disbursement shall be made by BIRAC. The Fund Recipient 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. In case of failure to repay, without prejudice to any other rights under this Agreement, the amount can be recovered by initiating any procedure available in Law.



7. DISPUTE RESOLUTION AND ARBITRATION

In the event of any dispute or difference whatsoever arising between the Parties out of or relation to the construction, meaning, scope, operation or effect of this agreement or the validity the breach thereof shall be resolved amicably by mutual consultation or through the good offices of the Chairman, BIRAC.

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. 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.

8. EFFECT AND AMENDMENTS TO THE GLA

- i. GLA shall remain in force for whichever of these is the longest time unless suspended sooner:
 - a. For **18 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.
- ii. 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.

9. 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.

10. 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 fund recipient, intending to be admittedly bound by the terms set forth above, undertake as stated below;

The recipient of the Grant 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, Utilization Certificate (UC) and Statements of Accounts Expenses (SOE) as per Schedule 1.
3. Comply with the fund utilization and accounting requirements as per Schedule 1.
4. 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.
5. 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.
6. Subject themselves to Project monitoring of the Project Monitoring Committee (PMC).
7. 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.
8. Shall verify the completion of the milestone and the utilization of the funds as stated which will be a pre requisite for the next fund release.
9. Complete the Project within the stipulated period subject to the Change Order(s) issued by the BIRAC from time to time.
10. The Fund Recipient shall not sub-delegate or outsource the obligations under this GLA without express permission of BIRAC except as provided for in the Project Document.
11. 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.
12. 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.
13. Acknowledge the assistance of BIRAC while publishing or presenting in any manner the details of the Project, its progress or its success or commercialization of the Product.



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

For and on behalf of B.K.L. Walawalkar Hospital, Diagnostic & Research Centre , the “Trust” “Fund Recipient”	
Date and Place:	
Signature	
Name	
Designation	
Seal	
Witness	
Name:	Name:
Signature:	Signature:
Address:	Address:



Project Document:

OBJECTIVE AND TIMELINES
PROPOSAL OBJECTIVES & WORK PLAN
Objective1: Levels of Serum, urinary and Salivary progesterone will be measured early morning of all women participants during 4 consecutive premenstrual days
Methodology/Experimental Design To Accomplish The Stated Objective: Total 100 girls/ women from fertile age will be selected. Early morning blood, urine & Saliva sample will be collected for progesterone PG . PG will be measured by ELISA method for 4 premenstrual days till the onset of menses. Data will be collected and analysed.
Alternate Strategies: Blood, urine and saliva can be collected simultaneously and results will be correlated. But saliva can be tested once the kit is ready and correlation can be established.
Objective 2: Prototype development of a kit using lateral flow technology for quantitative estimation of salivary progesterone.
Methodology/Experimental Design To Accomplish The Stated Objective: Methodology- Kit will be outsourced to Bhat Biotech company and they will supply the kits. 2 ml of early morning saliva will be deposited on the sample pad and will migrate towards the conjugate. In the middle, the conjugated antibodies will bind the target analyte and bottom migrate to the test line, where the bound target analyte will be captured. Detection limit will be tested. It will detect particular range of progesterone in the form of colour bands. Range of band will be in three groups less than 10 ng/dl, 10-50 ng/dl & greater than 50 ng/dl.
Alternate Strategies: The technology is based on a series of capillary beds, such as pieces of porous paper or sintered polymer. Each of these elements has the capacity to transport fluid e.g., saliva spontaneously. Accordingly membrane type can be changed during experiment. Chemicals used like tetrachlorouric acid, tween 20, tritonx100, ovalbumin,substrate etc. will be used as per the availability or will be replaced by available ones.
Objective3:Kit will be used for prediction of onset of menstrual cycle in all women
Methodology/Experimental Design To Accomplish The Stated Objective: Kit will be used for 4 days prior to onset of menstrual cycle in selected women on daily basis.Data will be analysed. Graphs will be plotted. Results will be verified.
Alternate Strategies: If kits are designed in time we may start all the steps simultaneously.



Sajjan

TIME LINES		
Activities	Month Of End Of Activity	Indicators Of Progress
OBJECTIVE 1: Levels of Serum, urinary and salivary progesterone will be measured early morning of all women participants during 4 consecutive premenstrual days.		
Developing SOP for Progesterone testing and protocol. Enrolment of participants.	3	Staff appointment and training done.SOP and protocols ready. Equipment installation
Testing of blood, urinary & salivary progesterone by ELISA method in 100 participants. Selection of the sample and showing correlation of progesterone in salivary samples. Data analysis.	5	SOP will be prepared. Serum progesterone, urine progesterone and salivary progesterone levels will be correlated to ensure that saliva is an equally good source of progesterone. Also the data will be correlated with the individual's menstrual cycle.
Activities	Month Of End Of Activity	Indicators Of Progress
OBJECTIVE 2 : Prototype development of a kit using lateral flow technology for quantitative estimation of salivary progesterone.		
Prototype development of the Kit. ELISA testing for saliva with Kit prototype, and initiation of study for prediction of onset of menstrual cycle in 100 women	14	Outsource to a company-design of kit. Getting the required raw materials
Activities	Month Of End Of Activity	Indicators Of Progress
OBJECTIVE 3 : Kit will be used for prediction of onset of menstrual cycle in all women		
Scheduling participants for usage of kit as per the time table of their menstrual cycle.	18	Salivary Progesterone levels detected by kit and correlation with day of menstrual cycle.
Validation of kit Sensitivity and Specificity in 100 women	18	Testing and Development stage



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INTELLECTUAL PROPERTY GOVERNING FRAMEWORK

a. Background IP Rights:

All rights, title and interest in or to any information, data, reports, documents, procedures, forecasts, technology, know-how, and inventions, including any patents, designs, copyrights, trademarks and any applications for patents, designs, copyrights or trademarks, in India and anywhere else in the world, that are owned by or vest in any Party before execution of this Agreement (“Background IP”) shall remain the property of such Party.

b. New IP:

For the purpose of PACE, New IP means intellectual property generated during the conduct of the Project by the Fund Recipient excluding the intellectual property generated by the Trust before execution of this Agreement and any New IP generated by the Fund Recipient outside the scope of this Agreement even during the term of this Agreement. All rights, title and interest in New IP in India and anywhere else in the world, shall be owned by or vest in the applicant academia unless agreed otherwise between the parties.

The fund recipient will not publish in any manner with regard to the results of the Project which will be in derogation to the creation and protection of IP and related rights as stated above.

NOTE:For the purpose of this GLA, New IP means intellectual property generated during the conduct of the Project by the Fund Recipient, 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 before execution of this GLA are as provided hereunder;

I.	Background IP of the Trust
	IN201921024182: A Menstruation Prediction Kit
	APPLICANT: B. K. L. Walawalkar Hospital and Research Center



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