

**Social Innovation programme for
Products: Affordable & Relevant to
Societal Health**



Touching a Billion Lives

Solicitation Document



**Biotechnology Industry Research Assistance
Council (BIRAC)**

(A GOVT. OF INDIA ENTERPRISE)

Table of Content

About BIRAC	3
Sparsh - Overview & Genesis	4
Objectives	5
Focus of Sparsh – Addressing the unmet National need	5
Components of Sparsh	6
Affordable Product development	7
Social Innovation Immersion Program	9
Operational Mechanism	10
Application Process	10
The Verticals of Evaluation Process	11
Eligibility Evaluation	11
Technical Evaluation	12
SIIP – Implementation Mechanism	15
Sparsh Funding Mechanism	17
Award capital	17
Fund Disbursement policy	18
Project Monitoring and Mentoring	18
Confidentiality	19
Data Access Principles	20
Indemnification	20
Research Ethics and Regulatory Approvals	20
Intellectual Property Management and Translation	20
Patent policy	21
Licensing policy	22
Timelines	23
Other Requisites for Funds Disbursements to Applicant	24

Biotechnology Industry Research Assistance Council (BIRAC)

(A G O V T . O F I N D I A E N T E R P R I S E)

Biotechnology Industry Research Assistance Council (BIRAC) is a Section 25 'Not-for-Profit Company' of Government of India, which is registered under Indian Companies Act 1956, and has been set up as Department of Biotechnology's interface agency, which serves as a single window for the emerging biotech industries. BIRAC is guided by an Independent Board of Directors comprising senior professionals, academicians, policy makers and industrialists.

As a Government of India enterprise, it endeavours to bring professionalism, transparency and efficiency into its functioning while providing support to catalyse the transformation of the emerging Indian bio-economy.

BIRAC's Mandate

- i. Empower and enable the Indian biotechnology sector by fostering innovation and commercialisation of affordable, accessible, novel high quality biotechnology products and technologies that provide solutions to the unmet needs of the nation such as in healthcare, food and agriculture, bio-energy and green chemistry.
- ii. Nurture biotech start-ups to convert innovative research into affordable and competitive products and technologies.
- iii. Provide infrastructural, institutional and mentoring support to reduce the entry barriers for the budding entrepreneurs.
- iv. Support and strengthen small scale and medium enterprises to facilitate high risk innovative research for product development through targeted gap funding.
- v. Acquire key technologies that help leapfrog domestic industry as well as provide access to critical products for the end users.
- vi. Build national and international strategic partnerships for leveraging strengths to enhance competence of the biotech enterprises as well as deliver common mandates.
- vii. Encourage and support networking among biotech entrepreneurs to enhance scientific, technological, regulatory and business knowledge.
- viii. Engage with other major stakeholders such as DBT, ICAR, ICMR, DST, MSME, CSIR and other agencies to promote and support their biotechnology developmental activities.

Social Innovation Scheme - Overview & Genesis

Sparsh is the **Social Innovation programme for Products: Affordable & Relevant to Societal Health**. The programme is initiated by BIRAC under the aegis of Department of Biotechnology, Government of India.

The programme is highlighting the need of Innovative solutions to society's most pressing social problems. The scheme is tackling major social issues and offering new ideas for wide-scale change. The scheme aims to invest in ideas and innovations that improve health care of all Indians and provide affordable product development in social sector.

The scheme is also creating a pool of social innovators in the biotech arena who will identify the specific needs and gaps in healthcare. The social innovators will be supported for developing market-based solutions that has potential to bring health care breakthroughs to vulnerable populations.

The focus of the first Call of Sparsh was on Maternal and Child Health. It aims to foster biotechnology in national priority areas such as Maternal & Child Health (MCH). The call is aligned with the Millennium Development Goal 4 and 5 of WHO i.e Reducing Child mortality and

improving Maternal Health. MCH remains one of the key determinants of health of a society. India shows poor MCH indicators especially infant mortality rate (IMR) and maternal mortality ratio (MMR). The MCH area needs products and services that can alleviate the current situation that India and several developing countries face.

The Genesis

The Sparsh program germinated through a discussion meeting on "**Affordable Technologies for Women and Child**" in Sep 2012. The discussion meeting was well attended by participants from Government (DBT, BIRAC, ICMR), international Agencies (WHO, PATH, GATES, Wellcome Trust, USAID), NGO's, Private Industry, Academia

The meeting has highlighted several potentially high impact technologies, with regards to improvement of women and children health, which require special attention and are currently, at different stages of development and could benefit from a coordinated effort to scale up their production and dissemination.

