

SANCTION ORDER

1. Subject: BIRAC support for title “Early Translation Accelerator-YENEPOYA.

2. The details are as follows:

i. The designated Project Coordinator:

Asim Syed Sheeraz ,
 Incubator Manager,
 Yenepoya Foundation for Technology Incubation,
 Yenepoya (Deemed to be University).
 University Road, Deralakatte, Mangalore, Karnataka, India
asim@ytincubator.com

ii. Duration: 21 Months (3 Months for Planning to setup of the ETA +18 Months for completion of all the identified project).

iii. Implementation Agency:

Yenepoya Foundation for Technology Incubation,
 Yenepoya (Deemed to be University).
 University Road, Deralakatte, Mangalore, Karnataka, India

Industry Partner: Yenepoya Foundation for Technology Incubation.

iv. Technical Milestones and Timelines:

TECHNICAL MILESTONES & TIMELINES:		
Sr. No.	Milestone Name	Month End of Activity
1	To implement ETA-Yenepoya objectives through identification and administration of the projects	8
2	To conduct such meetings for coordinating the implementation activities.	16
3	To become self-sufficient by the end of third year to continue the ETA-Yenepoya core activities	18

1

v. Project Cost:

- In Figures: Rs. 100.00 lakhs in Grant
- in words: Rupees One Crore only

3. Budget Summary:

S.N.	Head	Year 1	Year 2	Total
1	Non Recurring (A)	59.80	0.00	59.80
2	Recurring (B)	21.60	18.60	40.20
3	Total (A+B)	81.40	18.60	100.00

ATTESTED


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



Note: Rs. 10.00 Lakhs has already been given as planning grant.

4. Budget details (Rs. in lakhs):

S. No	Budget Head	Year 1	Year 2	Total
1.	Equipment	59.80	-	59.80
2.	Manpower	9.60	6.60	16.20
3.	Travel	2.00	2.00	4.00
4.	Contingency	10.00	10.00	20.00
Total		81.40	18.60	100.00

Note: Rs. 10.00 Lakhs has already been given as planning grant.

5. For implementation of the project the grant will be released in instalments as per the following schedule:

Instalments	BIRAC contribution (Rs.In lakhs)
1 st Instalment, Signing of the contract & Acceptance of the project.	30.00 (30% of the BIRAC contribution)
2 nd Instalment, Review of Eight months technical progress of the projects	25.00 (30% of the BIRAC contribution)
3 rd Instalment, Review of Sixteen months technical progress of the projects	25.00 (30% of the BIRAC contribution)
4 th Instalment, Submission of Final report for all the projects	10.00 (10% of the BIRAC contribution)
Total	Rs. 90.00

Note: Rs. 10.00 Lakhs has already been given as planning grant.

The above budget is grant for core ETA activities.

- In addition to the above, specific project related expenditure (with a minimum of 10% contribution from the Industry) for Each ETA Project will be considered. Hence BIRAC contribution for each ETA projects will be maximum of 90% of the total Project Cost.
- First Installment will be released on signing of the Agreement by all the parties. A copy of the Agreement and Other necessary documents would be sent by BIRAC after accepting the sanction order. Release of further installments will be subject to the review of the progress in the project.
- The Implementing organization will maintain a separate auditable account for the Project. The interest if any earned on the grant-in-aid kept in a bank account should be reported to BIRAC and such amount will be adjusted towards further installment of the fund.
- The Company would submit the Utilization Certificate (UC) and Statement of Expenditure (SOE) to BIRAC pertaining to the fund released. A consolidated UC/SOE would be submitted immediately after the end of each financial year.

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

10. The expenditure incurred before the effective Date of the governing Agreement of the Project will not be accounted for this Project.
11. No budget Re-appropriation should be done without prior approval from BIRAC.
12. The Sanctioned amount for the Project does not automatically confirm release of the complete sanctioned amount; the fund disbursement will be based on execution of the governing agreement and on the technical progress of the project and actual expenditure based on evaluation of UC/SoE submitted by ETA-YENEPOYA.
13. The accounts shall be open to inspection by the sanctioning authority/ audit as per the rule 150(1) of GFR 15(A). The accounts are also liable and shall be open to inspection by the BIRAC/CAG.
14. The Expenditure is debitable to "BIRAC I & M sector, Translational facilities Head of Account: B.08 for financial year 2020-21.
15. This issue with the approval of competent authority vide Sanction order no.. **BFD/AO/B.08/0163/2020-2021**, dated 18/03/2021
16. . The Sanction order has been noted at Serial No.1, page 345 in the Register of Grant.

Dr. PKS Sarma
GM & Head Technical

To,

Asim Syed Sheeraz ,
Incubator Manager,
Yenepoya Foundation for Technology Incubation,
Yenepoya (Deemed to be University).
University Road, Deralakatte, Mangalore, Karnataka, India
asim@ytincubator.com

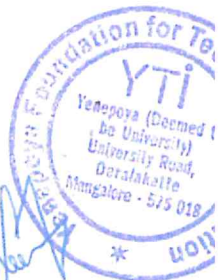
Copy to:

1. Executive secretary to MD
2. BIRAC-Technical Head Folder
3. Accounts Folder
4. Finance Folder

Dr. PKS Sarma
GM & Head Technical

ATTESTED

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





Yenepoya Foundation for Technology Incubation

Yenepoya (Deemed to be University)
Deralakatte, Mangalore - 575 018.

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Contact@ytincubator.com
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To,
Dr. Rekha PD,
Professor and Dy. Director
Yenepoya Research Centre,
Yenepoya (Deemed to be University), Mangalore

Ref: YTI/ETA/SL/PR007

Date: 31/03/2021

Dear Dr. Rekha PD,

We are pleased to inform you that the project titled "Validation of a bioactive bacterial exopolysaccharide (EPS-A21) as novel biomaterial for wound care" has been approved for funding under the BIRAC - Early Translation Accelerator (ETA) at Yenepoya. The project will be implemented as per the Guidelines for BIRAC - Early Translation Accelerator at Yenepoya Foundation for Technology Incubation.

As per the documents received by the ETA-Yenepoya, the industry partner for this project will be Swakit Biotech Pvt Ltd and the total duration for the project will be 18 months effective from 31st March 2021.

The total budget approved for the project cost is Rs. 149.77 lakhs. As per the BIRAC – ETA implementation guidelines the Industry should contribute 10% of the total project cost (Rs. 14.977 lakhs). BIRAC contribution will be Rs. 134.793 lakhs (90% of the total project cost).

The following are the technical milestones and the timelines,

S. No.	Technical Milestones	Month of End of Activity
1	Completion preclinical studies and application for regulatory approvals for Phase I study	6
2	Completion of Phase I Clinical Trial and submission of the report of Phase I trial	12
3	Completion of Phase II Clinical Trial and submission of the report of Phase II trial	18

A separate Technology Accelerator Agreement will be signed between ETA-Yenepoya, Academia/Inventor entity and the industrial partner contributing towards the project.

Yenepoya Mohammed Farhad
Managing Director



ATTESTED

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

Ref No: BIRAC/TG/ETA-Yenepoya Proj 1/01/2020

Date: 18/03/2021

SANCTION ORDER

1. **Subject:** BIRAC support for title “*Validation of a bioactive bacterial exopolysaccharide (EPS-A21) as novel biomaterial for wound care*” submitted by Early Translation Accelerator – YENEPOYA .

2. **The details are as follows:**

i. **The designated Project Coordinator:**

Dr. Asim Syed Sheeraz ,
Incubator Manager,
Yenepoya Foundation for Technology Incubation,
Yenepoya (Deemed to be University).
University Road, Deralakatte, Mangalore, Karnataka, India
asim@Ytincubator.com

ii. **Duration:** 18 Months Effective from the date of execution of ETA agreement.

iii. **Implementation Agency:**

Yenepoya Foundation for Technology Incubation,
Yenepoya (Deemed to be University).
University Road, Deralakatte, Mangalore, Karnataka, India
Industry Partner: SWAKIT BIOTECH PVT. LTD.

iv. **Technical Milestones and Timelines:**

TECHNICAL MILESTONES & TIMELINES:		
Sl.	Milestone Name	Month End of Activity
1	Completion preclinical studies and application for regulatory approvals for Phase I study	6
2	Completion of Phase I Clinical Trial and submission of the report of Phase I trial	12
3	Completion of Phase II Clinical Trial and submission of the report of Phase II trial	18

v. **Project Cost:**

- In Figures: Rs. 149.77 lakhs in Grant
- in words: Rupees One Crore Forty Nine Lakhs Seventy Seven Thousand only

3. **Budget Summary:**

Sr. no.	Head	Total
1.	Non Recurring (A)	70.50

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



2.	Recurring (B)	79.27
Total (A+B)		149.77

4. Budget details (in lakhs):

Budget Head	Total (Rs. In Lakhs)
Equipment	70.50
Accessories	0.00
Total (A)	70.50
Manpower	14.40
Consumables	14.80
Travel	2.00
Contingency	48.07
Total (B)	79.27
Total (A+B)	149.77

2

The Industry should contribute 10 % of the total project cost (Rs. 14.977 Lakhs). Considering Industry commitment **BIRAC contribution will be Rs. 134.793 Lakhs (90% of the Total Project cost).**

5. For implementation of the project the grant will be released in instalments as per the following schedule:

Instalments	BIRAC contribution (Rs.In lakhs)
1 st Instalment, Signing of the contract & Acceptance of the project	40.4379 (30% of the BIRAC contribution)
2 nd Instalment, Review of Eight months technical progress of the projects	40.4379 (30% of the BIRAC contribution)
3 rd Instalment, Review of Sixteen months technical progress of the projects	40.4379 (30% of the BIRAC contribution)
4 th Instalment, Submission of Final report of the projects	13.4793 0% of the BIRAC contribution)

6. In addition to the above, specific project related expenditure (with a minimum of 10% contribution from the Industry) for Each ETA Project will be considered. Hence BIRAC contribution for each ETA projects will be maximum of 90% of the total Project Cost.

7. First Installment will be released on signing of the Agreement by all the parties. A copy of the Agreement and Other necessary documents would be sent by BIRAC after accepting the sanction order. Release of further installments will be subject to the review of the progress in the project.

8. The Implementing organization will maintain a separate auditable account for the Project. The interest if any earned on the grant-in-aid kept in a bank account should

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Registrar
Yenepoya (Deemed to be University)
University Road, Derlakatte
Mangalore 575 018, Karnataka.



be reported to BIRAC and such amount will be adjusted towards further installment of the fund.

9. The Company would submit the Utilization Certificate (UC) and Statement of Expenditure (SOE) to BIRAC pertaining to the fund released. A consolidated UC/SOE would be submitted immediately after the end of each financial year.
10. The expenditure incurred before the effective Date of the governing Agreement of the Project will not be accounted for this Project.
11. No budget Re-appropriation should be done without prior approval from BIRAC.
12. The Sanctioned amount for the Project does not automatically confirm release of the complete sanctioned amount; the fund disbursement will be based on execution of the governing agreement and on the technical progress of the project and actual expenditure based on evaluation of UC/SoE submitted by ETA-BETIC
13. The accounts shall be open to inspection by the sanctioning authority/ audit as per the rule 150(1) of GFR 15(A). The accounts are also liable and shall be open to inspection by the BIRAC/CAG.
14. The Expenditure is debitible to "BIRAC I & M sector, Translational facilities Head of Account: B.08 for financial year 2020-21."
15. This issue with the approval of competent authority vide Sanction order no. **BFD/AO/B.08/0164/2020-2021** dated .18/03/2021

16. . The Sanction order has been noted at Serial No.3, page 345 in the Register of Grant.

Dr. PKS Sarma
GM & Head Technical

To,

Dr. Asim Syed Sheeraz ,
Incubator Manager,
Yenepoya Foundation for Technology Incubation,
Yenepoya (Deemed to be University).
University Road, Deralakatte, Mangalore, Karnataka, India
asim@Ytincubator.com

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4. Finance Folder



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Dr. Gangadhara Somayaji K S
Registrar
Yenepoya (Deemed to be University)
University Road, Deralakatte,
Mangalore - 575 015

Dr. PKS Sarma
GM & Head Technical



Yenepoya Foundation for Technology Incubation

Yenepoya (Deemed to be University)
Deralakatte, Mangalore - 575 018.

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To,
Dr. K Sudhakaraprasad,
Assistant Professor
Yenepoya Research Centre,
Yenepoya (Deemed to be University), Mangalore

Ref: YTI/ETA/SL/PR009

Date: 31/03/2021

Dear Dr. K Sudhakaraprasad,

We are pleased to inform you that the project titled "Clinical Validation of Novel Dual PAD Microfluidic Device for screening of Parkinson' disease" has been approved for funding under the BIRAC - Early Translation Accelerator (ETA) at Yenepoya. The project will be implemented as per the Guidelines for BIRAC - Early Translation Accelerator at Yenepoya Foundation for Technology Incubation.

As per the documents received by the ETA-Yenepoya, the industry partner for this project will be Papersens Pvt Ltd and the total duration for the project will be 18 months effective from 31st March 2021.

The total budget approved for the project cost is Rs. 110.97 lakhs. As per the BIRAC – ETA implementation guidelines the Industry should contribute 10% of the total project cost (Rs. 11.097 lakhs). BIRAC contribution will be Rs. 99.873 lakhs (90% of the total project cost).

The following are the technical milestones and the timelines,


S. No.	Technical Milestones	Month of End of Activity
1	Application for the permission to manufacture the device from Zonal DCGI office (or NOCs) for the device, performance in human.	6
2	With CDSCO Permissions- Manufacture device and conduct Clinical Trial	12
3	Submission of clinical performance outcome to CDSCO	18

A separate Technology Accelerator Agreement will be signed between ETA-Yenepoya, Academia/Inventor entity and the industrial partner contributing towards the project.


Yenepoya Mohammed Farhad
Managing Director



ATTESTED


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

Ref No: BIRAC/TG/ETA-YENEPOYA Proj 2/01/2020

Date: 18/03/2021

SANCTION ORDER

1. **Subject:** BIRAC support for title “*Clinical Validation of Novel Dual PAD Microfluidic Device for screening of Parkinson's disease*” submitted by Early Translation Accelerator – YENEPOYA .

