

To,
Dr. Sunil Nadkarni
Samarthakrupa Lifesciences Private Limited
sunil.nadkarni@skls.co.in

Date: 28/08/2024

Copy To,
Dr. Onkar Sudame
SVJCTs BKL Walawalkar Hospital, Diagnostic and Research Centre
onkar.sudame@gmail.com

Ref: Project Title "A Phase I/II clinical trial to examine the safety and efficacy of autologous, cultured disc chondrocytes embedded in PRF transplanted in patients' disc to maintain its function" **under strategic funding for Small Business Innovation Research Initiative (SBIRI).**

Dear Dr. Sunil Nadkarni,

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 is **Rs. 51.33 Lakhs**, with BIRAC support of **Rs. 37.80** as Grant-in-Aid to Company and **Rs. 13.53 Lakhs** as Grant-in-aid to Collaborator for 24 months as per the terms of the Grant-in-Aid Letter Agreement (GLA) enclosed.

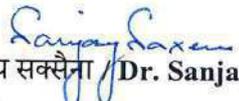
If you are in acceptance with the terms of funding support as mentioned in the GLA, the following documents should be executed within a time period of two weeks from the date of issue of this communication

- **Grant-in-aid Letter Agreement (GLA)** including all the Schedules: All pages to be clearly initialled by the Fund Recipient and the Company should affix the Company Common seal with Director Signatures on the signature page to the GLA.
- **Royalty Agreement:** All pages to be clearly signed by the Fund Recipient and the Company should affix the Company Common seal with Director Signatures on the signature page to the Royalty Agreement.
- **No-lien account letter (for further release)** to be submitted by the applicant with regard to specific project amount in the prescribed format of BIRAC.
- **Board resolution of the Company** in the prescribed format of BIRAC.

Kindly take a coloured printout of the GLA and the schedules (two copies – (BIRAC and Samarthakrupa Lifesciences Private Limited), execute the same from your end. The scanned copy to be shared with BIRAC. The hard copy of the semi- executed GLAs (after affixation of organisation Official Seal) to be shared with BIRAC.

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.


डॉ. संजय सक्सेना / Dr. Sanjay Saxena,
महाप्रबंधक एवं प्रमुख -निवेश / GM & Head Investment

संदर्भ संख्या (Ref No.) BT/BIPP1436/BIPP-53/21-SBIRI

दिनांक (Dated): 28/08/2024

विषय (Subject): Funding of Project entitled " A Phase I/II clinical trial to examine the safety and efficacy of autologous, cultured disc chondrocytes embedded in PRF transplanted in patients' disc to maintain its function " for funding under Small Business Innovation Research Initiative (SBIRI)

GRANT-IN-AID LETTER AGREEMENT

This Grant-in-aid Letter Agreement (hereinafter called as "GLA") is between Biotechnology Industry Research Assistance Council, a Government of India enterprise, incorporated under the Companies Act, 2013 having its office at Fifth Floor, NSIC Business Park, NSIC Bhawan, Okhla Industrial Estate, New Delhi – 110020 (the "BIRAC") and the entity mentioned below for research proposal entitled "A Phase I/II clinical trial to examine the safety and efficacy of autologous, cultured disc chondrocytes embedded in PRF transplanted in patients' disc to maintain its function "

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

S. No.	Recipient(s)	Designated Project Investigator
1	M/s Samarthakrupa Lifesciences Private Limited , a Company incorporated under the Companies Act, 2013 having its registered office at Floor-1, Plot-52, Parijat Building, Gokhale Road North, Dadar W, Mumbai, MAHARASHTRA, 400028, +91-022-24302517, +91-9822096340 , hereinafter referred to as the "Applicant" (which expression shall wherever the context so admits include its successors in interest, liquidators, administrators and permitted assignees).	Dr. Sunil Nadkarni Samarthakrupa Lifesciences Private Limited Director, Shanta Society, 394B Kusalkar Road, Pune -411016 sunil.nadkarni@skls.co.in
Pan Card No.	AAZCS7759N	
2	SVJCTs BKL Walawalkar Hospital, Diagnostic and Research Centre , a Trust, having its registered office at BKL Walawalkar Hospital, Sawarde, Dist. Ratnagiri, Maharashtra, 415606 hereinafter referred to as the "Collaborator" (which expression shall wherever the context so admits include its successors in interest, liquidators, administrators and permitted assignees).	Dr. Onkar Sudame onkar.sudame@gmail.com Consultant Orthopedic surgeon, B4 Shatadru, BKL Walawalkar Hospital, Sawarde, Chiplun -415606
Pan Card No.	AABTS7103H	