The Objectives

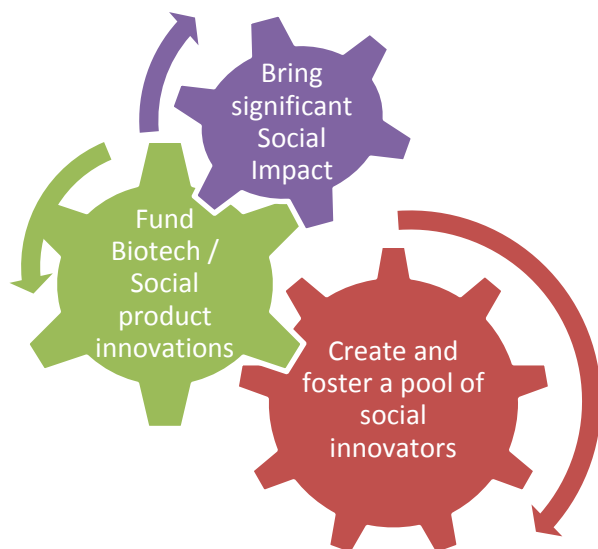


Fig: Sparsh objectives

1. Identify and provide support to cutting edge innovations towards affordable product development that can bring significant **social impact and address challenges of inclusive growth**.
2. Provide support in form of **impact funding of biotech product innovations** (with social goals) that can be **scaled**.
3. Create and foster a **pool of social innovators** in biotech and provide a **platform** to share best practices, understand intricacies of business models in social innovation and network.

Focus of Sparsh

BIRAC's vision is "creation of affordable products addressing the needs of the largest section of society" which mandates it to foster biotechnology in national priority areas such as Maternal & Child Health (MCH). MCH remains one of the key determinants of health of a society. India shows poor MCH indicators especially infant mortality rate (IMR) and maternal mortality ratio (MMR). BIRAC's first call focus under SPARSH pertains to fostering innovative solutions in the MCH arena which are:

- Prognosis of treatment of post-partum haemorrhage
- Neonatal and maternal screening for metabolic disorders, infections such as sepsis, infectious diseases such as HPV, HIV, Hepatitis, malaria
- Monitoring of physiological parameters such Hb count, ECG, blood pressure, neonatal and infant care and child birth
- Monitoring and treatment of fetal growth and restrictions
- Food & Nutrition: Innovative projects in food & nutrition that could make an impact in nutritional intake of expectant mothers and children especially those that incorporate bio-fortification (including micronutrient enhancement) or deriving valuable secondary products such as nutrients from primary

agricultural products (nutrients from rice bran for example) could be supported under MCH theme.

- Delivery models using approved commercialized MCH products including telemedicine initiatives for mother & child

Other Areas

The first call of Sparsh is addressing Maternal and Child Health while the other examples could be Wash and Hygiene, Neglected Tropical Disease, IT in Health (Telemedicine), Synthetic Biology, IVD etc.

Addressing the unmet National Need

Each call of the Sparsh programme will address an unmet national need, which needs special attention and has large societal implications. These areas will be decided after thematic discussion meetings and comprehensive brainstorming sessions with various stakeholders.

Sparsh Components

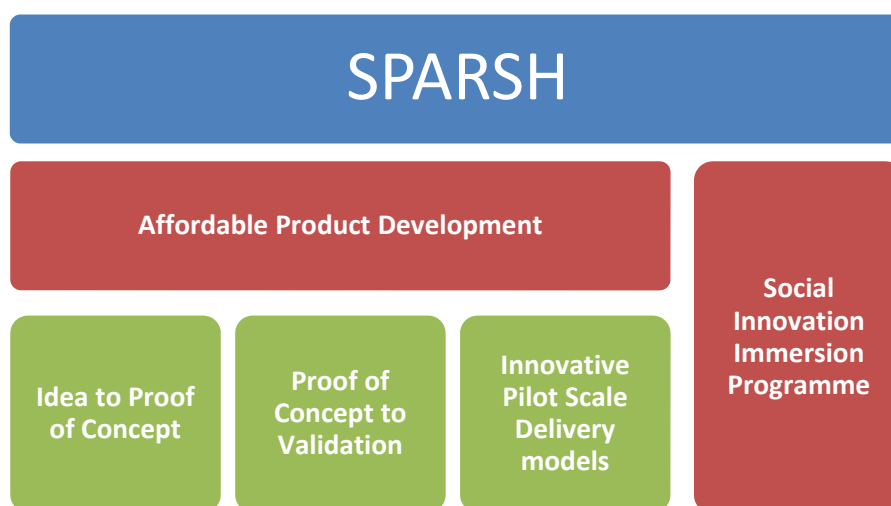


Fig: Components of Sparsh

Component I: Affordable Product Development

Category A: Idea to proof of concept (PoC): Proposals are invited for taking an **Idea to PoC**, which is at an ideation or nascent stage and that would aim to bridge significant challenges in the socially relevant area.