2. **The details are as follows:**

i. **The designated Project Coordinator:**

Dr. Asim Syed Sheeraz ,
Incubator Manager,
Yenepoya Foundation for Technology Incubation,
Yenepoya (Deemed to be University).
University Road, Deralakatte, Mangalore, Karnataka, India
asim@Ytincubator.com

ii. **Duration:** 18 Months Effective from the date of execution of ETA agreement.

iii. **Implementation Agency:**

Yenepoya Foundation for Technology Incubation,
Yenepoya (Deemed to be University).
University Road, Deralakatte, Mangalore, Karnataka, India
Industry Partner: Papersens Pvt. Ltd.

iv. **Technical Milestones and Timelines:**

TECHNICAL MILESTONES & TIMELINES:		
Sl.	Milestone Name	Month End of Activity
1	Application for the permission to manufacture the device from Zonal DCGI office (or NOCs) for the device performance in human.	6
2	With CDSCO Permissions- Manufacture device and conduct Clinical trial	12
3	Submission of clinical performance outcome to CDSCO	18

v. **Project Cost:**


- In Figures: Rs. 110.97 lakhs in Grant
- in words: Rupees One Crore Ten Lakhs Ninty Seven Thousand only

3. **Budget Summary:**

Sr. no.	Head	Total
1.	Non Recurring (A)	22.50
2.	Recurring (B)	88.47

ATTESTED

(Signature)
Dr. Gangadhara Somayaji K.
Registrar
Yenepoya (Deemed to be University)
University Road, Deralakatte
Mangalore - 575 015



Total (A+B)	110.97
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4. Budget Breakup (in lakhs):

Budget Head	Total (Rs. In Lakhs)
Equipment	22.50
Accessories	0.00
Total (A)	22.50
Manpower	17.70
Consumables	38.81
Travel	1.50
Contingency	28.46
Outsourcing	2.00
Total (B)	88.47
Total (A+B)	110.97

3 The Industry should contribute 10 % of the total project cost (Rs. 11.097 Lakhs). Considering Industry commitment **BIRAC contribution will be Rs. 99.873 Lakhs (90% of the Total Project cost).**

5. For implementation of the project the grant will be released in instalments as per the following schedule:

Instalments	BIRAC contribution (Rs. in lakhs)
1 st Instalment, Signing of the contract & Acceptance of the project	29.9619 (30% of the BIRAC contribution)
2 nd Instalment, Review of Eight months technical progress of the projects	29.9619 (30% of the BIRAC contribution)
3 rd Instalment, Review of Sixteen months technical progress of the projects	29.9619 (30% of the BIRAC contribution)
4 th Instalment, Submission of Final report of the projects	9.9873 0% of the BIRAC contribution)

- In addition to the above, specific project related expenditure (with a minimum of 10% contribution from the Industry) for Each ETA Project will be considered. Hence BIRAC contribution for each ETA projects will be maximum of 90% of the total Project Cost.
- First Installment will be released on signing of the Agreement by all the parties. A copy of the Agreement and Other necessary documents would be sent by BIRAC after accepting the sanction order. Release of further installments will be subject to the review of the progress in the project.
- The Implementing organization will maintain a separate auditable account for the Project. The interest if any earned on the grant-in-aid kept in a bank account should be reported to BIRAC and such amount will be adjusted towards funds in the account of the fund.

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



9. The Company would submit the Utilization Certificate (UC) and Statement of Expenditure (SOE) to BIRAC pertaining to the fund released. A consolidated UC/SOE would be submitted immediately after the end of each financial year.
10. The expenditure incurred before the effective Date of the governing Agreement of the Project will not be accounted for this Project.
11. No budget Re-appropriation should be done without prior approval from BIRAC.
12. The Sanctioned amount for the Project does not automatically confirm release of the complete sanctioned amount; the fund disbursement will be based on execution of the governing agreement and on the technical progress of the project and actual expenditure based on evaluation of UC/SoE submitted by ETA- YENEPOYA.
13. The accounts shall be open to inspection by the sanctioning authority/ audit as per the rule 150(1) of GFR 15(A). The accounts are also liable and shall be open to inspection by the BIRAC/CAG.
14. The Expenditure is debitible to "BIRAC I & M sector, Translational facilities Head of Account: B.08 for financial year 2020-21.
15. This issue with the approval of competent authority vides Sanction order no. **BFD/AO/B.08/0165/2020-2021**. dated .18.03.2021
16. . The Sanction order has been noted at Serial No. 2, page 345 in the Register of Grant.

Dr. PKS Sarma
GM & Head Technical

To,

Dr. Asim Syed Sheeraz ,
Incubator Manager,
Yenepoya Foundation for Technology Incubation,
Yenepoya (Deemed to be University).
University Road, Deralakatte, Mangalore, Karnataka, India
asim@Ytincubator.com

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4. Finance Folder



Dr. PKS Sarma
GM & Head Technical

ATTESTED

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

SANCTION ORDER

1. **Subject:** BIRAC support for title “*Human Studies of a Novel Gel Formulation Containing HalofuginoneHydrobromide to establish the Safety, Tolerability and Preliminary Efficacy in single dose and multiple does studies in Healthy Subjects and Patients with Oral Submucosal Fibrosis*” submitted by Early Translation Accelerator – YENEPOYA .

2. The details are as follows:

i. **The designated Project Coordinator:**

Dr. Asim Syed Sheeraz ,
Incubator Manager,
Yenepoya Foundation for Technology Incubation,
Yenepoya (Deemed to be University).
University Road, Deralakatte, Mangalore, Karnataka, India
asim@Ytincubator.com

ii. **Duration:** 18 Months Effective from the date of execution of ETA agreement.

iii. **Implementation Agency:**

Yenepoya Foundation for Technology Incubation,
Yenepoya (Deemed to be University).
University Road, Deralakatte, Mangalore, Karnataka, India
Industry Partner: CTX7095 Analytics

iv. **Technical Milestones and Timelines:**

TECHNICAL MILESTONES & TIMELINES:		
Sl.	Milestone Name	Month End of Activity
1	Production of three batches in GMP setup	6
2	Obtaining of Ethics and DCGI approval for Phase I/II study	12
3	Submission of protocol for confirmatory human studies	18

v. **Project Cost:**

- In Figures: Rs. 192.94 lakhs in Grant
- in words: Rupees One Crore Ninty Two Lakhs Ninety Four Thousand only


3. **Budget Summary:**

Sr. no.	Head	Total
1.	Non Recurring (A)	57.00
2.	Recurring (B)	135.94

ATTESTED

Handwritten signature in green ink

Dr. Gangadhara Somayaji
Registrar
Yenepoya (Deemed to be Unive
University Road, Deralaka
Mangalore 575 018, Karnat
Deralakatta
Mangalore - 575 018



Total (A+B)	192.94
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4. Budget details (in lakhs):

Budget Head	Total (Rs. In Lakhs)
Equipment	57.00
Accessories	0.00
Total (A)	57.00
Manpower	16.90
Consumables	34.84
Travel	2.00
Contingency	82.20
Total (B)	135.94
Total (A+B)	192.94

4

The Industry should contribute 10 % of the total project cost (Rs. 19.294 Lakhs). Considering Industry commitment .BIRAC contribution will be Rs. 173.646 Lakhs (90% of the Total Project cost).

5. For implementation of the project the grant will be released in instalments as per the following schedule:

Instalments	BIRAC contribution (In lakhs)
1 st Instalment, Signing of the contract & Acceptance of the project	52.0938 (30% of the BIRAC contribution)
2 nd Instalment, Review of Eight months technical progress of the projects	52.0938 (30% of the BIRAC contribution)
3 rd Instalment, Review of Sixteen months technical progress of the projects	52.0938 (30% of the BIRAC contribution)
4 th Instalment, Submission of Final report of the projects	17.3646 (10% of the BIRAC contribution)
Total	Rs. 173.646 Lakhs

- In addition to the above, specific project related expenditure (with a minimum of 10% contribution from the Industry) for Each ETA Project will be considered. Hence BIRAC contribution for each ETA projects will be maximum of 90% of the total Project Cost.
- First Installment will be released on signing of the Agreement by all the parties. A copy of the Agreement and Other necessary documents would be sent by BIRAC after accepting the sanction order. Release of further installments will be subject to the review of the progress in the project.
- The Implementing organization will maintain a separate auditable account for the Project. The interest if any earned on the grant-in-aid kept in a bank account should be reported to BIRAC and such amount will be adjusted towards further installment of the fund.

ATTESTED

Dr. Gangadhar Somayaji K S
 Registrar
 YTI
 University Road
 Mangalore 575 018, Karnataka

9. The Company would submit the Utilization Certificate (UC) and Statement of Expenditure (SOE) to BIRAC pertaining to the fund released. A consolidated UC/SOE would be submitted immediately after the end of each financial year.
10. The expenditure incurred before the effective Date of the governing Agreement of the Project will not be accounted for this Project.
11. No budget Re-appropriation should be done without prior approval from BIRAC.
12. The Sanctioned amount for the Project does not automatically confirm release of the complete sanctioned amount; the fund disbursement will be based on execution of the governing agreement and on the technical progress of the project and actual expenditure based on evaluation of UC/SoE submitted by ETA- YENEPOYA.
13. The accounts shall be open to inspection by the sanctioning authority/ audit as per the rule 150(1) of GFR 15(A). The accounts are also liable and shall be open to inspection by the BIRAC/CAG.
14. The Expenditure is debitible to "BIRAC I & M sector, Translational facilities Head of Account: B.08 for financial year 2020-21.
15. This issue with the approval of competent authority vides Sanction order no. **BFD/AO/B.08/0166/2020-2021**. dated 18/03/2021.
16. . The Sanction order has been noted at Serial No. 4, page 345 in the Register of Grant.

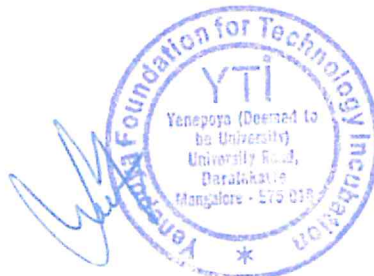
Dr. PKS Sarma
GM & Head Technical

To,

Dr. Asim Syed Sheeraz ,
Incubator Manager,
Yenepoya Foundation for Technology Incubation,
Yenepoya (Deemed to be University).
University Road, Deralakatte, Mangalore, Karnataka, India
asim@Ytincubator.com

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4. Finance Folder



Dr. PKS Sarma
GM & Head Technical

ATTESTED

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

Ref No: BIRAC/TG/ETA-YENEPOYA Proj 4/01/2020

Date:18/03/2021

SANCTION ORDER

1. **Subject: BIRAC support for title “Phase I/II clinical trial of a novel asparaginase mutant for the treatment of primary and relapse Acute Lymphoblastic Leukemia” submitted by Early Translation Accelerator – YENEPOYA .**

2. **The details are as follows:**

i. **The designated Project Coordinator:**

Dr. Asim Syed Sheeraz ,
Incubator Manager,
Yenepoya Foundation for Technology Incubation,
Yenepoya (Deemed to be University).
University Road, Deralakatte, Mangalore, Karnataka, India
asim@Ytincubator.com

ii. **Duration:** 18 Months Effective from the date of execution of ETA agreement.

iii. **Implementation Agency:**

Yenepoya Foundation for Technology Incubation,
Yenepoya (Deemed to be University).
University Road, Deralakatte, Mangalore, Karnataka, India
Industry Partner: Epygen Biotech Pvt Ltd.

iv. **Technical Milestones and Timelines:**

TECHNICAL MILESTONES & TIMELINES:		
Sl.	Milestone Name	Month End of Activity
1	Production of 3 batches at GMP facility	6
2	Obtaining of regulatory approval for Phase I/II studies	12
3	Submission of protocol for confirmatory human studies.	18


v. **Project Cost:**

- In Figures: Rs. 199.90 lakhs in Grant
- in words: Rupees One Crore Ninty Nine Lakhs Ninety Thousand only


3. **Budget Summary:**

Sr. no.	Head	Total
1.	Non Recurring (A)	10.00
2.	Recurring (B)	189.90
	Total (A+B)	199.90

ATTESTED



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



4. Budget details (in lakhs):

Budget Head	Total (Rs. In Lakhs)
Equipment	0.00
Accessories	10.00
Total (A)	10.00
Manpower	27.10
Consumables	68.03
Travel	3.00
Contingency	25.19
Outsourcing	66.58
Total (B)	189.90
Total (A+B)	199.90

5

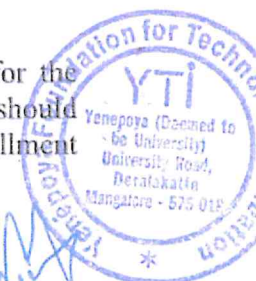
The Industry should contribute 10 % of the total project cost (Rs. 19.99 Lakhs). Considering Industry commitment **BIRAC contribution will be Rs. 179.91 Lakhs (90% of the Total Project cost).**

5. For implementation of the project the grant will be released in instalments as per the following schedule:

Instalments	BIRAC contribution (In lakhs)
1 st Instalment, Signing of the contract & Acceptance of the project	53.973 (30% of the BIRAC contribution)
2 nd Instalment, Review of Eight months technical progress of the projects	53.973 (30% of the BIRAC contribution)
3 rd Instalment, Review of Sixteen months technical progress of the projects	53.973 (30% of the BIRAC contribution)
4 th Instalment, Submission of Final report of the projects	17.991 (10% of the BIRAC contribution)
Total	Rs. 179.91 Lakhs

- In addition to the above, specific project related expenditure (with a minimum of 10% contribution from the Industry) for Each ETA Project will be considered. Hence BIRAC contribution for each ETA projects will be maximum of 90% of the total Project Cost.
- First Installment will be released on signing of the Agreement by all the parties. A copy of the Agreement and Other necessary documents would be sent by BIRAC after accepting the sanction order. Release of further installments will be subject to the review of the progress in the project.
- The Implementing organization will maintain a separate auditable account for the Project. The interest if any earned on the grant-in-aid kept in a bank account should be reported to BIRAC and such amount will be adjusted towards further installment of the fund.

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



9. The Company would submit the Utilization Certificate (UC) and Statement of Expenditure (SOE) to BIRAC pertaining to the fund released. A consolidated UC/SOE would be submitted immediately after the end of each financial year.
10. The expenditure incurred before the effective Date of the governing Agreement of the Project will not be accounted for this Project.
11. No budget Re-appropriation should be done without prior approval from BIRAC.
12. The Sanctioned amount for the Project does not automatically confirm release of the complete sanctioned amount; the fund disbursement will be based on execution of the governing agreement and on the technical progress of the project and actual expenditure based on evaluation of UC/SoE submitted by ETA- YENEPOYA.
13. The accounts shall be open to inspection by the sanctioning authority/ audit as per the rule 150(1) of GFR 15(A). The accounts are also liable and shall be open to inspection by the BIRAC/CAG.
14. The Expenditure is debitible to "BIRAC I & M sector, Translational facilities Head of Account: B.08 for financial year 2020-21.
15. This issue with the approval of competent authority vides Sanction order no.

BFD/AO/B.08/0167/2020-2021. dated .18/03/2021

16. . The Sanction order has been noted at Serial No. 5, page 345 in the Register of Grant.