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

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

- Conduct of Clinical Trial Phase I – Clinical Phase
- Conduct of Clinical Trial Phase I – Bioanalytical Phase
- Clinical Trial Data Analysis



3. **Project Duration:** The Recipients shall complete the Project within the stipulated period of **24 months** from the date of execution of the Royalty agreement ("**Effective Date**"). Project Duration is subject to the Change order(s) issued by the BIRAC from time to time under this provision.
4. **Project Implementation Site:** BKL Walawalkar Hospital, GMP Facility, IPD block, 1st Floor, Sawarde, Dist. Ratnagiri, Maharashtra, 415606
5. **Project Cost and Contribution:** The total estimated cost of the Project is **Rs. 51.33 Lakhs** (Rupees Fifty-One Lakhs and Thirty-Three Thousand only). The contribution of BIRAC is **Rs. 51.33 Lakhs** (Rupees Fifty-One Lakhs and Thirty-Three Thousand only) as Grant-in-aid towards the Project. The contribution of BIRAC is **Rs. 37.80 Lakhs** (Rupees Thirty-Seven Lakhs and Eighty Thousand only) as Grant-in-aid to the **M/s Samarthakrupa Lifesciences Private Limited**. The contribution of BIRAC is **Rs. 13.53 Lakhs** (Rupees Thirteen Lakhs and Fifty-Three Thousand only) as Grant-in-aid to the **SVJCTs BKL Walawalkar Hospital, Diagnostic and Research Centre** on the terms and conditions detailed in this GLA.
6. **BIRAC Budget break-up: (Rs.in Lakhs)**

Budget Head	Applicant Contribution (Rs. in Lakhs)	BIRAC Contribution (Rs. in Lakhs)		Total (Rs. in Lakhs)
		Applicant	Collaborator	
Non-recurring	0.00	0.00	1.73	1.73
Recurring	0.00	37.80	11.80	49.60
Total	0.00	37.80	13.53	51.33

BUDGET Break-up Recurring (Rs In Lakhs)				
Recurring items	Applicant Contribution (Rs. in Lakhs)	BIRAC Contribution (Rs. in Lakhs)		Total (Rs. in Lakhs)
		Applicant	Collaborator	
Manpower	0.00	16.80	4.80	21.60
Consumables	0.00	14.00	5.00	19.00
Travel	0.00	2.00	1.00	3.00
Outsourcing	0.00	4.00	0.00	4.00
Contingency	0.00	1.00	1.00	2.00
Total	0.00	37.80	11.80	49.60

BUDGET Break-up Non-Recurring (Rs In Lakhs)				
Non-Recurring items	Applicant Contribution (Rs. in Lakhs)	BIRAC Support (Rs. in Lakhs)		Total (Rs. in Lakhs)
		Applicant	Collaborator	
Equipment's	0.00	0.00	1.23	1.23
Accessories	0.00	0.00	0.50	0.50
Total	0.00	0.00	1.73	1.73



Details of Equipment Proposed To Be Acquired Through BIRAC Contribution For Collaborators

S.No	Infrastructure/ Equipment	Capacity	Quantity	Specific Requirement In The Project	Estimated Value (Rs.In Lakhs)
1	Refrigerator	350L	1	For storing antibodies, reagents, media etc.	0.30
2	Bar code printer and scanner	1	1	For labelling samples and preparing labels	0.50
3	Desktop computer with software	1	1	For storing patient information	0.43
Total					1.23
Accessories To Be Acquired (Rs in Lakhs):					0.50

7. Milestones/Timelines

S. No.	Milestone(s)	Month of end of activity	Required financial input (Rs. In Lakhs)
1	Acceptance of Undertaking under GLA And Fulfilment of fund release requirements	0	15.399 (30% of SBIRI input)
2	Status report on Completion of the Clinical Phase of the Clinical Trial (Total 10 subjects) and Submission of the Report (TRL 3) And Submission of UC/SOE for the corresponding milestone certified by internal finance.	12	10.266 (20% of SBIRI input)
3	Status report on Completion of Bioanalytical Phase of the study and submission of the report (TRL 3) And Submission of UC/SOE for the corresponding milestone certified by internal finance.	18	10.266 (20% of SBIRI input)
4	Status report on Clinical Trial Data Analysis and Submission of the Clinical Trial Report (TRL 6) And Submission of UC/SOE for the corresponding milestone certified by internal finance.	22	10.266 (20% of SBIRI input)
5	Submission of final completion report and consolidated Utilization Certificate (UC) and Statement of Expenses (SOE) certified by internal finance.	24	5.133 (10% of SBIRI input)