Funding Support: Grant-in-aid assistance up to Rs. 50 lakhs for a period up to 18 months

Eligibility: This category is open to:

- Biotechnology Indian start-ups (Incorporated under the Indian Companies Act and having a minimum of 51% Indian Ownership) (Less than 3 years old as on the date of advertisement)/Indian entrepreneurs (Indian citizen willing to form a Company as per Indian Law).
- Limited Liability Partnership (LLP) incorporated under the Limited Liability Partnership Act, 2008 (less than three years old as on the date of advertisement) having a minimum half of the persons who subscribed their names to the LLP document as its Partners should be Indian citizens.
- Indian Academic Scientists, Researchers, PhDs, Medical Degree Holders, Biomedical Engg Graduates (who must be willing to incubate in a business incubator)
- Proprietorship concern established by an Indian citizen under the Certificate/license issued by the municipal authorities/ under Shop & Establishment Act /under other relevant statute
- No DSIR certification is required

Category B: Proof of Concept to Validation: Grant-in-aid assistance up to Rs. 50 lakhs over the period up to 24 months

Funding Support: Grant-in-aid assistance up to Rs. 50 lakhs over the period up to 24 months

Eligibility: This category is open to:

FOR COMPANIES (For profit/ nor for Profit)

- Incorporated under the Indian Companies Act having a minimum of 51% Indian ownership.
- DSIR recognition.

FOR LIMITED LIABILITY PARTNERSHIP

- Limited Liability Partnership (LLP) incorporated under the Limited Liability Partnership Act, 2008 having a minimum half of the persons who subscribed their names to the LLP document as its Partners should be Indian citizens.

- The Applicant should own the background Intellectual Property based on which the proposal is made.

FOR INDIAN INSTITUTION/ UNIVERSITIES/ PUBLIC RESEARCH ORGANIZATION WHO CAN BECOME CO-APPLICANTS ALONG WITH THE COMPANY/LLP AS MAIN APPLICANT

Established in India and having NAAC/ UGC/ AICTE or any equivalent recognition certificate.

FOR PARTNERSHIP FIRMS/ SOCIETY/ TRUST/ NGO/ FOUNDATION/ ASSOCIATION WHO CAN BECOME CO-APPLICANTS ALONG WITH THE COMPANY/LLP AS MAIN APPLICANT

Partnership Firms/ Society/ Trust/ NGO/ Foundation/ Association established in India under the relevant Indian Law having at least half of the stakeholders (partners/ trustees/ members/ associates etc) as Indians.

NOTE: Applicants and Co- applicants should not have any other legal disqualification that will prohibit them from participating in the scheme process and execution of necessary agreements thereafter.

Category C: Access to innovative pilot scale delivery models: Proposals are invited for Implementation of delivery models of innovative healthcare products and services pertaining to social innovation (which have gained necessary regulatory approvals) and services that can show positive social impact, sustainability of the operations and potential for scale up in the near to medium term.

Funding Support: Grant-in-aid for a period up to 24 months. The project cost sanctioned for the Company would be matched equally by BIRAC and the Company.

Eligibility: This category is open to:

FOR COMPANIES (For profit/ nor for Profit)

- Incorporated under the Indian Companies Act having a minimum of 51% Indian ownership.
- DSIR recognition
- The product should have gained necessary approvals from the concerned regulatory authority (-ies) for pilot studies.
- It is desirable that the projects show partnership or a consortium between product/service innovator Company, an implementer/deployer (Research Foundations, Section 25 companies etc) and clinical partner(s). Any such Partner for execution/implementation can become Co-Applicant in the proposal. Co-Applicant should have been established as a legal entity under the relevant Law of India having at least half of the stakeholders (owners/partners/ trustees/

members/ associates etc) as Indians. Local/state/ Central Departments can also become part of the execution/ implementation/ survey etc.

Component II: Social Innovation Immersion Program (SIIP)

SIIP is a fellowship scheme under 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 then be bridged and serviced through innovative product development and services.

To encourage researchers to understand the milieu of Maternal & Child Health and generate pipeline of possible technologies in this arena, BIRAC invites proposals from organisations such as venture centres, , Foundations, Technology Centres, Incubators, Public Research Institutions, Private Research Institutions, Public & Private Hospital to initiate and operationalize a structured 12-18 months of social innovation immersion programme.

The need identification could be through immersion and embedding the fellows with clinicians and/or rural communities. The SIIP fellows will receive a fellowship from BIRAC (amounting to INR 35,000 – 50,000/month) and a mini-kickstart grant of INR 5lakhs per fellow.

Successful fellows in this programme are expected to be graduates and postgraduates from Lifesciences, Biotechnology, Biomedical, Medicine and Engineering background.

Objective of SIIP programme:

The primary objective of SIIP is to create a pool of biotech “Social Innovators” who can identify needs & gaps within communities and then can help bridge the gaps either through an innovative product development or services. This program is envisaged to be operationalised with partners (academic technology centers, business incubators and related organizations) who help provide a whole host of technical, business and Marketing mentoring to the fellows.