Dr. PKS Sarma
GM & Head Technical

To,

Dr. Asim Syed Sheeraz ,
Incubator Manager,
Yenepoya Foundation for Technology Incubation,
Yenepoya (Deemed to be University).
University Road, Deralakatte, Mangalore, Karnataka, India
asim@Ytincubator.com

Copy to:

1. Executive secretary to MD
2. BIRAC-Technical Head Folder
3. Accounts Folder
4. Finance Folder



Dr. PKS Sarma
GM & Head Technical

ATTESTED

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

Ref No: BIRAC/TG/ETA-YENEPOYA Proj 5/01/2020

Date:18/03/2021

SANCTION ORDER

1. **Subject:** BIRAC support for title “*Demonstration of safety, tolerability and determination of the dose of 3’3’- diselenopropionicacid (DSePA) in Humans*” submitted by Early Translation Accelerator – YENEPOYA .

2. The details are as follows:

i. **The designated Project Coordinator:**

Dr. Asim Syed Sheeraz ,
 Incubator Manager,
 Yenepoya Foundation for Technology Incubation,
 Yenepoya (Deemed to be University).
 University Road, Deralakatte, Mangalore, Karnataka, India
asim@Ytincubator.com

ii. **Duration:** 18 Months Effective from the date of execution of ETA agreement.

iii. **Implementation Agency:**

Yenepoya Foundation for Technology Incubation,
 Yenepoya (Deemed to be University).
 University Road, Deralakatte, Mangalore, Karnataka, India
Industry Partner: IDRS Labs Pvt Ltd.

iv. **Technical Milestones and Timelines:**

TECHNICAL MILESTONES & TIMELINES:		
Sl.	Milestone Name	Month End of Activity
1	Completion of manufacture of 3 GMP batches	6
2	Obtaining regulatory approvals for Phase I/II studies	12
3	Submission of regulatory package for confirmatory studies with the novel drug	18

v. **Project Cost:**

- In Figures: Rs. 199.10 lakhs in Grant
- in words: Rupees One Crore Ninty Nine Lakhs Ten Thousand only

3. **Budget Summary:**

Sr. no.	Head	Total
1.	Non Recurring (A)	0.00
2.	Recurring (B)	199.10

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



Total (A+B)	199.10
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4. Budget details (in lakhs):

Budget Head	Total (Rs. In Lakhs)
Equipment	0.00
Accessories	0.00
Total (A)	0.00
Manpower	27.10
Consumables	43.92
Travel	3.00
Contingency	35.91
Outsourcing	89.17
Total (B)	199.10
Total (A+B)	199.10

6

The Industry should contribute 10 % of the total project cost (Rs. 19.91 Lakhs). Considering Industry commitment .BIRAC contribution will be Rs. 179.19 Lakhs (90% of the Total Project cost).


5. For implementation of the project the grant will be released in instalments as per the following schedule:


Instalments	BIRAC contribution (In lakhs)
1 st Instalment, Signing of the contract & Acceptance of the project	53.757 (30% of the BIRAC contribution)
2 nd Instalment, Review of Eight months technical progress of the projects	53.757 (30% of the BIRAC contribution)
3 rd Instalment, Review of Sixteen months technical progress of the projects	53.757 (30% of the BIRAC contribution)
4 th Instalment, Submission of Final report of the projects	17.919 (10% of the BIRAC contribution)
Total	Rs. 179.19 Lakhs

6. In addition to the above, specific project related expenditure (with a minimum of 10% contribution from the Industry) for Each ETA Project will be considered. Hence BIRAC contribution for each ETA projects will be maximum of 90% of the total Project Cost.

7. First Installment will be released on signing of the Agreement by all the parties. A copy of the Agreement and Other necessary documents would be sent by BIRAC after accepting the sanction order. Release of further installments will be subject to the review of the progress in the project.

8. The Implementing organization will maintain a separate auditable account for the Project. The interest if any earned on the grant-in-aid kept in a bank account should

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



be reported to BIRAC and such amount will be adjusted towards further installment of the fund.

9. The Company would submit the Utilization Certificate (UC) and Statement of Expenditure (SOE) to BIRAC pertaining to the fund released. A consolidated UC/SOE would be submitted immediately after the end of each financial year.
10. The expenditure incurred before the effective Date of the governing Agreement of the Project will not be accounted for this Project.
11. No budget Re-appropriation should be done without prior approval from BIRAC.
12. The Sanctioned amount for the Project does not automatically confirm release of the complete sanctioned amount; the fund disbursement will be based on execution of the governing agreement and on the technical progress of the project and actual expenditure based on evaluation of UC/SoE submitted by ETA- YENEPOYA.
13. The accounts shall be open to inspection by the sanctioning authority/ audit as per the rule 150(1) of GFR 15(A). The accounts are also liable and shall be open to inspection by the BIRAC/CAG.
14. The Expenditure is debitible to "BIRAC I & M sector, Translational facilities Head of Account: B.08 for financial year 2020-21.
15. This issue with the approval of competent authority vide Sanction order no.

BFD/AO/B.08/0168/2020-2021, dated .18.03.2021.

16. . The Sanction order has been noted at Serial No. 6, page 345 in the Register of Grant.

Dr. PKS Sarma
GM & Head Technical

To,

Dr. Asim Syed Sheeraz ,
Incubator Manager,
Yenepoya Foundation for Technology Incubation,
Yenepoya (Deemed to be University).
University Road, Deralakatte, Mangalore, Karnataka, India
asim@Ytincubator.com

Copy to:

1. Executive secretary to MD
2. BIRAC-Technical Head Folder
3. Accounts Folder
4. Finance Folder



ATTESTED

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

BIRAC/EG/ETA-YENEPOYA/01/20

Dated: 11th March, 2020

SANCTION ORDER

Subject: Planning grant for setting up Early translation Accelerator (ETA)

Sanction of the Competent Authority is hereby accorded to planning grant for setting up Early translation Accelerator submitted by **Yenepoya Foundation for Technology Incubation** hereinafter called as 'Fund Recipient' at an estimated cost of 10 lakhs (Ten Lakhs) with BIRAC funding of 10 lakhs as Planning grant to the applicant.

On the terms and conditions detailed hereunder.

1. The designated Project Coordinator from the Applicant is:

Dr. Asim Syed Sheeraz,
Incubator Manager
Yenepoya Foundation for Technology Incubation
University Road, Deralakatte, Mangalore, Karnataka- 575018
+91-824-2206000/ 9060741988
Email: asim@ytincubator.com

2. Objectives/ Specific aims:

1. To Constitute an ETA expert committee (with representation from BIRAC) for the evaluation of the Projects to be considered under ETA (List of experts to be shared with BIRAC for final approval).
2. To Identify the Projects recommended by ETA expert committee within three months of signing the agreement (Projects from other institutes to be included in the final list)

3. Duration: 3 months

4. Project Implementation site:

Yenepoya Foundation for Technology Incubation
University Road, Deralakatte, Mangalore, Karnataka- 575018
+91-824-2206000/ 9060741988
Email: asim@ytincubator.com

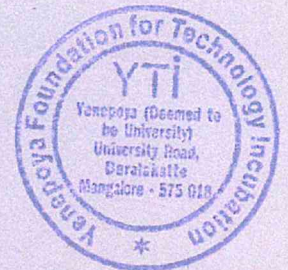
5. Project Cost:

In Figures: 10.00 lakhs
In words: Rs. Ten lakhs

Note: Separate Grant in Aid Letter Agreement (GLA) will be issued for further funding.

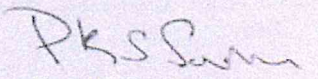
6. Activities under planning budget:

To identify Projects to be funded under ETA.



7. The Fund Recipient will maintain a separate auditable No Lien Account for the Project Cost. The interest if any earned on the grants-in-aid kept in a bank account should be reported to BIRAC and such amount will be adjusted towards further installment of the fund.
8. The Fund Recipient would submit the Utilization Certificate (UC) and Statement of Expenditure (SOE) to BIRAC pertaining to the fund released. A consolidated UC/SOE would be submitted immediately after the end of each financial year.
9. The expenditure incurred before the Effective Date of the governing Agreement of the Project will not be accounted for this Project.
10. No extension will be entertained.
11. The accounts of Fund Recipient shall be open to inspection by the sanctioning authority/ audit as per the rule 150(1) of GFR 15(A). The accounts are also liable and shall be open to inspection by the BIRAC.
12. The Expenditure is debitable to "Translation Activities" scheme under BIRAC Head of Accounts B-08 for the financial year 2019-20
13. This issue with the approval of competent authority vides BFD No. BFD/A0/B-08/0166/17 dated 24/03/2020
14. The Sanction order has been noted at Serial No. 1/ 340 in the Register of Grant.
15. The execution of the Grant in Aid Letter Agreement, fulfillment of collateral or security requirements & completion of associated formalities should be a carried out within a period of one week form the issue of the present Sanction Order, unless, specific waiver is obtained for any delay from BIRAC.

Note: Yenepoya Foundation for Technology Incubation, may please return a duly signed copy of this Sanction Order as token of acceptance to the same.


Dr. PKS Sarma
GM & Head - Technical

Copy to:

1. BIRAC Finance folder.
2. Sh. Nand Kishore, BIRAC, New Delhi. E-mail: nkishore.birac@nic.in
3. Sanction Folder





ATTESTED


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

To,
Mr. Asim Syed Sheeraz, Incubator Manager
Yenepoya Foundation for Technology Incubation,
Yenepoya Deemed to be University
Deralakatte Mangalore 575018.

Ref: SPARSH Project Title "Establishment of SPARSH Center in a Hospital Centric Incubator Ecosystem"

Dear Mr. Asim Syed Sheeraz,

With reference to your above, mentioned SPARSH proposal, we are pleased to inform that your proposal has been approved by BIRAC at a total estimated cost for Rs.200 Lacs (Rupees Two hundred Lacs Only) as Grant-in-aid with Rs. 100 Lacs (Rupees One hundred Lacs Only) as cost per thematic Cycle. (If the SPARSH Centre continues with same Project Manager in Cycle 2 that it had hired for Cycle 1 then the budget for the 2nd cycle will get reduced to Rs. 97.60 Lacs). This project shall be implemented in two thematic cycle of 20 months each with an overlap of 4 months. Each such thematic Project shall be governed as per the terms of the Grant in Aid Letter Agreement (GLA) enclosed.

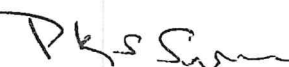
If you are in acceptance with the terms of funding support as mentioned in the GLA, the following documents should be executed within a time period of **TWO WEEKS** from the date of issue of this communication

- Grant-in-aid Letter Agreement (GLA) including all the Schedules: All pages to be clearly initialled by the Fund Recipients and the Company should affix the Company common seal on the signature page to the GLA.
- Board resolution from the Company in the prescribed format of BIRAC
- No lien document on the Bank's letter head to be submitted by the Company with regard to specific project account in the prescribed format of BIRAC (*No-Lien account should be opened in the Bank that provides Cheque Book Facility. A copy of cancelled cheque need to submit along with GLA*)


The Grant-in-Aid Letter agreement has been executed by BIRAC kindly take a colour printout of this GLA and the schedules (as many copies as the Parties- BIRAC, Company and/or institute) and execute the same from your end, and then the collaborator (if any).

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 & Head Technical)

ATTESTED


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



BT/0587/SPARSH-CENTRE/01/2019

Date : 23.12.2019

Sub: Establishment of SPARSH Centre with project entitled “Establishment of SPARSH Center in a Hospital Centric Incubator Ecosystem”

GRANT-IN-AID LETTER AGREEMENT

Social Innovation Immersion Program (SIIP) is a component under **Social Innovation programme for Products: Affordable & Relevant to Societal Health (SPARSH)** which intends to create a pool of social innovators in the biotech arena who can identify specific needs and gaps in healthcare of different communities which can be bridged and serviced through innovative product development and services.

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 entity mentioned below for the Implementation of Social Innovation Immersion Program (SIIP)

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

Sr.no	Recipient(s)	Designated Project Investigator
1	Yenepoya Foundation for Technology Incubation, An Incubator having its registered office at Yenepoya Deemed to be University Deralakatte Mangalore 575018. hereinafter referred to as the Company (which expression shall wherever the context so admits include its successors in interest, liquidators, administrators and permitted assignees).	Mr. Asim Syed Sheeraz (Incubator Manager) Address: Yenepoya Deemed to be University Deralakatte Mangalore 575018 Email: asim@ytincubator.com Contact: +91-9060741988

2. Aims & Objectives: The detailed implementation framework for SPARSH CENTERS is appended herein as **Schedule 3**.

3. Project Duration: This Agreement shall remain effective for 3 years from the date of acceptance ** of the GLA (“**Effective date**”) to be implemented under SPARSH partnership. Project Duration is subject to the Change order(s) issued by the BIRAC from time to time under this provision. This project shall be implemented in two thematic cycle of 20 months **each with an overlap of 4 months**. Each such thematic Project shall be governed by distinct Orders of BIRAC.

** 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 in fructuous and the project will be treated as withdrawn.

4. Thematic Areas:

Cycle 1: Maternal and Child Health
Cycle 2: Ageing and Health

5. Project Implementation Site:

Yenepoya Deemed to be University Deralakatte Mangalore 575018

ATTESTED


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



6. Cost and Contribution: The total estimated cost for project is Rs.200 Lakhs(Rupees Two hundred Lakhs Only) as Grant-in-aid with Rs. 100 Lakhs(Rupees One hundred Lakhs Only) as cost per thematic Cycle. (If the SPARSH Centre continues with same Project Manager in Cycle 2 that it had hired for Cycle 1 then the budget for the 2nd cycle will get reduced to Rs. 97.60 Lakhs)

7. BIRAC Budget break-up (per thematic cycle)

Cycle	Cycle1	Cycle2
Budget Head	Proposed Budget	Proposed Budget
Research Fellowship	Rs. 50,000 x 5 fellows x 18 months = Rs. 45 Lakhs	Rs. 50,000 x 5 fellows x 18 months = Rs. 45 Lakhs
Kick Start Grant	5 lakhs * 5 = 25 Lakhs	5 lakhs * 5 = 25 Lakhs
Sub Total(A)	70 Lakhs	70 Lakhs
Management Fees for SPARSH Centre	4 Lakhs	4 Lakhs
Manpower Cost	Rs. 60,000 x 20 = Rs.12 Lakhs	Rs. 60,000 x 20 = Rs.12 Lakhs or Rs. 60,000 x 16 = Rs. 9.60 Lakhs*
Honorarium to experts clinical/rural partners	3 Lakhs	3 Lakhs
Workshop Conference	4 Lakhs	4 Lakhs
Contingency	2 Lakhs	2 Lakhs
Travel/Field/site visits	5 Lakhs	5 Lakhs
Sub Total (B)	30 Lakhs	30 Lakhs
Total (A + B)	100 Lakhs	100 Lakhs
Total Project Cost	200 Lakhs	

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 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 seven months of the completion of the financial year ending 31st March till the Project duration.

