

Small Business Innovation Research Initiative (SBIRI)

(A scheme for establishing proof-of-principle/early stage research leads/prototype/process optimization)

Complete Scheme Document including Proposal Submission, Evaluation and Review Guidelines



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1. Introduction

The Small Business Innovation Research Initiative (SBIRI) scheme of the Department of Biotechnology, Ministry of Science & Technology was launched in 2005 to boost Public-Private-Partnership (PPP) efforts in the country. SBIRI was the first of its kind, early stage, innovation focused PPP initiative in the area of Biotechnology. Launching of SBIRI has worked as an enabling platform for the target organizations to realize their potential in terms of product and process development and taking them to the market. It has facilitated innovation, risk taking by small and medium companies and bringing together the private industry, public institutions and the government under one roof to promote the research and innovation in the Indian Biotech Sector. The projects supported under the scheme have resulted in prominent outcomes in the form of some products which have already come to the market and some promising research leads seeing ray of hope for commercialization.

As a unique institutional mechanism, SBIRI has consistently prioritized early stage funding for high risk innovative research in small and medium companies led by innovators with science backgrounds to get them involved in development of products and processes which have high societal relevance.

2. Aims and Objective of SBIRI Scheme:

The SBIRI aims to:

- strengthen those existing private industrial units whose product development is based on in-house innovative R&D
- encourage other smaller businesses to increase their R&D capabilities and capacity
- create opportunities for starting new technology-based or knowledge-based businesses by science entrepreneurs
- stimulate technological innovation

The SBIRI objectives:

- to provide support for early stage, pre-proof-of-concept research in biotechnology by industry,
- to support new indigenous technologies particularly those related to societal needs in the healthcare, food and nutrition, agriculture and other sectors,
- to nurture and mentor innovative and emerging technologies/entrepreneurs, to assist new enterprises to forge appropriate linkages with academia and government

3. Eligibility

1. The proposals can be submitted
 - a. solely by a Company incorporated under the Companies Act, 2013 *or* Limited Liability Partnership (LLP) incorporated under the Limited Liability Partnership Act, 2008 *or* Joint Ventures either in the form of Company/ LLP
 - b. by any of the above entities jointly with other private or public partner(s) (Universities *or* Institutes).
2. Minimum 51% of the shares of the Company should be held by Indian Citizens holding Indian passport (Indian Citizens do not include Person of Indian Origin (PIO) and Overseas Citizenship of India (OCI) holders)
3. Minimum half of the persons who subscribed their names to the LLP document as its Partners should be Indian citizens.
4. The main industry applicant should have DSIR* recognized in-house R&D unit *or* patent granted or acquired, that will be used for the proposed project; alternatively the applicant should be incubated at an Incubation Centre/ Biotech Park which has a valid DSIR/SIRO Certificate.

**(The Companies in the process of obtaining DSIR recognition may also apply along with the proof of application for DSIR. However, the final decision on such applications would be subject to their getting DSIR recognition)*

4. Proposal Submission

Proposals are required to be **submitted online** only. Online proposal submission can be done by registered users during an active call only. Generally 3calls are advertised each year. Process for submitting the proposals online is detailed below:

- Log on the BIRAC website (www.birac.nic.in)
- If you are a registered user, log-in using the credentials, else you need to register your institution with by clicking on New User Registration.
- In case of new user registration, a computer generated password would be sent to the email-id provided at the time of registration. The password can be changed later.
- Once you login, you would be navigated to the page displaying SBIRI link.
- Click on the SBIRI link under Programmes and the active call would be highlighted.
- Click on the active call against which you wish to submit the proposal.
- Further details on How to submit a proposal would be available in the SBIRI User Guide available on the website.