Eligibility Criteria for SIIP Partners

The Applicant venture centers, Foundations, Technology Centers, Incubators, Public Research Institutions, Private Research Institutions, Public & Private Hospital should have been established as a legal entity under the relevant Law of India having at least half of the stakeholders (owners/partners/ trustees/ members/ associates etc) as Indians. It is desirable that the applicant organisation have

- a. A clinical partner for facilitating need identification.
- b. Experts who can provide mentorship to fellows

Eligibility criteria for SIIP Fellows & BIRAC Fellowship Support:

SIIP fellow should be an Indian Citizen. Fellow could be drawn from fields such as life sciences, biomedical engineering, design (including product design), medicine & human biology with educational qualification ranging from undergraduate (BSc, BTech, BE, MBBS) or postgraduate degree of (MSc, MS, MTech, MPhil, MD & PhD).

Selected Fellows would have the designated as '**BIRAC Social Innovators**' who would receive a fellowship from BIRAC (amounting to INR 35,000 – 50,000/month for 18 months) and a onetime mini-kickstart grant of INR 5 lakhs per fellow which will be provided during the course of the fellowship. The BIRAC Fellowship requires the Innovators to work fulltime and cannot be combined with fellowships from other funding organisations.

Operational Mechanism

Application Process

1. The call for letter of Intent will be announced twice a year on a thematic area with high societal impact for component 1 and once a year for SIIP
2. The LoI will be submitted online through registration at BIRAC website
3. The eligible LoIs will be scrutinised online by the SPARSH Technical advisory Group (STAG -1)
4. Submission of Full proposal by the shortlisted applicants
5. Full proposal will be reviewed online by subject experts
6. Mentoring and Evaluation (M&E) Induction Program will be organised for shortlisted Category "A" applicants. The applicants will get mentorship on grant writing skills, proposal technicalities, Documentation skills, financial requirements and Technical aspects.
7. Site visits will be organised for Category "B" and "C" applicants.
8. Revised proposal submission by the applicants (If required based on the M&E Induction program or site visit recommendations.
9. Advanced Evaluation and Recommendation will be carried out by STAG-2 based on the revised proposal, the reports of the lead discussants and the BIRAC facilitators for shortlisted Component I proposals.
10. STAG-2 will also evaluate and recommend the SIIP applicants through Presentation by the SIIP applicants. .
11. BIRAC shall process the sanction of fund after financial, legal concurrence, due approval etc

The verticals of Evaluation Process

A. Evaluation of eligibility of the applicants and the co-applicants

Document needed for evaluation of eligibility:

FOR COMPANIES (For profit/ nor for Profit)

1. Legal status- Certificate of incorporation
2. DSIR certificate or application applied for DSIR
3. Custom duty/ Income tax exemption for DSIR units should not be uploaded for documenting eligibility
4. Shareholding pattern in required format
5. A pdf stating year of establishment, Manufacturing, Trading, Imports and Marketing as well as R&D activities.
6. True copy of the Section -25 License

FOR PARTNERSHIP firms/ Society/ Trust/ NGO/ foundation/ Association

1. Legal status-Registration Certificate under Society Act, if the firm is registered. State/Central Act or any relevant certificate of registration
2. Partnership Deed Or Trust Deed
3. DSIR/ SIRO recognition
4. Income tax exemption certificate such as 12AA
5. Document listing out the names, citizenship and addresses of the partners, trustees, members of the governing body, directors as applicable ,
6. Pan Card copy of the establishment as Proof of Legal identity
7. Bye-laws of the entity
8. A pdf stating organization involvement in social innovation or S&T activities must have active participation in India. They need to submit an illustration of their active programs in the country as well as their accomplishment when requested.

FOR SOLE PROPRIETORSHIP

1. Legal status- Registration Certificate (in case of registered unit)
2. Name, citizenship and addresses of the proprietor.
3. Certificate/registration document issued by the sales tax/professional tax authorities.
4. Certificate/license issued by the municipal authorities under Shop & Establishment Act or other relevant statute
5. Registration / licensing document issued by the Central Government or State Government Authority / Department.

6. Importer Exporter Code (IEC) issued by the Office of Directorate General of Foreign Trade (DGFT) etc., (Any two of the above documents would suffice. These documents should be in the name of the proprietary concern.)

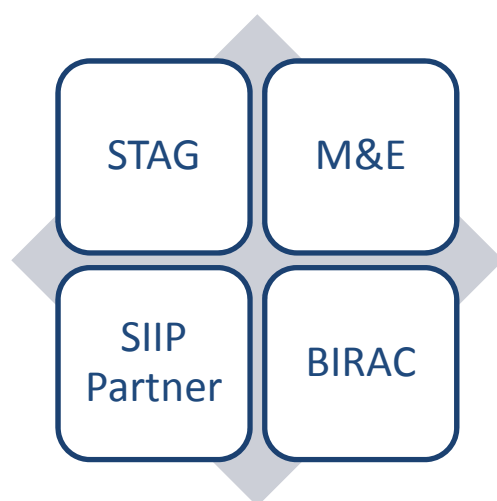
FOR LIMITED LIABILITY PARTNERSHIP

1. LLP agreement.
2. The Incorporation document and DPIN of the designated partners.
3. Specific production, manufacturing, sale, distribution or business licenses issued by local authorities

For Institution/ Universities/ Public research organization

1. Establishment certificate or Founding document indicating year of establishment
2. NAAC/ UGC/ AICTE or any equivalent recognition certificate.