8. Milestones/Timelines

The project duration of 3 years shall be completed in two thematic cycles of 20 months each with an overlap of 4 months. The milestones/timelines for both the cycle as mentioned below:-

Sr no.	Milestone Name	Timelines for Cycle 1(Months)	% release of funds for cycle 1
1	Acceptance of Undertaking under GLA and Fulfillment of fund release requirements	0	10%
2	Status report on "Completion of Recruitment of SPARSH fellows and their pre-Immersion Induction" And Submission of UC/SOE for the corresponding milestone certified by internal finance	2	20%
3	Status report on "Post Immersion Filtration and Submission of dossier on final idea " And Submission of UC/SOE for the corresponding milestone certified by internal finance.	8	30%

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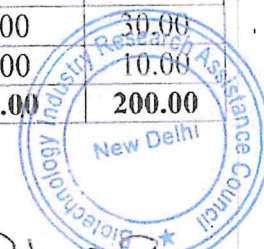
4	Status report on "Product designing and prototyping by the social Innovators based on the final idea " And Submission of UC/SOE for the corresponding	16	30%
5	Submission of final completion report and consolidated UC/SoE certified by Internal finance	20	10%

The second thematic cycle shall start at the end of 16 month of the first thematic cycle after reviewing progress of the initial cycle and shall be governed by distinct Orders issued by BIRAC in a timely manner.

Sr no.	Milestone Name	Timelines of full project	Timelines for Cycle 2(Months)	% release of funds for cycle 2
1	Acceptance of Undertaking under BIRAC order and Fulfillment of fund release requirements	16	0	10%
2	Status report on "Completion of Recruitment of SPARSH fellows and their pre-Immersion Induction" And Submission of UC/SOE for the corresponding	18	2	20%
3	Status report on "Post Immersion Filtration and Submission of dossier on final idea" And Submission of UC/SOE for the corresponding	24	8	30%
4	Status report on "Product designing and prototyping by the social Innovators based on the final idea" And Submission of UC/SOE for the corresponding	32	16	30%
5	Submission of final completion report and consolidated UC/SoE certified by Internal finance	36	20	10%

9. Periodic Payment/Release Arrangements of the project support based on milestones for the Project, "Establishment of SPARSH Center at Yenepoya Foundation for Technology Incubation ":

Installment	Total Cost of Project	Percentage of the sanctioned amount		Contribution by BIRAC as GIA		Total
		Cycle1	Cycle2	Cycle1	Cycle2	
1	200.00	10%	-	10.00	-	10.00
2		20%	-	20.00	-	20.00
3		30%	-	30.00	-	30.00
4		30%	10%	30.00	10.00	40.00
5		10%	20%	10.00	20.00	30.00
6		-	30%	-	30.00	30.00
7		-	30%	-	30.00	30.00
8		-	10%	-	10.00	10.00
Total				100.00	100.00	200.00



(If the SPARSH Centre continues with same Project Manager in Cycle 2 that it had hired for Cycle 1 then the budget for the 2nd cycle will get reduced to Rs. 97.60 Lakhs)

10. Inclusion by Reference:

This GLA includes and incorporates by this reference:

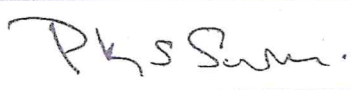

- Terms and Conditions (Schedule 1)
- Acceptance and Undertaking (Schedule 2)
- SPARSH CENTER Guidelines (Schedule 3)
- Intellectual Property Governing Framework (Schedule 4)

11. The Expenditure is debitable to **B.03** - Head of Accounts for the financial year 2019-20.

12. This issue with the approval of competent authority vide BFD No. BFD/10/B.03/0103/19-20 dated 26/12/19

13. The GLA has been noted at 17 in the Register of Grant/Cost.

THIS GLA is between **Biotechnology Industry Research Assistance Council ("BIRAC")** and **Yenepoya Foundation for Technology Incubation**, and is effective as of the date of last signature. Each party to this GLA may be referred to individually as a "Party", and all Party together as the Parties

1)	For and on behalf of BIRAC
Name	: Dr. P K S Sarma
Designation	: GM & Head - Technical
Signature	: 
Official Seal	: 

For and on behalf of **Yenepoya Foundation for Technology Incubation**, "Fund recipient" duly authorized vide Resolution No..... Date of its Board of Directors.

Name :

Designation:

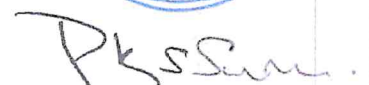
Signature:

Institute Seal

ATTESTED



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



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 fulfillment of the terms and conditions for such release by the relevant Parties. The present GLA shall govern the fund release of the Project on "Maternal and Child Health". Further release of funds of the Project on "Ageing and Health" 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).
- b. The other thematic Projects shall be governed by distinct Orders of BIRAC having specific budgetary allocation and milestones.

2. FUND UTILISATION AND ACCOUNTING

- a. The funds towards the SIIP implementation activities including meetings, travel, arranging technical and financial due diligence etc and for Grant-in-aid disbursements to Innovators and other activities such as organizing workshops, training, entrepreneurship development program etc shall be in accordance with this GLA.
- b. BIRAC shall release the initial SIIP fund after signing of the GLA and subject to the fulfillment of the terms and conditions for such release as stated under Clause 1 (a) above. Further release of funds shall be subject to satisfactory progress against the objectives, outputs, milestones and targets specified in the SIIP scheme as determined by BIRAC, on submission of statement of accounts and disbursement details certificates as provided for in Clause 1(a) (vi) and (viii) and based on the further requirement of the SIIP;
- 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 SPARSII Partner shall keep the Grant-in-aid assistance in a separate account for SIIP, the payments from which account shall be subject to verification by BIRAC or the Comptroller and Auditor General (CAG) of India. The interest so earned should be reported to BIRAC.
- e. The SPARSH Partner shall refund immediately any funds out of grant-in-aid disbursed to it for the SIIP remaining unutilized with it on completion of its implementation along with detailed accounts of funds received, utilized and unutilized;
- f. That the fund for second thematic cycle will be released to the SPARSH Partner at the end of 16 month of the first thematic cycle after reviewing progress report of the initial cycle and shall be governed by distinct orders issued by BIRAC.
- g. The SPARSH Partner shall ensure that capital assets acquired by the Innovators through BIRAC's grant-in-aid, shall be cared for adequately and they shall not be disposed of without the specific prior written permission of BIRAC.
- h. The provision of SIIP fund by BIRAC does not create any liability, explicit or implicit, on BIRAC in respect of the manpower engaged in its implementation.
- i. Centre has to organize one workshop for SPARSH Social Innovators in collaboration with SPARSH knowledge partner once during each cycle. Budget for workshop is included in the approved cost of project.

ATTESTED

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



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3. PROJECT MONITORING & MENTORING

The Evaluation of the SIIP implementation shall be undertaken as provided for in the SIIP operational elements and work plan of the SIIP guidelines appended herein as **Schedule 3**.

The implementation of SIIP Projects undertaken by SPARSH partner will be monitored/and mentored regularly by **SIIP Review Committee** constituted by BIRAC. The SIIP Review Committee will be responsible:

- I. To monitor the progress of the Project in conformity with the outputs, milestones, targets and objectives contained in the GLA.
- II. Based on the foregoing, to assess and suggest:
 - a. Recommending the release of next installment or part release thereof by the BIRAC
 - b. Closing or dropping or modifying any of the components of the Project, within the overall approved objectives, budget and time-frame,
 - c. Inclusion of additional immersion/institutional partner(s), in the overall interest of the Project,
 - d. Mentoring to assist in overcoming any technological problem faced in the Project implementation; and
 - e. Revision of the financial assistance
- III. To advise on issues related to securing of IPR; and
- IV. 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 SIIP.

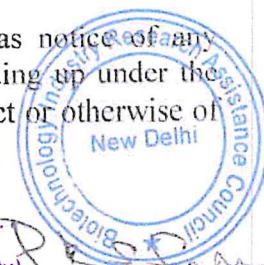
4. INDEMNIFICATION

- a. The SPARSH Partner 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 SPARSH Partner 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.

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 SPARSH Partner 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 SPARSH Partner 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 SPARSH partner and affecting the title to the properties of the SPARSH partner or if a receiver is appointed of any of its properties or business or undertaking.

- c. The SPARSH Partner shall notify BIRAC of any material change in its entity status, entity name, shareholding pattern, 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

- a. In case, during the Project Duration, it is found that implementation of SIIP or any SIIP component is not likely to lead to successful implementation by any of the SPARSH Partner, BIRAC may exercise the option of foreclosure. The decision with regard to refund of BIRAC's disbursements shall be governed by mutually acceptable terms based on the detailed accounts of funds received, utilized and unutilized by that particular SPARSH Partner. The entire outstanding amount as on the date of foreclosure will become due and payable immediately. However, BIRAC may by a specific written order, prescribe a repayment schedule for the amount outstanding.
- b. The SPARSH partner may, before the completion of the effective duration of the GLA, 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 breach of any term of this GLA by the SPARSH partner 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 and the SPARSH partner shall immediately refund any funds unutilized out BIRACs disbursements to BIRAC, along with detailed accounts of funds received, utilized and unutilized within 30 (thirty) days of termination of the GLA. 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.
- c. Notwithstanding the terms stated here above under the sub sections (a) and (b) of this Clause and in the event of such Foreclosure or Termination, the funding of the Innovators shall be considered by BIRAC on a case to case basis.

7. 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. 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. Till completion of the last thematic Project to be implemented under Sparsh partnership.
 - 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. CONFIDENTIALITY

During the tenure of the GLA, both the Parties, undertake to maintain strict confidentiality and refrain from disclosure thereof, of all or any part of the information and data exchanged/generated under this GLA for any purpose other than in accordance with this GLA. It shall be the responsibility of both the Parties to ensure maintenance of such confidentiality in respect of their behalf and on behalf of their employees, representatives and associates involved in the SIIP.

The Parties shall not have any obligation of confidentiality with respect to any information that:

- a) is in the public domain by use and/or publication at the time of its disclosure by the disclosing party; or
- b) was already in possession of the recipient prior to receipt from the disclosing party; or
- c) is properly obtained by the recipient from a third party with a valid right to disclose such information and such third party is not under confidentiality obligation to the disclosing party; or
- d) was disclosed to any third party on a non-confidential basis prior to commencement of the Project; or
- e) is required by public authority, by law or decree.

10. 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.

11. 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.

ATTESTED



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Dr. Gangadhara Somayaji K.S.
Registrar
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University Road, Deralakatte
Mangalore - 575 018, Karnataka



Acceptance & Undertaking

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

The SPARSH Partner shall;

- i. Carry out the core activities to implement the SIIP and conform to the specified guidelines appended herein as **Schedule 3**;
- ii. Meet the resources for the SIIP implementation activities to the extent as agreed to as per **Schedule 3**.
- iii. Execute the Implementation Mechanism in consultation with BIRAC with regard to grant opportunity announcements, selection criteria, disbursement of fellowships, reporting and monitoring modules and other related activities under SIIP.
- iv. Enter into necessary arrangements with the social Innovators and submit the true copy of such documents within a reasonable time period.
- v. Obtain all the necessary requisite approvals, clearance certificates, permissions and licenses from the Government/local authorities for conducting its operations in connection with SIIP ;
- vi. Submit disbursement details and statement of accounts for the expenditure incurred under SIIP for the half year, ending 30th September and 31st March, to BIRAC, within a month of closure of the accounts for respective half year, in the format prescribed by BIRAC;
- vii. Share the progress reports of the SIIP beneficiaries to BIRAC as per the corresponding milestones and participate in the meetings organized by BIRAC to review the progress of SIIP , as and when called for;
- viii. Permit BIRAC access to the premises, during regular business hours and provide all information and produce or make available the concerned records for inspection and monitoring of the SIIP activity, required by BIRAC;
- ix. Provide mentorship and handholding for activities related to SIIP implementation.
- x. Utilize the amounts sanctioned by BIRAC for SIIP only and for the purposes as specified in the scheme and shall not entrust the implementation of SIIP to another agency or divert the grant-in-aid assistance;
- xi. Abide by the decision of BIRAC to modify the objectives, outputs and funding modalities of SIIP or of its components after mutual discussion;
- xii. Acknowledge the assistance of BIRAC while publishing or presenting in any manner the details of SIIP, its progress or its success or commercialization of the Product.
- xiii. If required, SPARSH partner will enter into an agreement with Rural/ Clinical/ community Collaborators for enabling effective implementation as per the mechanism specified in the SIIP Guidelines.
- xiv. Refrain from sub-delegation or outsourcing of the obligations under this GLA without express permission of BIRAC except as provided for in the Project Document.

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- xv. Convey by incorporation of relevant terms in the corresponding Social Innovator agreements that the results of the supported Projects are to be managed as per **Schedule 3 & 4.**

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

For and on behalf of the "SPARSH Partner", "Yenepoya Foundation for Technology Incubation"	
Date and Place:	
Signature	
Name	
Designation	
Company Common Seal or Signatures of Two Directors or One Director and Company Secretary	
Witnesses	
Signature	
Name	
Address	



SIIP Guidelines including the Operational Elements & Work Plan

BIRAC - SPARSH Centres are responsible for implementation of Social innovation program of BIRAC and will provide a host of technical, IP, business and marketing mentoring to the fellows.

Roles and Responsibilities

- i. The SPARSH Centres will be responsible for selecting the social innovation fellows in consultation with BIRAC.
(In case of resignation of fellows, SPARSH Centres may recommend a new fellow under the program provided the previous SIIP fellow had availed less than six months of fellowship)
- ii. Provide desired infrastructure such as dedicated work space, common equipment and other services like mentoring, networking to the Fellows (As explained in the operational section of this document)
- iii. Overall implementation and management of SIIP
- iv. Monitoring the progress of SPARSH fellows and submitting the project progress report to BIRAC as per prescribed timelines.
- v. SPARSH Centres, if so desire, may share resources with other SPARSH Centers for optimal utilization of infrastructure.
- vi. The program manager is critical component of the SPARSH Centers, hence the eligibility criteria and roles & responsibilities of the SPARSH – Program Manager should be clearly defined. Also, attention should be paid to capacity building for program managers.
- vii. The Immersion partners should be very strong. They should be able to provide required infrastructure, experience and mentorship to the fellows. It is required to share the list of Immersion partners to BIRAC and a formal MoU between SPARSH Centres and Immersion partners shall be signed within 2 months of signing of GLA between BIRAC & the SPARSH Centre.
- viii. Along with the details of Immersion partners, engagement plan with mentors too should be submitted to BIRAC.

Tenure of SPARSH Centres

The project duration is 3 years for implementation of two thematic cycles of 20 months each with an overlap of 4 months.

Operational Elements & Work Plan:

The overall administrative responsibility of the Social Innovation Immersion would rest on the partnering organization which would implement the program.

The performance of the SPARSH Centre with respect to a particular cycle would be evaluated after 16 - 20 Months. However, the overall performance of SPARSH Centre for extending the contract will be reviewed only after completion of two cycles i.e., 3 years. After the review, the contract may be extended further.

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A SPARSH Center can recruit maximum of 5 fellows per theme for 18 months. Centre should complete two thematic cycles in a duration of three years with 4 months overlap between two themes.