5. Evaluation and Decision Making

- *Process of Evaluation*

The process of evaluation broadly comprises the following steps:

- Peer Review by a Panel of area-specific experts called as Area Review Panels (ARPs) created for evaluation.
- Presentation of technically sound projects recommended by the ARP to the Technical

- Expert Committee (TEC), comprising eminent scientists from all over the country
 - Site Visit for the projects shortlisted by the TEC
 - Expert Review, wherever required
 - Final review by TEC and scrutiny and decision by the Apex Committee comprising Senior Technical Experts of members from various ministries and Government departments
- Role and Responsibility of the Reviewer and Expert Member

Specific role of the Expert Reviewer of different panels is to:

 - Review the project and give a detailed evaluation based report on the established criteria.
 - Shortlist proposals based on Review score for a detailed presentation.
 - Assess proposals based on the interaction during the presentation and shortlist for an on-site visit.
 - Technical Due diligence during on-site visit after detailed interaction with Applicant.
 - Recommend proposals for support under SBIRI after Technical Expert Committee discussion.
 - Assist BIRAC in Monitoring the Project.
- Guidelines for Reviewers and Panel Members

The evaluation process is completely online and comprises following 4 level reviews:

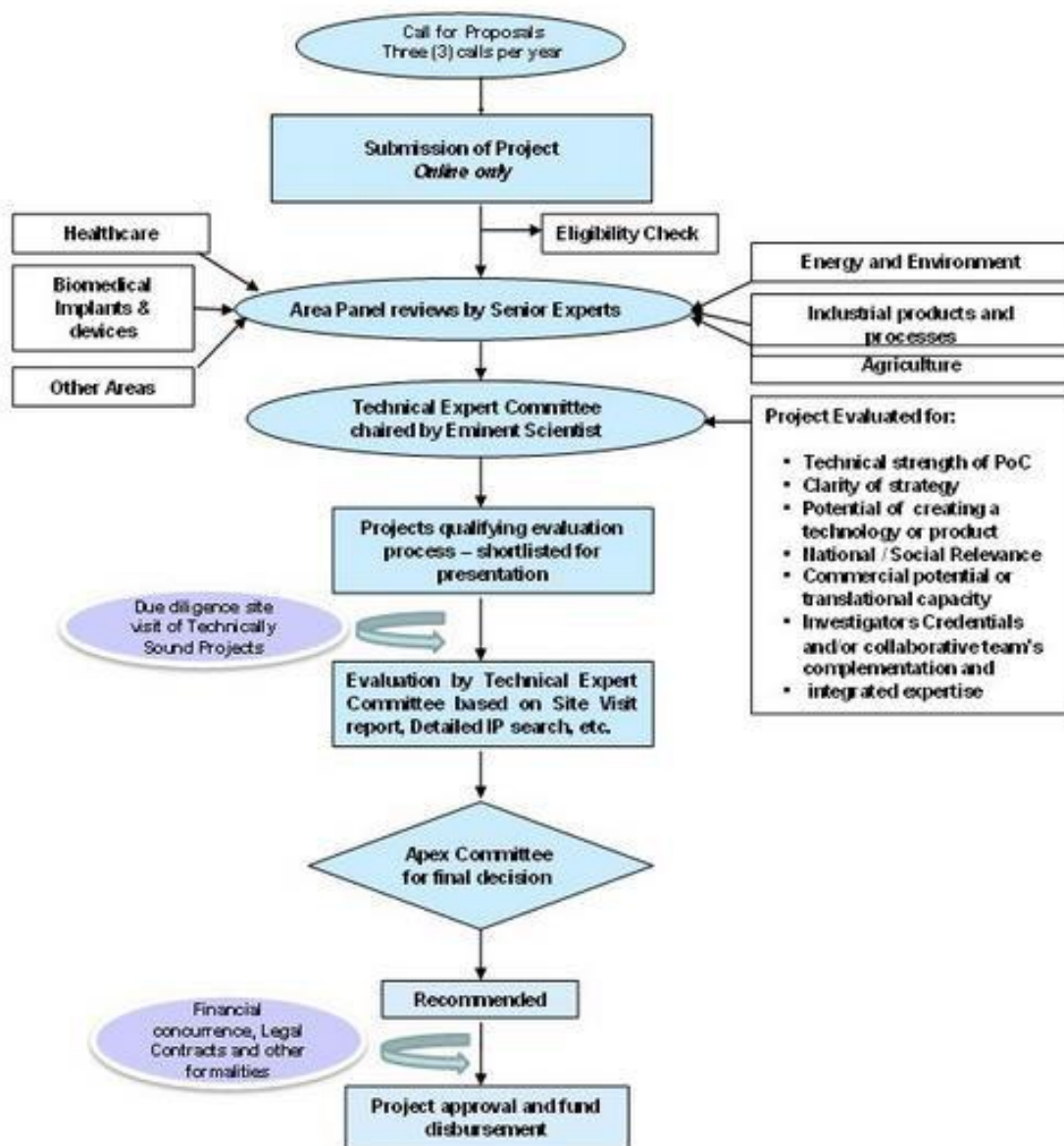
 - Initial Peer Review- Area Review Panel (ARP)
 - Technical Evaluation Committee (TEC)
 - Site visit and Due Diligence – (Technical & Financial)
 - Apex Committee
- Reviewers are senior scientists / experts in the relevant subject area and are assigned proposals along with a brief summary to provide an opinion about any conflict of interest. Those experts who have No conflict of interest with the applicant and/or the proposals and sign the confidentiality certificate are then given full access to the proposal.
- The proposals are evaluated based on following criteria:
 - a. Technical strength of PoC
 - b. Clarity of strategy
 - c. Potential of creating a technology or product
 - d. National / Social Relevance
 - e. Commercial potential or translational capacity
 - f. Investigators Credentials and/or collaborative team's expertise.