Note:- Utilization Certificate (UC) and Statements of Expenses (SOE) duly audited by a chartered accountant (except in the case of Government/ public academic institutes that are under CAG audit, where such Government/ public academic institutes are the fund recipients, UC & SOE shall be duly examined and signed by the internal Finance personnel/Officer/authorized signatory of such Government/ public academic institutes) for the expenditure incurred towards the Project for every half year period, ending 30th September and 31st March, to BIRAC, within a month of closure of the accounts for the respective half year should be submitted by the Fund Recipients till completion of Project Duration.



Regulatory Requirements:

- DSIR Recognition for the Existing R&D Facility before execution of the GLA.
- DCGI approval followed by CTRI registration for the proposed Clinical Trial before execution of the GLA.
- cGMP certificate of the facility for generation of clinical grade autologous, cultured disc chondrocytes before execution of the GLA.
- IEC for Hospital and Company before execution of the GLA.

Advisory: It was recommended that the source of different culture components (Growth medium and other growth factors etc.) used for ex vivo culture of disc chondrocytes should be of clinical grade (with specifications of the product)

IP requirements: None

Financial requirements: None

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

Instalment	Applicant Contribution (Rs. in Lakhs)	BIRAC Support (Rs. in Lakhs)		Total (Rs. in Lakhs)
		Applicant (Rs. in Lakhs)	Collaborator (Rs. in Lakhs)	
First	0.00	11.34	4.059	15.399
Second	0.00	7.56	2.706	10.266
Third	0.00	7.56	2.706	10.266
Fourth	0.00	7.56	2.706	10.266
Fifth	0.00	3.78	1.353	5.133
Total	0.00	37.80	13.53	51.33

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

10. Inclusion by Reference:

This GLA includes and incorporates by this reference:	<ul style="list-style-type: none">- Terms and Conditions (Schedule 1)- Acceptance and Undertaking (Schedule 2)- Project document (Schedule 3)- Intellectual Property Governing Framework (Schedule 4)- ROYALTY AGREEMENT: Under the SBIRI Scheme BIRAC and the Applicant Company shall enter into a distinct agreement with regard to governance of Royalty payment terms and associated conditions (Schedule 5)- Personal Guarantee (Schedule 6)
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11. The Expenditure is debitable to **B.02** - Head of Accounts for the financial year 2024-25.

12. This issue with the approval of competent authority vide BFD No. BFD/AO/B.02/030/24-25 dated 28.08.2024,

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



THIS GLA is between Biotechnology Industry Research Assistance Council ("BIRAC") and "M/s Samarthakrupa Lifesciences Private Limited", and SVJCTs BKL Walawalkar Hospital, Diagnostic and Research Centre is effective as of the date of execution of Royalty Agreement. Each party to this GLA may be referred to individually as a "Party", M/s Samarthakrupa Lifesciences Private Limited as "Company" and SVJCTs BKL Walawalkar Hospital, Diagnostic and Research Centre as "Collaborator", and Company and Collaborator together as "Fund recipients" and all Party together as the "Parties." As a condition of this grant, the Parties enter into this GLA by having their authorized representatives sign below:

I) For and on behalf of BIRAC
हस्ताक्षर/Signature: 
नाम/Name: डॉ. संजय सक्सेना /Dr. Sanjay Saxena
पद /Designation: महाप्रबंधक एवं प्रमुख -निवेश/GM & Head Investment
आधिकारिक सील/Official Seal 
II) For and of behalf of M/s Samarthakrupa Lifesciences Private Limited "the Company" duly authorized vide Resolution Nodated of its Board of Directors.
हस्ताक्षर/Signature
नाम/Name
पद/Designation
Company Common Seal with Signature of one Director/ Signature of two Directors with Stamp/ Signature of Director and Company Secretary with Stamp

III) For and on behalf of SVJCTs BKL Walawalkar Hospital, Diagnostic and Research Centre "the Collaborator" duly authorized vide letter dated by its concerned authority.
हस्ताक्षर/Signature
नाम/Name
पद /Designation
आधिकारिक सील/ Trust Seal