SPARSH Centre can recruit 5 SPARSH fellows under a particular theme. Total number of SPARSH Innovators at a time at a center should not increase 10.

The 18 months fellowship will start from Pre-Immersion orientation and Induction phase. The work flow would be as follows:

1. Recruitment & Selection of Social Innovator Fellows

The SPARSH Centres will complete the process of selection of SPARSH fellows within 2 months of approval from BIRAC to operationalize the program. Each partner shall recruit a maximum of 5 fellows for 18 months under a particular theme.

An ideal candidate would be one who has the basic understanding of the milieu of the particular theme in different resource settings, and drive to undertake product/technology development process independently. Any training in past on various aspects of Entrepreneurship would be desirable. Nevertheless, required training and mentorship would be provided to Social innovators during the course of Program.

2. Pre-Immersion orientation & Induction:

Once the fellows are selected, SPARSH partners are expected to brief the fellows about objectives & expected outcomes of the program as well as provide necessary tools and guidance to identify existing gaps & needs in the identified thematic area.

The centers are also responsible for training the innovators on process of systematic clinical & Community observation, needs assessment and refinement, affordable technology development & Commercialization, market and industry research and enabling rural / remote settings. For these aspects it is expected from SPARSH Centres to have clinical and rural partners and mentors in Healthcare and other areas. SPARSH knowledge partner will organize pre-Immersion workshop for the SPARSH fellows.

3. Immersion Program

The "immersion" component of the program would be for a period of 5-6 months. During this period the social innovators would ideally be exposed to both clinical/agricultural settings as well as rural (or urban resource poor) community settings. Within the clinical landscape, it would be desirable that the fellows gain exposure at 3 levels- primary, secondary & tertiary healthcare.

It is expected that during the immersion period, fellows would identify multitudes of needs and conduct detailed ethnography and need assessment studies of different communities. Rural or Urban resource poor community immersion would expose them to cultural aspects and other pain points faced by a community.

SPARSH Partners are expected to be in continuous engagement with fellows throughout this period and take periodic reviews of the fellows. Besides other support, they are also expected to provide mentoring on Intellectual Property Rights and technology commercialization issues.

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BIRAC expects a written report from each of the fellows at the end of the immersion program about the experiences and summary of the Ideas generated during the Immersion.

4. Post Immersion Filtration

On completion of the immersion component, fellows are expected to do desk research to understand various solutions explored and list out all the gaps & need analysis carried out during immersion. Further to this they are expected to filter their list and narrowed down to top 2-3 ideas that align well with possible product or service strategies. This would involve a mix of business & technical learnings related to market dynamics, technology landscaping, regulatory challenges, business plan formulation and grant writing skills.

It is expected that the SPARSH partners would mentor and provide them with connect points especially with mentors from business (such from business schools) technical and regulatory fields. The partners will also identify and encourage participation of SPARSH fellows in workshops and conferences for social innovators relevant to their requirements and connect them to opinion leaders or stakeholders for individual specific meetings.

The Social Innovators will come out with detailed report on the 2-3 final ideas shortlisted by them. The detailed requirements for the next stage should also be envisaged. Fellows are expected to submit to BIRAC a detailed plan of action for taking identified gap/need to the next stage either in terms of product design or delivery component with at least two milestone stages. SPARSH knowledge partner will organize Post-Immersion workshop for the fellows in collaboration with BIRAC and SPARSH implementation partner.

5. Product Design, Prototyping and Delivery Mechanism

This stage will provide the live prototype development environment or planning a delivery implementation to the Social innovators. The detailed plan of action submitted by applicant will be reviewed by Partner and a report for release of grant should be submitted to BIRAC. On submission of the plan, BIRAC would then release the mini kick-start grant of INR 500,000 in two stages of (INR 250000 each time) routed via the partner. If two or more fellows wish to work together as a team on developing a single identified need, they can combine their mini kick-start grants. However, this must be communicated to BIRAC in advance and a project lead for the joint project be identified and agreed upon. The team then has to submit a detailed milestone based plan to the SPARSH Centre & BIRAC for approval before the combined mini kick-start grant is released & routed via the SPARSH Centre. Once BIRAC approval has been provided for a joint project, it cannot be reversed. Wherever more than 2 Social innovators decide to work for a joint project, the combined mini Kick start grant will be provided in two milestone stages as for individuals.

It is expected that the SPARSH partner would help connect the fellows to product designers and engineers and various design labs during this period. SPARSH Centre will also provide access to its own Tinkering Labs to the Social innovators.

Outcome

On completion, BIRAC expects the Social innovators to reach a point where they have made enough advancements with respect to generation of data or development of product/technology for licensing or to apply for funding under BIG or equivalent funding source or pitch to investors or apply for a patent.

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The SPARSH Centre is expected to submit an outcome report to BIRAC at the end of the cycle highlighting the achievements of the SPARSH fellows in terms of awards won, patents filed, technology transferred, enterprise developed or follow on funding raised.

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INTELLECTUAL PROPERTY GOVERNING FRAMEWORK

1. SCOPE OF IP GENERATED DURING THE CONDUCT OF THE PROJECT

- i. The New Intellectual Property (IP) rights will be owned by the Innovators
- ii. It is the responsibility of the Innovator to protect the New Intellectual Property (New IP).

Notwithstanding the foregoing sub clause, the allocation of IP generated during the SIIP project execution may be negotiated based on special arrangements duly executed among the Parties thereto to avoid the encumbrance of existing intellectual property rights the IP policy of SIIP or to facilitate the commercial deployment of inventions conceived or first actually reduced to practice.

Outcome from SIIP

SPARSH partner shall strive for enabling the Innovators to reach a point where they either have a ready business plan to pitch to investors, or an advanced proposal with some preliminary results suitable for funding by SIIP or equivalent funding source or a technology / patent suitable for licensing.

2. GLOBAL ACCESS

The SPARSH partner agrees and shall further direct the SIIP Innovator 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 SPARSH Partner, but excluding the intellectual property generated by the SPARSH partner before execution of this GLA and any IP generated outside the scope of this GLA even during the term of this GLA.

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Dr. Gangadhara Somayaji K.S.
Registrar
Yenepoya (Deemed to be University)
University Road, Deralakuru
Mangalore - 575 001

Date: July 19, 2019.

To,

Dr. Akhter Husain
Professor and Head,
University Road, Deralakatte,
Mangaluru, Karnataka 575018

Ref: Proposal No. BT/NBM0118/03/18

Project Title "Establishment of MedTech Design and Rapid Prototyping Facility" under Industry-Academia Collaborative Mission for Accelerating Discovery Research to Early Development for Biopharmaceuticals - "Innovate in India (i3) Empowering biotech entrepreneurs & accelerating inclusive innovation"

Dear Dr. Akhter Husain

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. 457.85 Lakhs with Industry-Academia Collaborative Mission For Accelerating Discovery Research To Early Development For Biopharmaceuticals - "Innovate in India (i3) Empowering biotech entrepreneurs & accelerating inclusive innovation" support of Rs. 307.85 Lakhs and Fund Recipient Contribution of Rs. 150.00 Lakhs for 36 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 Recipients and the Fund Recipients should affix the official seal on the signature page to the GLA.
- Authority Letter from the Institute in the prescribed format of BIRAC.
- Saving Account details on the KYC format to be submitted by the Institute with regard to specific project account in the prescribed format of BIRAC (*A copy of cancelled cheque to be submitted along with executed GLA*).

The Grant-in-aid Letter agreement has been executed by BIRAC. Kindly take a colour printout of this GLA and the schedules and execute the same from your end.

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

Kavita Singh
Dr. Kavita Singh
Mission Director, NBM



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ATTESTED

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

Ref No. BT/NBM0118/03/18

Dated: July 19, 2019

Grant-In-Aid Letter Agreement

Sub: Funding of Project entitled “Establishment of MedTech Design and Rapid Prototyping Facility” for funding under National Biopharma Mission.

The Department of Biotechnology has received financing from the Government of India and the World Bank for effecting the National Biopharma Mission entitled- “Industry-Academia Collaborative Mission For Accelerating Discovery Research To Early Development For Biopharmaceuticals - “Innovate in India (i3) Empowering biotech entrepreneurs & accelerating inclusive innovation” (the “NBM”), and 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”) is the Project/program Implementation Agency (PIA) for NBM.

This Grant-in-aid Letter Agreement (hereinafter called as “GLA”) is between BIRAC as PIA of the NBM and the entity mentioned below for research proposal entitled “Establishment of MedTech Design and Rapid Prototyping Facility”

1. Recipient and Designated Project Investigator:

Recipient	Designated Project Investigator
Yenepoya is a deemed to be university having its registered office at University Road, Deralakatte, Mangaluru, Karnataka 575018 hereinafter referred to as the “ Fund Recipient ” (which expression shall wherever the context so admits include its successors in interest, liquidators, administrators and permitted assignees).	Dr. Akhter Husain Professor and Head, Department of Orthodontics and Dentofacial Orthopaedics Email id:quality@yenepoya.edu.in Mobile No.9845084266

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**.



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

Objectives	Activities
Objective 1: Establishment of Rapid Prototyping and Electronics fabrication facility	Hiring and training of the manpower for providing necessary services and technical support to med-tech innovators.
	Designing of lab space and refurbishment.
	Procurement and installation of the equipment.
	Fully functional Rapid Prototyping & electronics facility set-up.
Objective 2: Establishment of Bioprinting facility	Hiring & training of the manpower.
	Designing of the lab space in accordance with biosafety standard.
	Procurement and installation of the equipment.
	Fully functional Bioprinting facility setup.
Objective 3: Community outreach and engagement	Hiring of community engagement manager.
	Conduction of outreach activities and sensitization about the facilities.
	Engagement with the target users.
	Prototyping for 20 student projects, 10 startup projects and 5 industry projects.

- Project Duration:** The Fund Recipients shall complete the Project within the stipulated period of **36 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 signatures is affixed thereto ("Effective Date"). Project Duration is subject to the Change order(s) issued by the BIRAC from time to time under this provision.
- Project Implementation Site:** Yenepoya, University Road, Deralakatte, Mangaluru, Karnataka 575018.
- Project Cost and Contribution:** The total estimated cost of the Project is **Rs.457.85 Lakhs (Rupees Four Hundred Fifty Seven Lakhs and Eighty Five Thousand only)**. The contribution of BIRAC is **Rs. 307.85 Lakhs (Rupees Three Hundred Seven Lakhs and Eighty Five Thousand only)** as Grant-in-aid towards the Project. The amount put in by the Fund Recipient is **Rs.150.00 Lakhs (One Hundred and Fifty Lakhs only)** towards the Project on the terms and conditions detailed in this GLA.



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

6. BIRAC Budget:

Name of the Applicant	Budget Head	BIRAC support under NBM as Grant-in-aid to Fund Recipient (Amount in Rs. Lakhs)	Contribution by the Fund Recipient (Amount in Rs. Lakhs)	Total Project cost (Amount in Rs. Lakhs)
Yenepoya	Non-Recurring	228.25	125.00	353.25
	Recurring	79.60	25.00	104.60
Total		Rs. 307.85	150.00	Rs. 457.85

7. BIRAC Budget break-up:

S. No.	Details	BIRAC support under NBM as Grant-in-aid to Fund Recipient (Amount in Rs. Lakhs)	Contribution by the Fund Recipient (Amount in Rs. Lakhs)	Total Project cost (Amount in Rs. Lakhs)
(A) Non-Recurring				
	Equipment & Accessories	228.25	125.00	353.25
	Total (A)	228.25	125.00	353.25
(B) Recurring				
	a. Manpower	48.60	18.00	66.60
	b. Consumables	19.00	0.00	19.00
	c. Travel	6.00	0.00	6.00
	d. Contingency	6.00	7.00	13.00
	e. Outsourcing	0.00	0.00	0.00
	Total (B)	79.60	25.00	104.60
	Total (A+B)	307.85	150.00	457.85



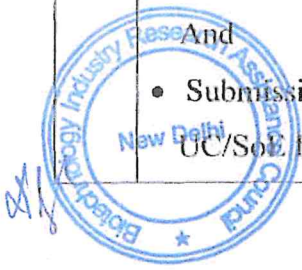
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Mangalore- 575 018, Karnataka

8. Schedule of Milestones/Timelines along with fund release:

S. No.	Milestones	Month of start of activity	Month of end of activity	BIRAC support under NBM as Grant-in-aid to Fund Recipient (Amount in Rs. Lakhs)	Contribution by the Fund Recipient (Amount in Rs. Lakhs)	Required financial input
1.	<ul style="list-style-type: none"> Acceptance of Undertaking under GLA And Fulfilment of fund release requirements 	0	1	153.925	75.00	50% of BIRAC contribution under NBM to Fund Recipient and 50% of Fund Recipient contribution
2.	<p>Status report on Fully functional Rapid Prototyping & electronics facility set-up And</p> <ul style="list-style-type: none"> Submission of UC/SoE for the corresponding milestone certified by internal finance. 	1	12	92.355	45.00	30% of BIRAC contribution under NBM to Fund Recipient and 30% of Fund Recipient contribution
3.	<p>Status report on Fully functional Bioprinting facility setup And</p> <ul style="list-style-type: none"> Submission of UC/SoE for the 	12	24	30.785	15.00	10% of BIRAC contribution under NBM to Fund Recipient and 10% of Fund Recipient contribution

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	corresponding milestone certified by internal finance.					
4.	Status report on Prototyping for 20 student projects, 10 startup projects and 5 industry projects And • Submission of UC/SoE for the corresponding milestone certified by internal finance.	24	34	15.3925	7.5	5% of BIRAC contribution under NBM to Fund Recipient and 5% of Fund Recipient contribution
5.	Submission of final report and consolidated Utilization Certificate (UC) and Statement of Expenses (SoE) certified by internal finance.	34	36	15.3925	7.5	5% of BIRAC contribution under NBM to Fund Recipient and 5% of Fund Recipient contribution

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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 till completion of Project Duration.

The Fund Recipients shall submit audited Annual reports along with the audited balance sheets to BIRAC within seven months of the completion of the financial year ending 31st March till completion of the Project duration.

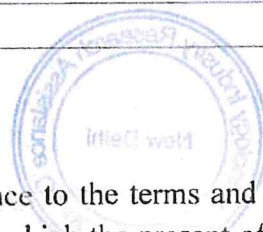
9. List of equipment proposed to be acquired through BIRAC contribution for Fund Recipient:

S.No.	Name of equipment
1.	3D CAD - CAM software with Workstation
2.	3D Bioprinter
3.	Microfluidic Printer
4.	SLA 3D Printer
5.	FDM Printer
6.	3D Scanner
7.	PCB Miller and Assembly Unit
8.	CNC Miller
9.	Metal Sheet Cutter
10.	Laser Cutter
11.	Mechanical Tools
12.	Function Generator
13.	Mixed Domain Oscilloscope
14.	DC Programmable Power Supplies
15.	Biomedical Acquisition Device
16.	Electronics Development Boards
17.	SLS Printer
18.	3D Metal Printer
19.	Vacuum Forming Machine

10. List of equipment proposed to be acquired through Fund Recipient contribution:

S.No.	Name of Infrastructure/Equipment
1.	Infrastructure and refurbishment

11. The recipients 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 unless a specific waiver is obtained for the delay.