Each reviewer is required to prepare a written critique for each application assigned based on the review criteria and allot scores for each defined parameter and sub parameters in the prescribed format. The reviewers would maintain complete confidentiality about the proposals. The reviewers are generally given two weeks for proposal evaluation and submission of report. The evaluations of the reviewers are then discussed by the Technical Expert Committee (TEC).The coordinator of each of the Review Panel would serve as the moderator for that area and would discuss and

normalize scores for the proposals for which there is a significant variation in the scores allotted by the reviewers. The Technical Committee then discusses each proposal finally after moderating. The Technical Expert Committee (TEC) shortlists proposals for next round of screening i.e. Presentation. During the presentation a detailed discussion is held and proposals are evaluated for the following.

- a. Presence of preliminary data or Proof of concept (PoC)
- b. Clarity of Milestones
- c. Competency of applicant and partnering entity to carrying out the proposed research
- d. Relevance of project deliverable as commercially viable product/process
- e. Any other relevant aspect

SBIRI – Operational Mechanism



Process of Evaluation/ Decision Making takes about 4-5 months. Decision is conveyed at each stage.

6. Guidelines to Reviewers regarding Confidentiality and Conflict of Interest

- In discharging their duties as Panel members, all Panel members must observe the Code of Conduct, Conflict of Interest and Confidential Information requirements set out below.
- These guidelines apply equally to everyone involved in the assessment of applications – including, but not limited to Panel members and Reviewer.

i. Confidentiality and Transparency

An effort has been made to ensure complete transparency in the proposal submission and evaluation. An important feature of the SBIRI process is the high level of confidentiality which is maintained throughout the proposal decision making process.

Each expert is clearly made aware of the following governing terms of the process;

“BIRAC receives applications under SBIRI in confidence and is responsible for protecting the confidentiality of their submission and contents. For this reason, confidentiality must be maintained; therefore, DO NOT copy, quotes, or otherwise use material from this summary application. When you have completed the review, please destroy all printed and electronic materials related to the application and maintain its confidentiality. If you are unable to review, please do not accept the Membership online. You can click on Not Available or state Conflict of Interest when it asks for your consent and destroy all printed and electronic materials related to the application, and maintain its confidentiality.

Any panel member can self-reveal the fact that he/she served on the panel, but CAN NOT reveal the composition of the panel or any of the discussions during the panel meeting or during the entire review processes.”

- ii. **Conflict of Interest:** These guidelines are designed to ensure that all such conflicts are:
 - a. Identified and disclosed;
 - b. Recorded; and
 - c. Managed in a rigorous and transparent way that promotes public confidence in the integrity, legitimacy, impartiality and fairness of the Panel’s decision making process.

What is a Conflict of Interest?