B. TECHNICAL EVALUATION



Sparsh - Technical Advisory Group (STAG)

For each call of the Sparsh programme a STAG will be formed. The STAG will comprise of Key Opinion Leaders and Subject Matter Experts from the sector in which the RFP's are invited.

The responsibilities of STAG

1. The STAG will be responsible for reviewing and short-listing the LoIs submitted.

2. The STAG will recommend the constitution of the Mentoring and Evaluation group
3. The STAG members may participate as mentors and as site visit experts
4. The STAG-2 will undertake advanced review and recommendation for funding.

The Mentoring and Evaluation Group (M & E)

The Mentoring and Evaluation group will be formed for the shortlisted LoI by STAG and will comprise of 3-4 members.

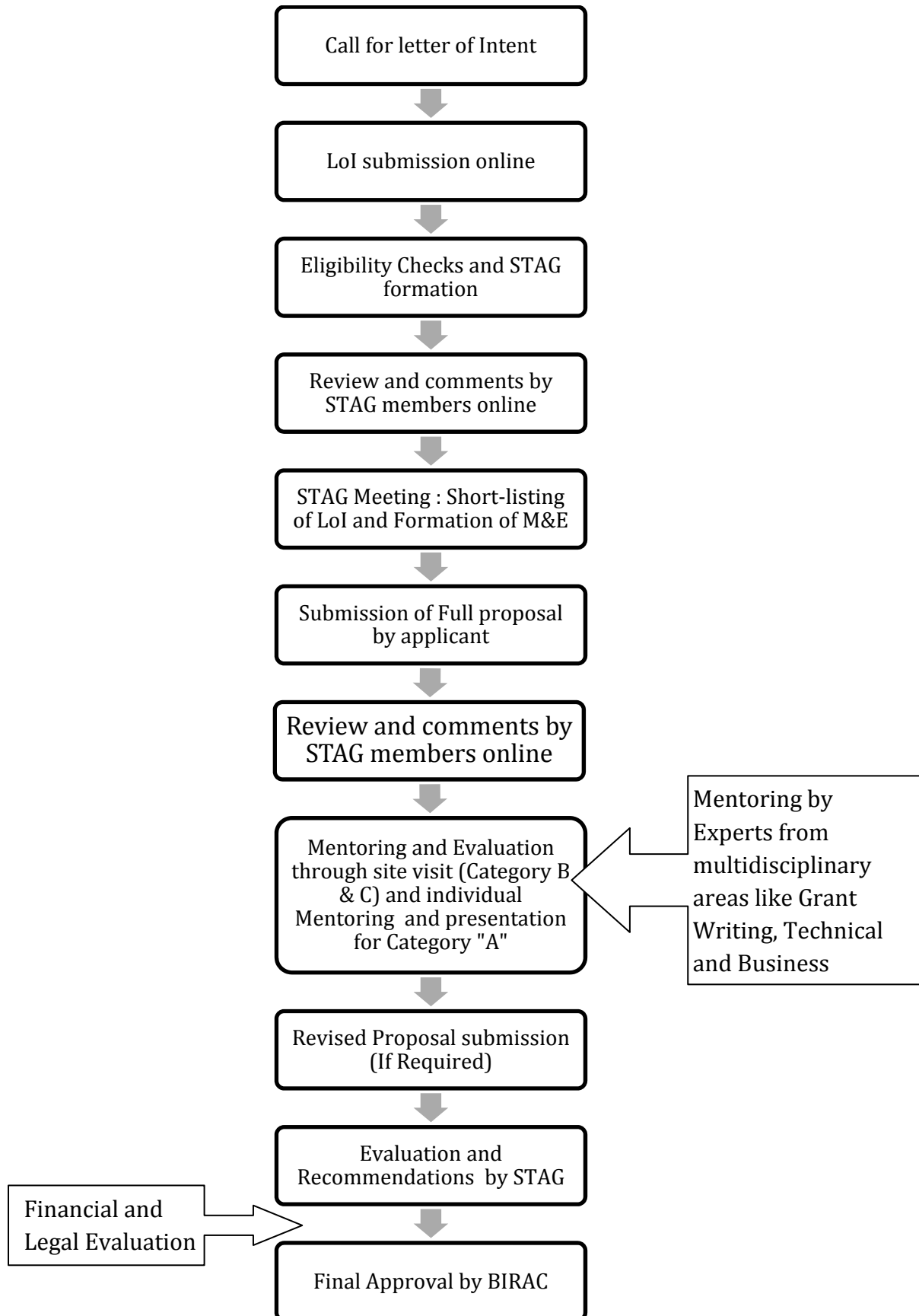
The responsibilities of M & E

- i. The M&E will be responsible for mentoring the applicant and evaluating the proposals as per evaluation indicators
- ii. The mentoring will be in the form of
 - a. Grant writing skills
 - b. Proposal requirements
 - c. Technical aspects
 - d. Financial requirements
 - e. Documentation Practices
 - f. Regulatory Requirements
 - g. Business models
- iii. The Evaluation of the proposal will be done as per the **evaluation indicators**
 - a. National Importance / Unmet Need
 - b. Societal Impact
 - c. The Commercial Value
 - d. The affordability
 - e. Innovation
 - f. Objectives and Timelines
 - g. Infrastructure requirements
 - h. Competence & Expertise
 - i. Budget Requirements
 - j. Business model
- iv. The M&E member may become the lead discussant before the STAG- 2.