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12. 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 including Project Risk Management Plan (Schedule 3)- Facility Governance Framework (Schedule 4)
---	---

13. The Expenditure is debitable to G.01.01 - Head of Accounts for the financial year 2019-20.

14. This issue with the approval of competent authority vide BFD No. BFD/Ao/G.01.01/09/2019-20 dated 18th July 2019

15. The GLA has been noted at Serial No. 09..... in the Register of Grant/Cost.

16. This GLA is between Biotechnology Industry Research Assistance Council ("BIRAC") and **Yenepoya** is effective as of the date of last signature. Each party to this GLA may be referred to individually as a "Party", **Yenepoya** 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:

For and on behalf of BIRAC
Signature: 
Name: Dr. Kavita Singh
Designation: Mission Director, National Biopharma Mission
Official Seal 
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Registrar
Yenepoya(Deemed to be University)
University Road, Deralakatt,
Mangalore - 576 013, Karnataka

For and on behalf of Yenepoya , the "Fund Recipient" duly authorized vide Authority Letter No.....datedby its concerned authority.
Signature
Name:
Designation:
Official Seal



ATTESTED

A handwritten signature in green ink, appearing to be 'Gangadhara Somayaji'.

Dr.Gangadhara Somayaji K.S.
Registrar
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Mangalore- 575 018, Karnataka

Terms and Conditions

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 fulfillment of the terms and conditions for such release by the relevant Parties. Further release of funds shall be subject to compliance with the safety frameworks for environment and clinical research, the satisfactory progress against the objectives, outputs, milestones and targets specified in the Project which progress shall be determined by BIRAC and on the 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. The CA shall also certify that there has been no change in the shareholding pattern and if there is any change, the particulars shall be specified.
- b. The Fund Recipient shall submit UC and SoE duly certified by Internal finance personnel/auditor 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 installment
- 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/ DBT/ World Bank/CAG. 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.

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-



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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.
- i. 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.
- j. 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. 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 compliance with various safety frameworks developed for undertaking the activities 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 Recipients jointly request 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, enable risk management framework 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.



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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.
- 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.

5. GRIEVANCE REDRESSAL MECHANISM

As per the World Bank Mandate, Communities and individuals who believe that they are adversely affected by a World Bank (WB) supported project may submit complaints to existing project level grievance redress mechanisms of the WB's Grievance Redress Service (GRS). Online and site specific Project platforms for anonymous contributions and reporting of incidents by the public, employees, data users, trial participants and other stakeholders shall be provided for by BIRAC. Grievance mechanism shall deal with the aspects of environmental, clinical trial, social, procurement and other complaints related to the Project.

6. 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 who are incorporated entities 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 who are incorporated entities 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



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other Act or otherwise of any suit or other legal process intended to be filed or initiated against the Fund Recipients and affecting the title to the properties of the Fund Recipients 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 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.

7. 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 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.
- 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 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) percent 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 GLA, the amount can be recovered by initiating any procedure available in Law.

8. 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 therefrom dispute shall be submitted for arbitration to International Centre 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 sole arbitrator 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



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become inoperative notwithstanding the GLA expiring or ceasing to exist or being terminated or foreclosed.

9. 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 **36 Months** (Project duration) 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.

10. 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.

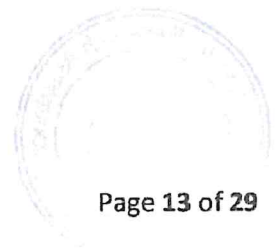
11. GOVERNING LAW

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.



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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 Fund Recipient shall

1. Execute the activities as set out in the Project document and shall conform to the specified objectives, outputs, milestones, safety frameworks, Risk Management Plan and targets therein at **Schedule 3.**
2. Submit periodic Progress report to BIRAC as per the Project milestones, risk mitigation, 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. Complete the Project within the stipulated period subject to the Change Order(s) issued by the BIRAC from time to time.
9. Not sub-delegate or outsource the obligations under this GLA without express permission of BIRAC except as provided for in the Project Document.
10. Manage the Intellectual Property and results developed through the funding Assistance of BIRAC in a manner that ascertains Global Access, regardless of whether this GLA expires, foreclosed or terminated, as per Schedule 4.
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 under NBM 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:

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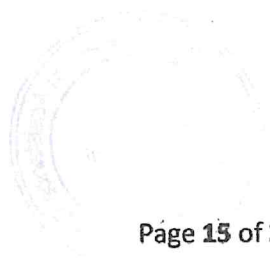


For and on behalf of Yenepoya , the "Fund Recipient"
Date and Place:
Signature
Name:
Designation:
Official Seal
Witnesses
Signature:
Name:
Address:



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 Registrar
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 University Road, Derakatti,
 Mangalore- 575 015, Karnataka



Project Document including Project Risk Management PlanPROPOSAL OBJECTIVES, ACTIVITIES AND MILESTONES

Objective 1: Establishment of Rapid Prototyping and Electronics fabrication facility.
Methodology/Experimental Design To Accomplish The Stated Objective: Instruments conforming to industrial standards would be identified and procured. Technical manpower with prior experience in handling these instruments would be hired and would be further trained at our industry partner facility.
Alternate Strategies: NA
Process Indicators for Measuring Success: Operationalisation of the facility.
Objective 2: Establishment of Bioprinting facility.
Methodology/Experimental Design To Accomplish The Stated Objective: A clean room compliant with BSL II facilities would be setup to house these instruments. Dedicated manpower would be hired and trained for this facility.
Alternate Strategies: NA
Process Indicators for Measuring Success: Operationalisation of the facility.
Objective 3: Community outreach and engagement.
Methodology/Experimental Design To Accomplish The Stated Objective: A community engagement manager would be recruited who would be tasked with outreach activities related to the facility and organising capacity building programs.
Alternate Strategies: Conducting hackathons and reaching out through word of mouth publicity.
Process Indicators for Measuring Success: Signing of contracts and service agreements with the clients.



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OBJECTIVE WISE ACTIVITIES & TIMELINES**Objective 1: Establishment of Rapid Prototyping and Electronics fabrication facility**

Activities	Month of Start of Activity	Month of end of activity	Deliverables
Hiring and training of the manpower for providing necessary services and technical support to med-tech innovators.	0	6	Qualified and trained staff for providing the necessary services and technical support to med-tech innovators
Designing of lab space and refurbishment	0	3	Facility designed conforming to GMP and Quality Standards
Procurement and installation of the equipment	0	6	Operational facility
Fully functional Rapid Prototyping & electronics facility set-up	0	12	Fully functional Rapid Prototyping & electronics facility set-up

Objective 2: Establishment of Bioprinting facility.

Activities	Month of Start of Activity	Month of End of Activity	Deliverables
Hiring & training of the manpower	8	12	Availability of qualified and trained staff
Designing of the lab space in accordance with biosafety standard	8	12	Facility ready conforming to BSL II
Procurement and installation of the equipment	8	13	Operational facility
Fully functional Bioprinting facility setup	12	24	Fully functional Bioprinting facility setup

Objective 3: Community outreach and engagement.

Activities	Month of Start of Activity	Month of End of Activity	Deliverables
Hiring of community engagement manager	0	3	Availability of the manpower
Conduction of outreach activities and sensitization about the facilities	3	36	Outreach activities such as bootcamps, hackathons, capacity building workshops, training programs
Engagement with the target users	5	36	Signing of service agreements and commencement of prototyping activities for the target users
Prototyping for 20 student projects, 10 startup projects and 5 industry projects	12	34	Prototyping for 20 student projects, 10 startup projects and 5 industry projects

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Milestones and Timelines:

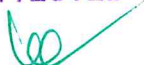
Milestones	Month of End of Activity
Signing of Contract	0
Fully functional Rapid Prototyping & electronics facility set-up	12
Fully functional Bioprinting facility setup	24
Prototyping for 20 student projects, 10 startup projects and 5 industry projects	34
Report submission	36

Project Risk Management Plan

To comply with DBT, World Bank & BIRAC's mission to promote innovation and self-sufficiency in the biotechnology sector while striving to reduce any social and environmental risks in its activities, Yenepoya (Deemed to be University), Fund Recipients for the proposal entitled "Establishment of MedTech Design and Rapid Prototyping Facility" has identified the following risks related to Project and Environment (including occupational health and community). Risk mitigation measures are being taken by Yenepoya (Deemed to be University) as defined in the following sections:

- i) Project Implementation Risk Management plan: identifies project monitoring mechanisms, complaint redressal mechanism and describes the mitigation measures being implemented for the programme components based on the identified risks. Institutional arrangements in order to implement safeguard parameters, methods for periodical review, monitoring strategy and grievance redressal mechanism are described in this annexure.
- ii) Environmental and Health Risk Management Plan: Compliance to corresponding legislations, Good practices in research and development methods, including while use of animals will be followed. We have referred to the Environment, Occupational Health and Safety Management Framework (EMF) document while preparing this annexure. Facility-specific occupational health and safety hazards have been identified based on risk assessment using established methodologies. The Community health and safety impacts related to handling and storage of solid, liquid and gaseous substances have been evaluated and accordingly mitigation measures will be implemented during project implementation. Impacts due to significant exposures to workers and potentially to surrounding communities, depending on quantities and types of accidentally released chemicals and biologicals have been thoroughly evaluated and addressed.
- iii) Governance Model: Mechanism to ensure smooth functioning of the facility in a transparent way, including regulatory mechanisms.

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Project Implementation Risk Management Plan

1. Project Risk Management:

Risk	Mitigation Measures	Monitoring parameters
Technical		
Breach of any license terms and termination of license agreement (if applicable)	<ul style="list-style-type: none"> • No specific licensing required as most equipment will be commercial. • NDA shall be signed having design and IP protection rights with the clients. • Confidentiality and NDA agreements will be signed with every employee and consultant with penal clauses. • Data logs will be used for tracking users of equipment/ HW/ SW. • Examining all the license agreements before signing to ensure compliance 	<ul style="list-style-type: none"> • Continuous supervision will be done by governing body. • Grievances by clients about breach of confidentiality at facility will be addressed by the governing body on priority within 1 week. • Checklist for review of license terms
Scientific failure that client product will not reach the market.	<ul style="list-style-type: none"> • Technical input will be done by experts for product design and fabrication process to ensure quality. • Clean room facility for product fabrication and packaging will be certified and periodically maintained to ensure quality of product. • Effective technical planning will be there to avoid failures. 	<ul style="list-style-type: none"> • Continual review and timely application for facility certification maintenance.
Project Non-Progress	<ul style="list-style-type: none"> • Advertisement of facility and services to attract more users. • Supervision on project outcomes. • Periodic review meetings by subject matter and industry experts to evaluate the progress (including procurement of equipment and manpower) and mentoring. 	<ul style="list-style-type: none"> • Milestones for progress monitoring will be followed. • If delay has been identified then address those issues in order to put it on track. • Track number of users to generate a sustainability structure for facility.
Manpower risk and backup plan and turnaround time to recruit an alternate person	<ul style="list-style-type: none"> • In addition to filling of the vacancies, the university will maintain an ordered waiting list to account for any joining delays or fresh vacancies. 	<ul style="list-style-type: none"> • Recruitment pipeline through a candidate database. • Training records of employees will be



	<p>Employment agreement will contain minimum notice period in accordance with the government rules.</p> <ul style="list-style-type: none"> • Skill training sessions per year will be conducted to retain employees and attract skilled personnel. 	<p>maintained and feedback will be encouraged to identify new areas for training.</p>
Social		
Failure to meet affordability	The facility will have a differential pricing model to ensure affordability for different user/client groups such as students, researchers, startups and SMEs.	Differential pricing model with periodic review of pricing structure of other facilities
Gender non-representation	The university has a policy for ensuring fair evaluation and equal opportunities.	Employee recruitment and promotion policy is in place. Meritorious women candidates will be given equal opportunity.
Employment generation	<ul style="list-style-type: none"> • Through this funding employment opportunities will be generated as per the requirement mentioned in the proposal. • Skill training sessions will be conducted every year to retain employees and attract skilled personnel. • Ensuring availability of mentors, trained and competent manpower for assisting in transformation of ideas into prototypes leading to startups creation. 	<ul style="list-style-type: none"> • Training will be imparted to ensure employability. • Direct and indirect jobs created through the facility
Financial		
Misutilization of funds	Routing decisions through purchase and procurement committee to ensure proper due diligence for utilisation of funds	<ul style="list-style-type: none"> • SOP for purchase committee is in place. • Internal and External audits to monitor utilization of funds. • Documents like receipts, purchase orders etc. will be maintained by the finance team.
Non-repayment of existing loans. Risk of being listed as NPA.	Yenepoya is using no-lien account for the project funds and is not listed NPA by any financial institution.	Opening no-lien bank account will reduce the risk of defaults. Defaults/ delays if any, would be addressed promptly.



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Adverse audit findings	Financial monitoring and internal audits will be done at regular intervals	Internal audit process and reports are in place
Late disbursement of funds from NBM	<ul style="list-style-type: none"> Timely submission of reports and records. In case of late disbursement of funds from NBM, the institute will use its own reserve funds. 	Monthly review of budget to foresee the requirements.
Data Management		
Loss of Data	<ul style="list-style-type: none"> Central data storage server with volume shadowing and automated backups for keeping multiple copies of the data, and usage of cloud data storage services. Use of online data security measures such as anti-spyware software. Restricted access within the system and restricted connectivity to external data-sharing websites (including emails). 	<ul style="list-style-type: none"> Automated and periodic backups and use of cloud data storage. Appropriate licensed software will be maintained. Periodic IT audits of the facility network.
Misutilization of Data	Signing of non-disclosure agreements (NDA), preventing unauthorized access by implementing passwords and encryption	Implementations of NDAs, data security and encryption measures
Data Integrity and Data Validation (including formats of reports and sharing of reports with clients and/ or agencies for regulatory approvals)	<ul style="list-style-type: none"> Standard report formats to be generated for clients – may differ on type of service rendered. All data to be generated on validated instruments with calibration traceability. 	<ul style="list-style-type: none"> Standard report formats to be adopted and modified, when required, after approval from governing body for data that will be used for regulatory submissions. AMC schedule for all major equipment will be monitored to ensure ISO 13485 compliance. Equipment past calibration due date will be temporarily kept out of service.
Procurement		
Irregularity in procurement	Procurement and the purchases of materials and/or services will be authorised by the procurement committee. The committee will take purchase decisions based on fair evaluation of technical and	Procurement and Purchase Committee is in place, Internal Audits will be done to avoid irregularity in procurement. ATTESTED



	financial aspects by comparing quotations from multiple vendors (minimum three, where possible).	
Failures during vendor validations processes.	Maintaining vendor database by including parameters such as price, delivery reliability, delivery date adherence and the quality of the item along with ratings based on any past experience with the vendors.	Developing tangible vendor validation parameters
Lack of vendor databases	Creation of vendor database	Multi-parameter based vendor database
Legal		
IP conflict regarding use of technology	The facility will sign service agreement with the clients clearly defining the ownership and assignment of any IP generated from the work carried out at the facility	Outlining Intellectual Property (IP) policy of the facility
Non-compliance to regulatory framework for conduct of study	The facility will be ISO 13485 compliant and any material manufactured here may be used for clinical evaluation.	Regular monitoring of ISO 13485 accreditation status, including audits.
Termination of license	Not applicable as we have not licensed any technology.	Not applicable as we have not licensed any technology.
Dispute with outsourcing agency	Outlining mutually agreeable terms for conflict resolution	Identification of dispute resolution processes
Change of entity status due to statutory non-compliance.	Including indemnity clauses in all the contracts and service agreements	Defining indemnity clauses
Regulatory		
Delay in approval by the competent authority	Timely filings and monitoring will be done for ISO 13485:2016 certification of the facility	Submission of all the prescribed documents and papers as per the guidelines of the authority
GLP Compliance	The facility will be designed in accordance with GMP and ISO 13485 as the proposed facility will deal only with design and rapid prototyping.	GMP and ISO 13485 mandates will be strictly adhered. Regular audits and sample checks for ISO 13485:2016 compliance will be conducted.