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SCHEDULE – 1

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

1. FUND DISBURSEMENT

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

2. FUND UTILISATION AND ACCOUNTING

- a. The Fund Recipients shall submit the Utilization Certificate (UC) and Statements of Expenses (SOE) duly audited by a Chartered Accountant (except in the case of Government/ public academic institutes that are under CAG audit, where such Government/ public academic institutes are the fund recipients, UC & SOE shall be duly examined and signed by the internal Finance personnel/Officer/authorized signatory of such Government/ public academic institutes) 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 Recipients shall submit the Utilization Certificate (UC) and Statements of Expenses (SOE) duly certified by internal finance personnel/auditor to BIRAC in the format provided on the completion of the respective milestones. The Fund Recipients shall submit final consolidated UC and SoE duly certified by a CA/ External Auditor (except in the case of Government/ public academic institutes that are under CAG audit, where such Government/ public academic institutes are the fund recipients, UC & SOE shall be duly examined and signed by the internal Finance personnel/Officer/authorized signatory of such Government/ public academic institutes) to BIRAC in the format provided on the completion of the project.
- c. The input credit for the expenditures incurred under the project out of Grant-in-aid shall be reported to BIRAC as a part of utilization certificate against the corresponding entry- "Amount of GST Input credit". Such amount, if any, will be considered accordingly at the time of the release of the next instalment.
- d. The Fund Recipients shall duly submit the periodic progress report for the project to BIRAC.
- e. The Fund Recipients shall submit audited Annual reports along with the audited balance sheets and profit & loss accounts to BIRAC within six months of the completion of the financial year ending 31st March till the completion of the Project Duration.

Sanjay Saxena



- f. The Company shall keep the Grant-in-aid assistance and their project contribution in a separate no-lien account in the name of the Company with a Scheduled Bank (as defined under the RBI Act, 1934), the withdrawals and payments from which account shall be subject to verification by BIRAC. It shall also obtain and furnish to BIRAC a letter from the concerned bank foregoing the right of set off or lien in respect of such account. Further, the interest earned on the Grant-in-aid if any should be reported to BIRAC. The interest thus earned will be adjusted towards further installment of the fund.

Trust collaborator shall keep the Grant-in-aid assistance in an interest-bearing account with a Scheduled Bank (as defined under the RBI Act, 1934), the withdrawals and payments from which account shall be subject to verification by BIRAC. The interest earned on the Grant-in-aid should be reported to BIRAC. The interest thus earned on the grant in aid will be adjusted towards further installment of the fund.

- g. The Fund Recipients shall ensure that the funds released for the Project are actually utilized only for the purposes of the Project and as expressly provided for in this GLA. Re-appropriation of BIRAC funds from one budget head to another shall not be affected without the specific written approval of BIRAC.
- h. The Fund Recipients shall refund such part of Grant-in-aid funds disbursed to it that remains unutilized with it upon completion of all the responsibilities, duties and functions specified in connection with the Project, within one month of such completion, to BIRAC along with consolidated accounts of the funds received and utilized and of the unutilized balance returned (UC & SOE);
- i. The Fund Recipients at their own cost, shall take adequate care to maintain the capital assets acquired for the Project through BIRAC's Grant-in-aid. The capital assets acquired through BIRAC's Grant-in-aid shall not be disposed of or hypothecated without the specific approval of BIRAC till full and final settlement of all dues to the satisfaction of BIRAC.

3. PROJECT MONITORING

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

The functions of the PMC shall be as follows:

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

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4. INDEMNIFICATION

- i. The Fund Recipients 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;
- ii. The Fund Recipients 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.
- iii. 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.
- iv. The Parties shall not be held responsible for non-fulfilment of their respective obligations in successful completion of the Project under this GLA due to the exigency of one or more force majeure events such as but not limited to acts of God, war, flood, earthquakes etc.

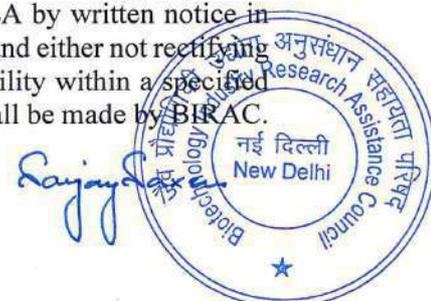
5. CHANGE OF CONTROL:

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

- a. The Fund Recipients 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 Recipients 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 Company and affecting the title to the properties of the Company or if a receiver is appointed of any of its properties or business or undertaking.
- c. The Fund Recipients shall notify BIRAC of any material change in its entity status, share holding pattern, entity name, Project Coordinator, implementation site, registered office or any such change that would impact on performance of its obligations under the Project and this GLA.