SIIP Partners

- i. The SIIP partners will be responsible for selecting the social innovation Fellows under the SIIP in coordination with BIRAC
- ii. Providing the mentoring, space, equipments and other services to the SIIP Fellows
- iii. Overall Management of the SIIP program implementation

The Application Evaluation Cycle – Process Flow



SIIP – Implementation Mechanism

The overall administrative responsibility of the SIIP would rest on the partnering organization which would operationalize the program (henceforth referred to as BIRAC SIIP Partner).

The following is a suggested work flow for SIIP, which will also act as the Milestones and Deliverables for SIIP. The formal 18 months of the SIIP will start from Pre-Immersion orientation and Induction phase.

1. Recruitment & Selection of Social Innovator Fellows (Upto 6 weeks)

SIIP Partners will float fellowship announcements and select fellows through an interview. The SIIP Fellows must be selected by the partners within 5 weeks of aforesaid announcement. Each partner is responsible for recruiting 4 fellows for upto 18 months.

An ideal candidate would be one who has a drive to understand the milieu of healthcare in different resource settings, work in teams & drive independent projects and has excellent communication skills. Training on various aspects of Entrepreneurship is desirable and should be provided to Social innovators throughout the Programme..

2. Pre-Immersion orientation & induction: (Upto 4 weeks)

Once the fellows are selected, SIIP partners are expected to brief the SIIP fellows about objectives & outcomes as well as provide tools for identifying gaps & needs of different communities and train them for 'ethnography' studies.

The SIIP is 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 SIIP partners to have clinical and rural partners and mentors of primary, secondary and tertiary Healthcare levels.

3. Immersion Programme (Upto 24 Weeks)

BIRAC envisages that the "immersion" component of the programme would be to a maximum of 6 months. During this period the social innovators would ideally be exposed to both clinical settings as well as rural (or urban resource poor) community settings. This is where BIRAC expects the programme to be different than other similar immersion programmes as it expects immersion not just with clinicians but also with related communities. 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. The clinical partners will assist the innovators

in need identification and refinement, understanding the clinical needs, disease states, basic biology and physiology. Rural or Urban resource poor community immersion would expose them to cultural aspects and other pain points faced by a community.

SIIP Partners are expected to be in continuous engagement with fellows throughout this period and take periodic reviews of the fellows. They are expected to provide mentoring on Intellectual property and technology commercialization issues.

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

4. **Post Immersion Filtration (Upto 12 weeks)**

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 analyses that were conducted & identified during the immersion component. Further to this they are expected to filter the list to 10 and further narrowed down to top 2-3 needs that align well with possible product or service strategies. This would involve a mix of business & technical understanding such as understanding market dynamics, technology landscaping, understanding regulatory challenges, business plan formulation and grant writing skills.

It is expected that the SIIP 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 explore the workshops and conferences for social innovators relevant to their requirements and few key opinion leaders or stakeholders for individual specific meetings.

The Social Innovators will come out with detailed document on the 2-3 final ideas shortlisted. 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 a identified gap/need to the next stage either in terms of product design or delivery component with at least two milestone stages.

5. **Product Design, Prototyping and Delivery Mechanism (Upto 36 weeks)**

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 as a team on developing a single identified need that they can combine their mini kickstart grants. However this has to be communicated 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 SIIP partner & BIRAC for approval

before the combined mini kick-start grant is released & routed via the SIIP partner. Once BIRAC approval has been provided for a joint project, it cannot be reversed. In such cases, if more than 2 Social innovators decide for a joint project then the combined mini Kick start grant will be provided in two milestone stages as for individuals.

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

SIIP Intellectual property

- i. Any Intellectual property generated through SIIP will be owned by the SIIP Fellow and BIRAC SIIP Partner.
- ii. 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

BIRAC expects the Social 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 BIG or equivalent funding source or a technology / patent suitable for licensing.

SPARSH Funding Mechanism

Award Capitals

Awards in the Sparsh Scheme will be in the form of Grant. The maximum cap for each category is pre-determined and is as mentioned below:

Affordable product Development

Category A: Grant-in-aid assistance up to Rs. 50 lakhs for a period of up to 18 months.

Category B: Grant-in-aid not exceeding a total of Rs. 50 lakhs, over the period up to 24 months.

Category C: Grant-in-aid over the period up to of 24 months. The project cost sanctioned

for the Company would be matched equally by BIRAC and the Company.