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Registrar
Yonapoya (Deemed to be University)
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Mangalore- 575 013, Karnataka

2. Complaint Redressal:

Internal Grievance/ Complaint Redressal	Mechanism/ Mitigation
Employees	Grievance Redressal Committee is in place to address the grievances of the employees.
Women Employees	The university has constituted Women's Grievance Committee and Prevention of Sexual Harassment in Work Place Committee.
Vendors/ Partners	Grievance Redressal Committee comprising of internal and external representatives is in place.
Customers	<ul style="list-style-type: none"> Standard procedures to be incorporated for addressing customer complaints. Regular customer feedback taking mechanism. Collecting feedback, grievance redressal mechanism with escalation matrix.

3. Project Monitoring Mechanism:

	Monitoring Mechanism	Strategy
1	Financial Audit Reports on monitoring Fund utilization, Fund re-appropriation	Conducting periodic financial audits and generating reports certified by a Chartered Accountant
2	Internal Technical Reviews	Mentor and advisory board would be created

4. Impact of the project:

- **Affordability:** How funding from NBM will impact: affordability of the product(s) – cost of product with/without NBM funding, product availability/ affordability under National missions, technology licensing to MSMEs/ start-ups.
 - Funding from NBM will ensure establishment of state-of-the-art facility which would otherwise be difficult for a private organisation to establish. This will ensure availability of advanced facilities in tier-II cities and across the country for various potential users.
 - Differential pricing model can be implemented with nominal pricing for students, researchers and start-ups while ensuring sustainability of the facility.
 - The facility will provide a platform for creation of new IP and technologies, leading to technology transfer and licensing.
- **Social:** Use of product/ technology/ facility, target population, public health programs, availability of product/ technology/ facility to MSMEs for further usage, generation of employment among local population.
 - The facility will foster creation of innovative healthcare devices and solutions which will result in better health outcomes, quality of care, disease prevention and monitoring.
 - The facility will encourage and aid in translation of research and patents.
 - The facility will ensure availability of mentors, trained and competent manpower for assisting in transformation of ideas into prototypes, leading to start-up creation.
 - The facility will aid in direct and indirect employment generation.



Environmental and Health Risk Management Plan

1. Institutional Arrangements

Requirements	Current Status	Mitigation Steps
Institutional Bio-Safety Committee (IBSC)	IBSC exists in the University. We also have NABH accreditation.	Approvals will be taken from the IBSC as per the projects that come to the facility.
EHS Team	Environmental Officer is employed by the organization. Dept. of studies for environmental sciences conducts annual audits of every department on campus.	Compliance to annual audits for environmental compliance
Documentation and Record Keeping in reference to the risks mentioned below and quantifiable records of generated waste and compliance measures.	All documentary records are stored for referrals. We have MoU with the state-identified waste management unit for safe disposal of biomedical waste.	Records will be maintained for all waste disposed.
SOPs related to Environment Compliance e.g Chemical spillage handling, waste segregation etc.	SOPs available as part of environmental audit compliance and NABH accreditation.	SOPs will be maintained and updated as per work and/ or audit findings.
General Safety and Storage	Storage areas for hazardous chemicals are properly marked. Fire fighting equipment are available and fire exits properly marked at all places.	Compliance with internal audit findings.

2. Environmental Impact and risk mitigation

Risks	Project Specific Risk	Potential Impact	Mitigation Steps
Air Pollution	Minimal Risk. Fumes from the laser cutter and PCB soldering. Use of volatile solvents. Fine (PM 2.5) metallic dust due activities such as metal grinding, milling and polishing.	Respiratory disorders due to inhalation. However, quantities of air pollutants will be very low.	No direct release of potential pollutants into the environment. Using fume hood and treating using the exhaust
Water Pollution and Waste water treatment	Minimal Risk. Waste water from post-processing of prototypes. Routine use of water as in any facility (cleaning, washrooms etc.).	Contamination of soil and water table, skin infections upon contact with untreated waste water.	Connecting the waste water line to the dedicated collection and storage tanks and disposal as per the standard reclamation methods and waste water treatment methods.

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Chemical waste (including signage, storage and SOP for spillage)	Moderate Risk. Using solvents will create chemical waste. Chemicals (such as plastics, organic polymers, oils etc.) and organic solvents will be used in a limited manner.	Organic solvents may lead to contamination of air, water and soil causing a large number of health problems upon exposure.	Chemical fume hoods will be used for handling liquid chemicals. Storage areas will be clearly demarcated. SOPs for spillage will be in place. We have a contract with Ramky Enviro Engineers Limited for handling of chemical wastes.
Biological Waste	Moderate Risk. Cell culture and tissue culture laboratory waste.	Release of biological toxins into the atmosphere, contamination of environment and the biosphere, release of mutant drug-resistant genes into the environment.	All biological waste from the facility will be autoclaved and then treated appropriately before discard. Contract agency will be on-board to handle biological waste from the facility.
Heavy metals	Minimal Risk. Use of metal 3D printers (such as Titanium) for design and fabrication of implants and other rapid prototyping work (wastage from sheet cutters, millers etc).	There can be an adverse effect on human health due to the presence of these heavy metal in the environment.	As the facility is primarily for development of medical devices, high-toxicity heavy metals and other non-biocompatible material will not be used. Lead-free solder will be used for electronic devices. Proper regulatory measures will be undertaken if at all there will be any incidence of heavy metal contamination, related to the handling and disposal
Electronic Waste	Minimal risk. Iterative designs of prototypes, PCBs, electronic chips, accessories, spares of equipment, metallic wires, other electronic consumables etc.	Environmental destruction due to improper waste disposal.	Software-based designs will be undertaken to minimize losses. Electronic waste generated will be disposed according to existing laws.
Radiation Waste	Not applicable as project implementation will not create any radiological waste.	Not applicable as project implementation will not create any radiological waste.	Not applicable as project implementation will not create any radiological waste.
Destruction/alteration of	Minimal Risk.	There will no destruction or alteration	All waste generated at the facility will be



surrounding ecosystem	No civil construction activities will be undertaken as part of the proposal.	of the surrounding ecosystem as the existing lab will be augmented for a full-fledged prototyping facility for MedTech devices.	treated as per regulation and not discarded as is which may harm the environment.
Construction and Demolition Waste	Minimal Risk. No civil construction activities will be undertaken as part of the proposal Only refurbishment will be done.	Possible destruction of surrounding ecosystem.	All waste generated at the site will be treated as per local regulations.

3. Occupational Health and Safety and Risk Mitigation

Risks	Project Specific Risk	Potential Impact	Mitigation Steps
Heat Hazards	Moderate Risk. Heat generated from the CNC, soldering and metal work might cause health hazards.	Burns and physical injuries due to heat and sparks.	Using appropriate protective gear and good lab design and instrument placement.
Chemical hazards, including fire and explosions	Minimal Risk. Fire and health hazards due to risk of fire from laser cutter and operation of other instruments	Destruction of material and property, health deterioration, loss of life and limb.	Building fire and evacuation plan, installing fire alarms and smoke detectors, and use of fire extinguishers. Emergency exits will be properly marked. Proper protective gear will be used when working with chemicals.
Pathogenic and biological hazards	Minimal Risk. Project implementation will not create any adverse pathogenic and biological hazards. Biological material used will be for research and laboratory use.	Not applicable as the facility will not handle any pathogenic material.	Project implementation will not create any adverse pathogenic and biological hazards.
Radiological hazards	Minimal Risk. Using UV and laser might create health hazards. Radioactive material will not be used.	Laser radiation of certain wavelengths are absorbed by the cornea and lens, leading to the development of cataracts or burn injuries. Skin burns are also possible.	Using protective gear and appropriate filters on equipment. Proper demarcation of areas and use of indicators when lasers are in use. Personal protective equipment will be provided.

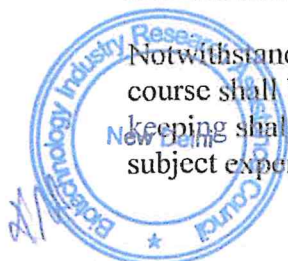


Noise	Minimal Risk. Noise generated from the CNC machines and other instruments might create noise pollution.	Continuous high decibel noise can lead to hearing impairment and deterioration of health.	Placing the noisy instruments in the sound-proof rooms and providing noise isolation gear for the employees and users
Process safety	Minimal Risk. Industrial processes will be used in the facility, leading to process-specific risk.	The facility can cause (i) material impairment to the health of the persons engaged in or connected therewith, or (ii) result in the pollution of the general environment.	Establishing SOPs for safe use of the instruments and implementing good lab design and practices. Following guidelines.

4. Community Health and Safety and risk mitigation

Risks	Project Specific Risk	Potential Impact	Mitigation Steps
Safety Transportation Management System (for transport of hazardous material)	Moderate Risk. 3D printed biological material is subject to risk management during transportation.	Potential exposure to individuals and contamination of environment, compromise integrity of the material itself.	Use of leak proof and temperature-controlled containers for shipment, proper and detailed documentation along with shipment, mention of material description and process of handling in case of accidents/spillage/ exposure.
Emergency preparedness and participation of local authorities and potentially affected communities	Moderate Risk. These are similar to process risk associated with operation of the facility.	Since the facility is relatively small and does not contain highly flammable material, potential impact of any accident or calamity is very limited.	The risk is modified by the level of the local preparedness of the institute by undertaking: <ol style="list-style-type: none"> 1. Mock trials 2. Safety workshop 3. Fire extinguishers drills. Emergency contact numbers will be listed in the facility. Emergency exit signs will be displayed appropriately in the facility. Fire extinguishers will be placed.
<p>In case your organization already has EHS guideline, please summarise the same. If not, please describe the impact because of hazardous material, release of chemicals, biologicals, management of catastrophic events like fire/explosion.</p>			

Notwithstanding the above other risk (relevant to the project activities) that will be identified in the course shall be addressed as per standard mitigation monitoring parameters and manner of records keeping shall be in accordance to the recommendations of the project monitoring committee on subject experts engaged by BIRAC.



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Bengaluru, Karnataka

Facility Governance Framework

Areas	Monitoring Parameters
Procurement Policy	The university has a procurement policy for the purchases of materials and/or services. Purchase and procurement committee constituted by the university is responsible for the technical and financial evaluation and making purchase decisions. The procurement professional will assist the committee by obtaining a minimum of three quotations (where possible) and preparing a comparative report.
Vendor Evaluation and Supply Chain Management	The university's purchase department maintains a database of vendors and includes parameters such as price, delivery reliability, delivery date adherence and the quality of the item. While making purchase decisions, objective criteria as outlined in the procurement policy along with past experience with the vendor are taken into account.
Manpower Recruitment Policy	The university has a recruitment policy based on the principles of open competition and equal opportunities. We always try to ensure that the recruitment and selection of staff is conducted in a professional, timely and responsive manner and in compliance with current legislation – UGC (Institutions Deemed to be University) regulations 2016 and 2019. For all the positions that are available the university conducts fair candidate evaluation from the applicants' database or through fresh vacancy listings. In addition to filling of the vacancies, we also maintain an ordered wait list to account for any joining delays or fresh vacancies. Training and skill upgradation activities are followed.
Subcontract and Outsourcing model	NA
Internal Monitoring Mechanism	An Internal Progress Monitoring Committee (IPMC) would be constituted comprising of the university functionaries, Dental/ Maxillofacial Surgeon, Researchers, subject matter experts and industry experts in order to evaluate the progress of the project. One BIRAC nominee will be present on the governing body. Internal and external audits will be conducted and reported to the governing body for review and appropriate action.
For Oversight by NBM-BIRAC 1. Implementation Governance model – Checks on fund utilization - Checks on Technical side	1a. All the purchase decisions would be in line with the procurement policy of the university and would be authorized by the purchase committee.
	1b. The Internal Progress Monitoring Committee (IPMC) and the mentor and advisory board would be responsible for ensuring the technical compliance and progress.
	1c. Fund utilization details will be shared with NBM/ BIRAC as per schedule provided in agreement.
	1d. Quarterly progress report about facility development, utilization, certification, products developed and technical difficulties will be shared with NBM/ BIRAC.



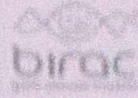
<p>2. Sustainability and Differential Costing Model</p>	<p>2a. The facility will operate on fee-for-service model and various outreach activities, workshops and training programs would be conducted, which will serve as source of additional revenue along with helping the facility in identifying new users and clients.</p> <p>The facility will also have a differential pricing model depending on the type of user and their affordability. The various user group identified for differential pricing model are – students, researchers, startups and SMEs.</p> <p>Based on zero-profit cost calculation for a particular service (X), students and faculty from Yenepoya will be charged 1.1X, start-ups, academia (excluding departments at Yenepoya) and other government organizations will be charged 1.3X, SMEs will be charged 1.5X, and industries will be charged 2X or higher. Material cost for all sectors will be based on actuals.</p> <p>2b. The list of available tests at the facility will be advertised on the Yenepoya website, Yenepoya Technology Incubator website, Yenepoya Research Center website and the Dept. of Orthodontics and Dentofacial Orthopaedics departmental websites. An online system for submission of test requests will be developed. Data of facility usage will be shared with BIRAC on a monthly basis.</p>
<p>3. Trainings (to be provided to identified segment – Researchers, academia, start-ups, SMEs (National and Global))</p>	<p>3 - Various outreach activities such as Ideathons, Hackathons along with Workshops and Training Programs would be conducted to facilitate knowledge dissemination and skill development among the user groups and potential clients.</p> <p>a. 4 ideathons/ hackathons with approximate 50 participants each will be organized. The winners/ winning ideas will be provided free incubation space in the University’s incubator along with mentorship. Depending on the availability of funds from the sponsors, cash prize will be decided.</p> <p>b. 3 workshops/ training programs will be conducted with topics such as “3D Designing and Prototyping”, “Design for Manufacturability”, “Bioprinting and Tissue Engineering”, “IP and Regulatory Outlook – Medical Devices”.</p> <p>c. In addition to the workshops/trainings, hands on training will be imparted to 10 students each in second and third year of the project implementation.</p>



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Quarterly BIG Progress Report - 2



IMPORTANT: The following documents need to be submitted to RIT TBI (email to naturata@incubator.in) with cc to birabi@incubator.in and upload in BIG PMS portal (<https://bigpms.in/>)

Please fill in the required information.