6. FORECLOSURE AND TERMINATION

- i. In case, during the 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 Recipients shall immediately refund the 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 Recipients shall submit Consolidated accounts of funds received, utilized and unutilized (UC&SOE). If the Fund Recipients like to continue the Project at their own cost, they would be able to do so without restrictions from BIRAC after complying with these provisions.
- ii. The Fund Recipients 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 the fund recipients 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 Recipients shall be liable to return immediately the amount of Grant-in-aid already availed of from BIRAC with additional simple interest at the rate of 12 (twelve) per cent per annum within 30 (thirty) days of termination of the GLA, along with consolidated accounts of funds received, utilized and unutilized (UC&SOE). 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.

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 therefrom dispute shall be submitted for arbitration to International Center for Alternate Dispute Resolution (ICADR), an autonomous organization working under the aegis of the Ministry of Law & Justice, Department of Legal Affairs, Government of India. The Authority to appoint the arbitrator(s) shall be the ICADR. The Arbitration under this Clause and provision of administrative services by ICADR shall be in accordance with the ICADR Arbitration Rules, 1996 read with the New Delhi International Arbitration Centre Act, 2019. The award made in pursuance thereof shall be binding on the Parties. The venue/seat of arbitration shall be New Delhi and the arbitration proceedings shall be conducted in English Language. The provision of this Clause shall not become inoperative notwithstanding the GLA expiring or ceasing to exist or being terminated or foreclosed.

8. EFFECT AND AMENDMENTS TO THE GLA

- i. GLA shall remain in force for whichever of these is the longest time unless suspended sooner:
 - a. For **24 months** (Project duration) months from the above Effective Date subject to the Change Order(s) issued by the BIRAC from time to time;
 - b. As long as any part of the amount disbursed for the Project remains unspent; or
 - c. For as long as any monitoring or recording or IP governance is required under any relevant laws and regulations.
- ii. No amendment or modification of this GLA shall be valid unless the same is made in writing by the Parties or their authorized representatives specifically stating the same to be an amendment of this GLA. The modifications / changes shall be effective from the date on which they are made / executed unless otherwise agreed to.

9. SEVERABILITY

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

10. GOVERNING LAW

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



SCHEDULE 2

Acceptance & Undertaking

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

The recipients of the Grant shall;

1. Execute the activities as set out in the Project document and shall conform to the specified objectives, outputs, milestones, and targets therein at **Schedule 3**.
2. Submit periodic Progress report to BIRAC as per the Project milestones, details of activities involved in performing the Project activities
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. The Fund recipients shall submit audited Annual reports along with the audited balance sheets and profit & loss accounts to BIRAC within six months of the completion of the financial year ending 31st March till the completion of the Project Duration
6. 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.
7. 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.
8. Subject themselves to Project monitoring of the Project Monitoring Committee (PMC).
9. 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.
10. Complete the Project within the stipulated period subject to the Change Order(s) issued by the BIRAC from time to time.
11. Shall not sub-delegate or outsource the obligations under this GLA without express permission of BIRAC except as provided for in the Project Document
12. Manage the Intellectual Property developed through the funding Assistance of BIRAC in a manner that ascertains Global Access, regardless of whether this GLA expires, foreclosed or terminated.
13. 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.
14. 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.
15. abide by the conditions related to Royalty Payment as per the terms of the corresponding "Royalty Agreement".
16. Acknowledge the assistance of BIRAC while publishing or presenting in any manner the details of the Project, its progress or its success or commercialization of the Product.