Immersion program

1. Research Fellowship – 35,000 – 50,000 /month/Innovator
2. Kick Start Grant – 5 Lakh / Innovator
3. SIIP Implementation overhead – Upto 3 Lakhs
4. Manpower Cost
 - i. One Faculty Lead Coordinator (15% of Full Time Employment) and
 - ii. One Full time Manager (upto 40,000 / month)
5. Workshop and Conferences – Upto One Lakh
6. Consumables cost – Upto One Lakh
7. Travel / Field site visits and Contingency - Upto 50,000 INR

Fund Disbursement Policy

The fund disbursement is milestone based and will be released in 4 - 5 instalments as per the timeline of the project

1st Instalment on signing of Contract - 30%

2nd Instalment on completion of 1st Milestone (6 months) and submission of corresponding fund utilization particulars- 20%

3rd Instalment on completion of 2nd Milestone (12 months) and submission of corresponding fund utilization particulars - 20%

4th Instalment on completion of 3rd Milestone (18 months) and submission of corresponding fund utilization particulars - 20%

5th Instalment on Submission of Report and submission of corresponding fund utilization particulars - 10%

More than one milestone can be clubbed for the projects which are less than 18 months duration.

Project Monitoring & Mentoring

The projects are monitored/and mentored regularly by an M&E group constituted by STAG for each project. Site visits are conducted by specially constituted Expert Committees comprising two to three Technical experts and one financial expert. The Mentoring and Evaluation (M&E) is responsible for

- I. To monitor the progress of the Project in conformity with the outputs, milestones, targets and objectives contained in the Agreement.
- II. To keep track of financial sustenance of the fund recipient. Based on the foregoing, to assess and suggest:
 - i. Recommend the release of next instalment or part release thereof by the BIRAC.

- ii. closing or dropping or modifying any of the components of the Project, within the overall approved objectives, budget and time-frame,
 - iii. inclusion of additional industrial/institutional partner(s), in the overall interest of the Project,
 - iv. mentor(s) to assist in overcoming any technological problem faced in the Project implementation; and
 - v. 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 the Scheme.

Reporting of Progress

1. On Successful completion of each monitorable Milestone the Company and other Partners are required to submit a detailed Milestone Completion Report (MCR) as per prescribed format.
2. The MCR is assessed by the M&E for its completion. On recommendation of the M&E, the next Milestone budget is released.
3. Each partner has to submit a statement of Expenditure for the Budget available for the specific milestone being reported upon. Both Company (if any) and BIRAC Contribution are to be accounted for.

Confidentiality

During the tenure of the Project, the BIRAC will undertake to maintain strict confidentiality and refrain from disclosure thereof, of all or any part of the information and data exchanged/generated from the Project for any purpose other than purposes in accordance this scheme document. The BIRAC 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. was developed by the recipient, as established by acceptable written record, independently of the disclosure of information by the disclosing party; or

- f. is required by public authority, by law or decree.

Please note that all proposals, documents, communications and associated materials submitted (collectively, "Submission Materials") will become the property of BIRAC and will be shared with other funding partners or potential funding partners. Number of applications received and the countries from which they originated will be published. The proposals will be subject to confidential external review by independent subject matter experts, in addition to in-house analysis.

Data Access Principles

BIRAC has the right to the technical data generated during the project for all the joint funded projects. The fund recipient shall permit BIRAC through its authorized representative access to the premises, during regular business hours, where the Project is being/shall be carried out and provide all information and produce or make available the concerned records for inspection and monitoring of the Project activity, required by BIRAC or the concerned committee under the RFP. BIRAC will as needed share this data with a Technical Advisory Group or with the funding partners.

Indemnification

Applicants shall, at all times, indemnify and keep indemnified the 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 its behalf. Further applicants 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 its responsibilities/work under the Project and this Agreement.

Research Ethics and Regulatory Approvals

Applicant(s) shall be responsible to 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.

- a. Any project that involves the use of animals must be compliant with Institutional Animal Ethics Committee
- b. All projects having Clinical Trial Component shall comply with all applicable national and International regulatory frameworks.

Intellectual property Management and Translation

If there are any pre existing restrictions on IPR or publications arising from the research, a written statement that details them should be provided. Restrictions on intellectual property may affect the eligibility to apply to BIRAC.

Establishing suitable Intellectual Property Management Agreements among the Applicants and Co-Applicants will be a pre-condition for receiving funding. Provisions

therein should govern the mechanisms and approaches to (a) identify Key Background Technologies and ensure freedom to achieve the goals of the Project (b) secure, if necessary, and manage and allocate IP rights (c) report inventions, (d) publish research results of the Project (including making available data and materials), (e) describe post-project development plans, and (f) develop strategies, to the extent possible, for the commercialization and sustainability of the Project's results.

Apart from the standard funding terms, project specific terms and conditions of funding will be negotiated on a case-by-case basis and a funding agreement will be put in place post the decision to fund the project.