A conflict of interest usually involves a conflict between the public duty and the private interests of a member, in which the member has private interests which could improperly influence the performance of their official duties and responsibilities.

These guidelines apply not only to actual conflicts of interest but also to ‘apparent’ or ‘perceived’ conflicts of interest. This kind of conflict of interest arises when it appears that the member has private interests which could improperly influence the performance of their

official duties and responsibilities.

These guidelines also apply to ‘potential’ conflicts of interest. This kind of conflict is one which may not have yet occurred but if the Panel member were to become involved in certain relevant activities an actual or apparent conflict could arise.

Conflict of interest may arise in respect of a particular application in the following situations (this list is indicative and not exhaustive):

- The involvement of a Panel member in any current application eg. as an applicant for funding or as the supervisor of an applicant;
- Membership/ Directorship of a Panel member in an organisation involved in any current submitted application under the programme; or
- Ownership of shares by a Panel member in a company involved in any current, established or submitted application, or if the future of the company will be significantly affected by the success of the application.
- Holding of any technical/scientific positions in an organisation involved in any current submitted application under the programme

Note: a conflict of interest may also exist where a member’s spouse or immediate family member has any of the interests or involvements listed above.

The expert must disqualify himself as a reviewer of an application if any conflict of interest in the project exists including the following:

- a. Had a consulting/financial arrangement or other conflict of interest in the past 3 years, including receiving compensation of any type (e.g., money, goods, or services)
- b. Have a known family relationship such as a spouse, child, sibling, or parent, or other relationship, such as a close personal friendship, that you think might affect your Judgment or be seen as doing so by a reasonable person familiar with the relationship.

7. Funding Guidelines

The fund disbursement is milestone based and is released in 5 instalments:

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| 1st Instalment on signing of Contract | - 30% |
| 2nd Instalment on completion of 1st Milestone | - 20% |
| 3rd Instalment on completion of 2nd Milestone | - 20% |
| 4th Instalment on completion of 3rd Milestone | - 20% |
| 5th Instalment on Submission of Report | - 10% |

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| Project Cost | BIRAC Support to the Company (as Grant-in-aid) |
|--------------|--|

| | |
|------------------------------|---|
| Up to 25 lakh | Up to 80% of the Project Cost |
| Above 25 lakh to Rs 100 lakh | Up to 50% of the Project Cost (with a minimum of Rs. 20 lakh) |

If the Project proposal has Academic Collaborator(s) and the total Project Cost exceeds Rs. 100 Lakh, then the total contribution of BIRAC to a Company/ LLP for the Project will not exceed Rs. 50 Lakhs as Grant-in-aid. The contribution to the Academic Collaborator will be in addition to the Grant-in-aid approved for the Company/ LLP applicant.

8. Intellectual Property Governing Framework

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

- a) The New Intellectual Property (IP) rights belong to the recipient of funds, in a joint manner unless mutually agreed otherwise.

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 Recipients to protect the New Intellectual Property (New IP). They shall bear the expenditure involved in protecting the New IP.

B. GLOBAL ACCESS

The Fund Recipient(s) jointly and severally 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 Recipient(s), but excluding the intellectual property generated by the Fund Recipient(s) before execution of this GLA and any IP generated outside the scope of this GLA even during the term of this GLA.

9. Project Monitoring & Mentoring

i. Project Monitoring Committee (PMC)

The projects under SBIRI Scheme are monitored/and mentored regularly by an Expert Committee constituted by BIRAC for each project. Site visits are conducted by specially constituted Expert Committees comprising two to three Technical experts and one financial expert. The Project Monitoring Committee (PMC) is responsible to;

- a. Monitor the progress of the Project in conformity with the outputs, milestones, targets and objectives is contained in the Agreement.
- b. Based on the foregoing, to assess and recommend:
 - the release of next instalment or part release thereof by the BIRAC.
 - revision of project duration
 - closing or 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 applicant requests involvement of such partner(s), in the overall interest of the Project,
 - mentor(s) to overcome any technological problem faced in the Project implementation; and
 - Revision of the financial assistance.
- c. To advise on issues related to securing of IPR; and
- d. 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 SBIRI Scheme.

ii. Reporting of Progress:

- a. On Successful completion of each Milestone, the applicant is required to submit a detailed Milestone Completion Report (MCR) as per prescribed format.
- b. The MCR is assessed by the PMC for its completion. On recommendation of the PMC, the next Milestone budget is released.
- c. The Applicant has to submit a duly certified Statement of Expenditure for the Budget available for the specific milestone being reported upon.
- d. Format for Milestone Completion Report (MCR), Utilization Certificate and Statement of Expenditure will be made available as per requirement.