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



D) For and on behalf of M/s Samarthakrupa Lifesciences Private Limited "the Company"

Date and Place:

हस्ताक्षर:
Signature

नाम:
Name

पद /Designation

Company Common Seal or Signatures of Two Directors or One Director and Company Secretary

Witnesses

हस्ताक्षर:
Signature

नाम:
Name

पता:
Address

हस्ताक्षर:
Signature

नाम:
Name

पता:
Address



II) For and on behalf of SVJCTs BKL Walawalkar Hospital, Diagnostic and Research Centre “the Collaborator” duly authorized vide letter dated by its concerned authority.	
हस्ताक्षर: Signature	
नाम: Name	
पद /Designation	
Trust Seal	
Witness	
हस्ताक्षर: Signature	हस्ताक्षर: Signature
नाम: Name	नाम: Name
पता: Address	पता: Address



PROJECT DOCUMENT

OBJECTIVE AND TIMELINES				
PROPOSAL OBJECTIVES & WORK PLAN				
Objective 1: Conduct of Clinical Trial Phase I – Clinical Phase				
Methodology/Experimental Design To Accomplish The Stated Objective:				
1. Site Initiation and Enrolment of patients, and ex vivo culture and expansion of autologous chondrocytes initiated				
2. Ex vivo culture and expansion of clinical grade chondrocytes from surgically removed disc tissue				
3. Characterization of Cells along with evaluation of differential potential evaluation				
4. Completion of QC tests				
5. Completion of the Clinical Phase of the Clinical Trial (Total 10 subjects) and Submission of the Report				
Alternate Strategies: If poor cell growth is observed at day 4, autologous serum will be added at 10 percent final concentration.				
Objective 2: Conduct of Clinical Trial Phase I – Bioanalytical Phase				
Methodology/Experimental Design To Accomplish The Stated Objective:				
1. Database Lock				
2. Completion of Bioanalytical Phase of the study				
Alternate Strategies: None				
Objective 3: Clinical Trial Data Analysis				
Methodology/Experimental Design To Accomplish The Stated Objective:				
1. Follow up of the patients will be carried out. Adverse events, if any will be reported				
2. Bio-statistical data analysis of the study				
3. Clinical Trial Data Analysis and Submission of the Clinical Trial Report				
Alternate Strategies: None				
TIME LINES				
Activities	Month Of Start Of Activity	Month Of End Of Activity	Indicators Of Progress	Collaborator(s) Role
OBJECTIVE 1: Conduct of Clinical Trial Phase I – Clinical Phase				
1.Site Initiation and Enrolment of patients, and ex vivo culture and expansion of autologous chondrocytes initiated	0	12	Surgically removed disc tissue will be cultured in the GMP facility, QC tests will be completed and Clinical trial phase on 10 patients will be completed	Enrolling patients, taking informed consent, collecting all clinical data, carrying out QC tests.
2.Ex vivo culture and expansion of clinical grade chondrocytes from surgically removed disc tissue				
3.Characterization of Cells along with evaluation of differential potential evaluation				
4.Completion of QC tests				
5.Completion of the Clinical Phase of the Clinical Trial (Total 10 subjects) and Submission of the Report	0	12		--NA--



OBJECTIVE 2: Conduct of Clinical Trial Phase I – Bioanalytical Phase				
Database Lock	10	18	Completion of bioanalytical phase of the study, including followup of the 10 patients	Collecting radiology data MRI scans, etc, evaluating the patient progress, followup and adverse event reporting, if any. Reporting to IEC.
Completion of Bioanalytical Phase of the study	10	18	Completion of bioanalytical phase of the study, including followup of the 10 patients	Collecting radiology data MRI scans, etc, evaluating the patient progress, followup and adverse event reporting, if any. Reporting to IEC.
OBJECTIVE 3: Clinical Trial Data Analysis				
Follow up of the patients will be carried out. Adverse events, if any will be reported	20	22	Clinical Trial report will be ready	Clinical trial data analysis and report preparation.
Bio-statistical data analysis of the study	20	22	Clinical Trial report will be ready	Clinical trial data analysis and report preparation.
Clinical Trial Data Analysis and Submission of the Clinical Trial Report	20	22	Clinical Trial report will be ready	Clinical trial data analysis and report preparation.

Sanjay Saxena



INTELLECTUAL PROPERTY GOVERNING FRAMEWORK

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

- a) The New Intellectual Property (IP) rights belong to the recipients of funds and commercialization rights remains with the Company.

Provided, this Project is not determined as a “Nationally Important Project” to be governed through specific ‘Order of BIRAC’. Such cases of “Nationally Important Project” shall have specific terms of licensing, pricing or March-in-rights for the purposes of public interest/ demand of Government of India.

- b) It is the responsibility of the Fund Recipient to protect the New Intellectual Property (New IP). They shall bear the expenditure involved in protecting the New IP.

2. GLOBAL ACCESS

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

Global Access requires that

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

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

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

I.	Background IP of the Fund Recipient
	None

Rajay Saxena