Apart from SIIP, Intellectual property that arises under the award will be owned by the applicants' and co-applicant(s). Background intellectual property must be freely available to enable both the project to be performed and translation of the arising intellectual property to be realised. They will be responsible for the filing, prosecution and maintenance of IP arising out of the project and its own pre-existing (background) IP which is used in the project.

Patent Policy

- a. No cost shall be borne by BIRAC to protect or maintain any background IP.
 - b. Any patent applications and patents directed toward BIRAC supported inventions, if subsequently granted, for BIRAC supported inventions shall not be sold or assigned without prior written approval of BIRAC.
 - c. The cost towards the protection and /or maintenance of the Project IP can be built-in as one of the budget components.
 - d. Patents or patent applications directed toward BIRAC supported inventions shall not be abandoned without first notifying BIRAC and permitting BIRAC to elect to take title and pursue the application at its own expense. At the election of BIRAC, Applicant shall assign title of any BIRAC supported inventions to BIRAC at no additional charge.
 - e. The results of BIRAC supported research shall be submitted for publication within a reasonable time, consistent with the need to protect intellectual property when indicated.
 - f. Prosecution of patent applications directed toward BIRAC supported inventions and payment of all costs involved with seeking patent protection is the responsibility of the Applicant. Government filing and prosecution fees for BIRAC supported inventions may be charged to the grant.
 - g. Certain provisions for March-in-rights, price control and licensing are applicable for nationally important proposals if notified by specific "Order of BIRAC" as provided hereunder.
- I. With respect to the Project IP in which the Applicant has acquired title under this project, the BIRAC under whose funding Agreement the IP was made may exercise the right to receive a royalty-free license for the use of the intellectual

property for the purposes of Government of India; the BIRAC reserves its right to require the fund recipient to license others and requires that any one exclusively licensed to market the innovation in India must manufacture the product in India, if the BIRAC determines that such -

- (i) Action is necessary because the Company or licensee/s has not taken, within a reasonable time, effective steps to commercialize the New IP in such field of use;
- (ii) Action is necessary to meet requirements for public use or national interest and such requirements are not reasonably satisfied by the Company or licensee/s;

II. Licensing/Sale of technology:

Subject to the determination of any of the two conditions under the preceding clause, the BIRAC, after taking into consideration the fund recipients' requirement for reasonable expansion and the demand supply gap at the appropriate time, shall have the right to require the fund recipient to provide the technical know-how of the product/process developed under the Project to other entrepreneur(s), on such terms and conditions as may be mutually agreed among the BIRAC, the fund recipient and such other entrepreneur(s).

III. Price control:

If invoked, this aspect is based on case-to-case negotiation and based on other relevant demand and supply factors.

Licensing Policy

- a. Applicant must include provisions in all licenses and other revenue generating agreements for BIRAC supported inventions with third parties that bind the third parties to provisions of this agreement relating to the Global Access Strategy of BIRAC for the benefit of the developing world.
- b. Applicant may not enter into any license or other revenue generating agreement with a third party for the development and or exploitation, in any way, of a BIRAC supported invention without first providing written notice to BIRAC.
- c. BIRAC may opt for a transferable, irrevocable, perpetual, nonexclusive, royalty free license for BIRAC supported inventions with the right to sublicense, to use, manufacture, make, have made, produce, reproduce, copy, distribute, offer to sell, and sell the invention for the benefit of the developing world. Exercise of the license is at BIRAC' sole discretion, which it does not intend to undertake unless BIRAC determines that the Applicant or licensee(s) has taken inadequate steps toward making the invention available to the developing world within a reasonable time at a reasonable cost

Publication of Research Results

Applicant shall seek to publish the results of BIRAC supported research as expeditiously as is consistent with the need to seek patent protection. Data and materials produced with BIRAC funding shall be made available through peer reviewed Journals, trade publications, public databases or repositories where suitable ones are available or, where these are not available, through other appropriate means of sharing.

Timelines

Activity	Aug	Sep	Oct	Nov	Dec	Jan	Feb	Mar	Apr	May	June	July
Call for Proposal												
Eligibility Checks												
STAG-1 Meeting												
Proposal Submission												
SV and MEIP												
STAG-2 Meeting												
Final Approval												
Financial and Legal Concurrence												
Contract and Agreement Signing												

Other Requisites for Funds Disbursements to Applicant

In addition to signing of agreement between all the concerned parties, certain requirements need to be completed before the first installment of the funds as will be specified in the corresponding Sanction Order.

Formats

- a. Milestone Completion Report (MCR)
- b. Utilization Certificate and Statement of Expenditure
- c. Agreement of funding
- d. Board Resolution template
- e. No-lien account certificate template

Contact Information

Further information can be obtained at BIRAC website www.birac.nic.in or

Sonia Gandhi

Project Manager - Investments

E: sgandhi.birac@nic.in

Biotechnology Industry Research Assistance Council (BIRAC)

A Government of India Enterprise

Tel: +91-11- 47744500-510