10. Foreclosure and Termination

- i. In case, during the Project Duration, if it is found that the Project or any Project component is not likely to lead to successful completion, SMA/ 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 submit detailed accounts of funds received and utilized. The Company shall immediately refund any grant-in-aid unutilized out of BIRAC's disbursements to SMA/ BIRAC, SMA/ BIRAC, at its discretion, allow deduction of, the future committed expenses to third party vendors on pro-rata basis according to the quantum of BIRAC's funding. If the Fund Recipient likes to continue the Project at its own cost, it would be able to do so without restrictions from SMA/ BIRAC after complying with these provisions.

- ii. The Fund Recipient may, before the completion of the Project, terminate this Agreement by giving **three months' notice** in writing to SMA/ BIRAC. SMA/ BIRAC may also terminate this Agreement by written notice in the event of “the Fund Recipient” committing breach of any term of this Agreement and either not rectifying it to the satisfaction of SMA/ BIRAC or not satisfying SMA/ BIRAC about its inevitability within a specified period. In the event of termination of the Agreement, no further disbursement shall be made by SMA/BIRAC and the Fund Recipient shall be liable to return immediately the amount of grant-in-aid already availed from SMA/BIRAC within 30 (thirty) days of termination of the Agreement. In case of failure to repay, without prejudice to any other rights under this Agreement, the amount can be recovered by initiating any procedure available in Law.

11. Terms & Conditions and Requisites for Fund Disbursement

11.1 Agreement of funding

On announcement of Award, all concerned applicants need to sign the Grant-in-aid Letter Agreement (GLA) with BIRAC.

11.2 Other Requisites for Funds Disbursements to Company

In addition to signing of agreement between all the concerned parties, following requirements need to be completed before the first instalment can be released:

- a. A Board Resolution needs to be passed for acceptance of the Grant-in-aid offer by the BIRAC under SBIRI
- b. Opening up a No-Lien Account with a scheduled/nationalized Bank in case of a Company
- c. Letter of Authorization in case of Institute in the prescribed format of BIRAC
- d.

12.Guidelines for Extension

Extension of projects is DISCOURAGED. Request for extension of project on account of Change in Coordinator/Principal Investigator, delay in purchase of equipment, hiring of manpower, submission of Milestone Completion Reports, Statement of Expenditure (SoE), Utilization Certificate (UC), Bank Guarantee (wherever applicable) or any other financial/technical document by the company/collaborator necessary for release of funds by BIRAC will NOT BE ENTERTAINED.

Request for extension of milestone/project can be considered (without any additional financial implications) only in selective cases where accomplishment of technical milestone is prolonged due to delay in securing regulatory approvals, or where the TEC feels that some additional studies are needed to take the project to a logical conclusion/product development or due to any other technical reasons not envisaged at the time of submission of proposal. However, such request must be communicated to BIRAC at least TWO MONTHS before the scheduled date of completion of milestone/project with proper justification.

13. Acknowledgement of BIRAC support

Acknowledge the assistance of BIRAC while publishing, marketing the resultant Product or presenting in any manner the details of the Project, its progress or its success along with the “Disclaimer” that reference therein to any specific commercial product, process, views or service by trade name, trademark, manufacturer, or otherwise does not necessarily constitute or imply its endorsement, recommendation, or assuming liability of any sort by the BIRAC. Use of BIRAC logo is not permitted without written approval.

All the above tools and instruments may be seen at:

<http://www.birac.nic.in/programmes.php>

Contact Information

Further information can be obtained at

BIRAC Website: www.birac.nic.in

Contact Person

Head - Investment, BIRAC

Email: investment.birac@gov.in