(You may mention the status as: Not yet started/ Initiated/ Completed)

1. Project Details

BIG Reference Number	BIRAC/KIT19555/BIG-14/19
Title of the Project	THE SAVE APPLIANCE- AN INNOVATIVE DEVICE FOR CORRECTING SKELETAL CLASS III MALOCCLUSION
Project Unique ID Code	
Name of the company/BIG Innovator	EISHITA HEALTHTECH Pvt Limited
Name of the Project Leader	Dr.SandeepShetty
Name of the Team Members	NilotpaiMajumdar
Total Sanctioned Amount	Rs. 49.06 lakhs
Start Date of the Project	20/02/2020

2. Quarterly Progress Report: Mention "Yes" against the relevant period

1 st (0-3 months)		4 th (10-12 months)
2 nd (4-6 months)	Yes	5 th (13-15 months)
3 rd (7-9 months)		6 th (15-18 months)

3. Reporting Period:

31/07/2020

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----- Forwarded Message -----

From: "BIRAC" <biracbig.dbt@nic.in>

To: "sandeepshettyortho@yahoo.in" <sandeepshettyortho@yahoo.in>

Cc: "sped.birac@gov.in" <sped.birac@gov.in>, "biracbig.dbt@nic.in" <biracbig.dbt@nic.in>

Sent: Thu, Feb 14, 2019 at 11:58

Subject: Acknowledgement for Proposal submission -BT/TEMP6408/BIG-14/19

Dear Dr. SANDEEP SHETTY

This is to confirm that your proposal titled, **THE SAVE APPLIANCE-AN INNOVATIVE DEVICE FOR CORRECTING SKELETAL CLASS III MALOCCLUSION** has been successfully submitted under **BIG** Scheme. Temporary reference number of the proposal is BT/TEMP6408/BIG-14/19. The proposal is being examined for preliminary eligibility requirements.

In case your proposal qualifies the mandatory eligibility criteria, a permanent reference number will be communicated to you. However, if the proposal does not meet the same, it shall not be considered for further review and you would be informed accordingly.

Regards,

Programme Manager

BIG

Note: This is an auto generated email

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Dr.Gangadhara Somayaji K.S.
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Mangalore- 575 010, Karnataka

Project title: "Save Appliance" (PI: Dr. Sandeep Shetty) and Duration of the Project: 2 Years

On Tuesday, December 17, 2019, 5:32 PM, Swati Chhattar BIG Project <swati@kiitincubator.in> wrote:

Eishita Healthtech Pvt. Ltd. ,

Congratulations!!

Your BIG Budget has been approved by BIRAC as mentioned below:

Name of the Applicant

Eishita Healthtech Pvt. Ltd.

Proposal Reference No.

BIRAC/KIIT0555/BIG-14/19

Applicant Type

Company

Budget(INR in Lakhs)

Heads

Requested Budget by Partner

Approved By BIRAC

Total

49.06 INR

In further continuation to the Due Diligence process, please find attached the agreement template that needs to be signed between the innovator and BIG partner for release of funds.

We request you to email the filled version at the earliest. Only after confirmation from us, you can take a print out of the agreement on a Rs 100/- stamp paper (only the first page), **duly signed on each page , including the annexures (two copies)** and then send us both the original signed copies by speed post to KIIT-TBI address. One copy would be returned to you by post after our signature.

Following that, you would need to open a "no-lien" bank account in a bank of your choice following which the funds would be released. A template of the letter to be obtained from the bank is attached for your reference.

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Dr. Gangadhar S. Nayaji K.S.
Registrar
(Deemed to be University)
University Road, Derlakatte
Karnataka

Note:

1. **Fill in all the highlighted sections.**
2. **Project title and project sanctioned amount should exactly match with that of BIRAC approved budget, mentioned above**
3. **Put your signature on page 9**
4. **In page 9, Give details of two witness from your side and their signature. They could be anybody . But I cannot be a witness on behalf of the applicant. So please, do not put my name in page 9 as witness**
5. **Give justification for each budget head (equipment, manpower, consumables, rental, travel, IP, outsourcing and contingency)**
6. **Please keep check of the formatting.**
7. **The objectives and milestones should match exactly that is sent to BIRAC, in some cases, BIRAC might have later suggested few changes in objectives and milestones. Please ensure that the agreement should reflect the final changes.**
8. **please keep the current date.**

Let us know if you need any clarifications.

Please email me the filled in word document by Thursday and only after my confirmation you can take a print out of the agreement on a Rs 100/- stamp paper, **duly signed on each page, on annexures (two copies) as well and then** send us both the original signed copies by speed post to KIIT-TBI address . One copy would be returned to you by post after our signature. Please treat this as urgent and do it asap, so that we will confirm it to BIRAC and they can release the money. And please open your no lien bank account asap.

Please note that the release of the first tranche to your bank account will be counted as the starting date of your project.

Address:

KIIT-Technology Business Incubator
Campus 11, KIIT University, Bhubaneswar, Odisha 751024

Congrats once again!!

Regards

Swati Chhattar
Program Associate - BIG

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Dr.Gangadhara Somayaji K.S.
Registrar
Yenepoya(Deemed to be University)
University Road, Deralakatte
Mangalore- 575 010, Karnataka



LETTER OF TRANSFER OF FUNDS AGREEMENT

Between

The Research Institute of the McGill University Health Centre
(Herein the "RI MUHC" or "Primary Institution")
2155 Guy Street, Suite 500, Montreal, Quebec H3H 2R9
(Dr. Dick Menzies, herein the "Principal Investigator")

And

"Yenepoya University" (herein the "Non-Eligible Secondary Institution")
Office of Finance Officer, Yenepoya University Campus, University Road, Deralakatte, Mangalore,
575018, Karnataka
(Dr. Anurag Bhargava, herein the "Participating Investigator").

Project title

"Tacking the two greatest obstacles to Tuberculosis elimination: Treatment of latent infection and drug resistant disease"

Granting Agency

Canadian Institutes of Health Research (CIHR)

Program

Foundation Scheme

Agency reference no.

FDN-143350

RI MUHC reference no.

6626

Collaboration period

April 01, 2019 to March 31, 2021

Period Covered by this Agreement

April 01, 2019 to March 31, 2020

Transfer Amount

\$37,500.00 (CAD)

I. GENERAL TERMS AND CONDITIONS

1.1 Compliance with Rules and Regulations of the Funding Agency

Under the terms of this Letter of transfer of Funds Agreement the Non-Eligible Secondary Institution agrees to administer the funds for the benefit of the Principal Investigator and the Participating Investigator in accordance with the Agreement on the Administration of Agency Grants and Awards by Research Institutions: <http://www.science.gc.ca/default.asp?lang=En&n=56B87BE5-1> the Tri-Agency Financial Administration Guide: http://www.nscrc-ersng.gc.ca/Professors-Professeurs/FinancialAdminGuide-GuideAdminFinancier/index_eng.asp the Tri-Agency Framework: Responsible Conduct of research: <http://www.rcr.ethics.gc.ca/eng/policy-politique/framework-cadre/>, the tri-council policy statement for ethical conduct for research involving humans: <http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/eps2-eps2-01/default/>, the guidelines of the Canadian Council on Animal Care: <http://www.ccaa.ca/en/>, with any other applicable regulations, policies and guidelines of the granting agency, and with any other ethical policies and/or requirements of the country where the research is being conducted;

1.2 Certification Requirements

The Non-Eligible Secondary Institution must ensure that all appropriate certificates for research involving humans, animals, environmental impact assessment and/or biohazards are approved and remain valid at all times during the period covered by this Letter of Transfer of Funds Agreement. Funds should only be made available to the Participating Investigator once all specified certification requirements have been met. Copies of all appropriate certificates must remain on file at the Non-Eligible Secondary Institution and should be made available, upon request, to representatives of the RI MUHC and/or to CIHR.

1.3 Ownership of equipment

With respect to ownership of equipment, the RI MUHC stipulates that all equipment used for the purpose of this specific project is the property of the institution that makes the purchase regardless of where the funds are administered, unless otherwise agreed upon. If ownership of the equipment purchased with these funds is to be transferred, the RI MUHC shall obtain a written undertaking from the Non-Eligible Secondary Institution agreeing to abide by the terms under which the funds for equipment were granted.

2. Proposed use of funds

2.1 Budget

The Participating Investigator shall exert his/her best efforts to use the funds as described in the approved budget (see Appendix A). Any changes to the agreed budget must have the prior written approval of the Principal Investigator.

2.2 Eligible and non-eligible expenses

The use of funds must comply with the Tri-Agency (CIHR, NSERC & SSHRC) Financial Administration Guide – Use of Grant Funds: http://www.nserc-crsng.gc.ca/Professors-Professeurs/FinancialAdminGuide-GuideAdminFinancier/FundsUse-UtilisationSubventions_eng.asp.

The Non-Eligible Secondary Institution has the right and responsibility to withhold approval of expenses proposed by the Participating Investigator if they do not comply with CIHR requirements or with its own institutional policies. When appropriate the Non-Eligible Secondary Institution may seek advice or a ruling from the RI MUHC. Any use of funds that does not fully conform to CIHR guidelines shall be repaid to the RIMUHC.

2.3 Delegation of signing authority

The Principal Investigator agrees to delegate authority to the Participating Investigator and/or research personnel at the Non-Eligible Secondary Institution to sign on his/her behalf for expenses related to the research project mentioned herein during the period covered by this agreement.

3. Payment Schedule

The total amount transferred will be paid according to the schedule attached as Appendix B.

Any additional transfer of funds within the period covered by this agreement will require a duly-signed amendment of this agreement and will be conditional upon receipt of funding from CIHR, availability of funds at that time, the receipt of an accurate, detailed annual financial report from the Non-Eligible Secondary Institution and approval from the Principal Investigator.

The RI MUHC is not responsible for any amounts spent over and above the amount mentioned in this Letter of Transfer of Funds Agreement or for any amounts spent before or after the period covered by this agreement. Unspent funds may be carried over into the next fiscal year period to cover research expenses as indicated on Appendix A. Any unused funds must be returned to the RI MUHC at the end of the collaboration period or on notice of termination of this agreement. Note that these funds cannot be sub-granted to a third Party.

4. Termination of the agreement

ATTESTED

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

The RI MUHC has the right to terminate this agreement if there has been a breach of the terms or conditions stated herein; or in the event that the project is cancelled or funding has ceased.

5. Reporting requirements

5.1 Financial report

A detailed financial report of all revenues and expenditures in Canadian currency (Form 300, http://www.cihr-irsc.gc.ca/e/documents/Form300_e_fillable.pdf) from the period of April 1st to Mar. 31st, in accordance with Agency guidelines must be emailed to the RI MUHC by April 30th of each year at the following email address: ExpenseApprovalGrants@muhc.mcgill.ca

In addition, if salaries costs are incurred, please provide the name and title of the employee(s) in an accompanying document. Both the Participating Investigator and the Financial Officer of the Non-Eligible Secondary must sign this report; the signatures on the report certify that the funds were administered in accordance to relevant CIHR policies and requirements. Upon receipt, the RI MUHC will review the report to ensure that the information provided is compliant with any relevant CIHR policies and it's accurate in terms of the budget amount (or amount of funds transferred), balance forward amount and eligible expenditure categories in accordance with this Letter of transfer of Funds Agreement. The RI MUHC will consolidate the information provided with the information of its own financial report to create a consolidated financial report for the grant in question to be submitted to the funding agency by June 30 of each year.

5.2 Supporting documentation

Relevant financial supporting documentation for all expenditures must be maintained on file, for a minimum of seven years, for auditing purposes or for verification by the RI MUHC or CIHR. This includes, but is not limited to, a copy of the transfer agreement letter, certification(s), supporting documentation for all expenditures and Form 300. In particular, the Non-eligible Secondary Institution must be able to provide the Primary Institution, on request, with copies of documents that detail transactions involving the funds.

6. Required signatures

If the terms of this Transfer of Funds Agreement are accepted, an authorized representative of the Non-Eligible Secondary Institution must return a duly signed and dated copy by email to: ExpenseApprovalGrants@muhc.mcgill.ca

For The Research Institute of the McGill University health Centre



Susan James, MBA
Director,
Research Grants & Data Management Division

21 August 2019

Date



Dr. Dick Menzies
Principal Investigator

22-08-2019

Date

For Non-Eligible Secondary Institution

ATTESTED

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

Signature

Date

31/08/2019

Name

MAHAMMAD BADA P

Title

FINANCE OFFICER

Email Address

FINANCE OFFICER @ YENEPLOYA.EDU.IN.

Finance Officer
Yenepoya (Deemed to be University)



ATTESTED

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

**APPENDIX A
BUDGET JUSTIFICATION**

Category of Expense		Use of Funds Description
Salaries & Benefits	<input checked="" type="checkbox"/>	75%
Materials & Supplies	<input checked="" type="checkbox"/>	5%
Travel	<input checked="" type="checkbox"/>	5%
Professional/Technical Services	<input checked="" type="checkbox"/>	10%
Equipment	<input checked="" type="checkbox"/>	5%
Animals	<input type="checkbox"/>	
Others (Please specify)	<input type="checkbox"/>	

ATTESTED


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

APPENDIX B
PAYMENT SCHEDULE

\$37,500 Will be wire transferred to the following bank account upon receipt of a copy of the fully signed "Letter of Transfer of Funds Agreement" from your office

Beneficiary:

Beneficiary's Name YENEPOYA UNIVERSITY
Beneficiary's Address: UNIVERSITY ROAD, DERALAKATTE
MANGALORE – 575 018
KARNATAKE STATE, INDIA

Beneficiary's bank details:

Bank name: BANK OF BARODA (PREVIOUSLY NAMED VIJAYA BANK)
Branch number: 1132
MICR CODE: 575029012
Bank's address: FOUNDERS BRANCH, LIGHT HOUSE HILL ROAD
BALMATTA, MANGALORE – 575 003
KARNATAKA STATE, INDIA
Swift Code: VIJBINBBMLR
IBAN (If applicable): N/A
Account number: 113200301000289

ATTESTED


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