

Small Business Innovation Research Initiative (SBIRI)

*(A scheme for establishing proof-of-concept/prototype
development/process optimization)*

**Complete Scheme Document including Proposal Submission,
Evaluation and Review Guidelines**



जैव प्रौद्योगिकी उद्योग अनुसंधान सहायता परिषद
(भारत सरकार का उपक्रम)
Biotechnology Industry Research Assistance Council
(A Govt. of India Enterprise)

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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 (projects submitted under SBIRI should have end TRL up to 6)
- 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 by following
 - a. Single or consortia of Company (ies)*incorporated under the Companies Act, 2013
or
 - b. Limited Liability Partnership (LLP)** incorporated under the Limited Liability Partnership Act, 2008

jointly with or without the following:

- ❖ Public/private university/colleges in India
- ❖ National research laboratories
- ❖ Not-for-profit private research labs/societies/foundation/NGO

2. ELIGIBILITY CRITERIA

a. For Company/LLP: -

- ❖ 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]

** Minimum half of the persons who subscribed their names to the LLP document as its Partners should be Indian citizens.

The Applicant Company/ LLP should:

- i. Have adequate in-house facility to address the project implementation (which shall be evaluated during the site visit)
or
- ii. Incubated at any of the recognized Incubation Facility

b. For Academic collaborator:

Eligible Academia shall mean an entity which is having proper establishment documents

For Public or Private Institute, University, NGO, or Research Foundation, proper registration/accreditation from a government body is mandatory like UGC affiliation certification, AICTE, CSIR /DSIR/SIRO certificate etc.

3. Ineligibility:

- i. All companies who had withdrawn their proposal after approval from Apex committee or whose project was foreclosed due to inadequate funds or any other irregularity would be debarred from submitting fresh proposals for next 2 calls (1 year) unless the withdrawal was due to papers not being ready.

- ii. Proposals submitted by a company/subsidiary/sister concern either as main applicant or collaborator, who has been fund recipient in any of the schemes of BIRAC in past and has defaulted on (i) repayment of loan and/or interest, or is irregular with regard to repayment of instalments (ii) payment of unspent balance (if any) in the earlier BIRAC supported projects (iii) payment of Royalty to BIRAC would not be considered for financial assistance by BIRAC.
- iii. Proposal of any company having a Director of a defaulting company (as detailed above in point no. 2) would not be considered for financial assistance by BIRAC.

What is not supported?

- Concepts/exploratory research ideas without proper Proof-of-Principle
- Proposals without preliminary data and potential for product/technology development will NOT be supported.

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. 2 calls are advertised each year. All the calls would be regular ones wherein the applicant can use his/her discretion to decide on the research problem as per his/her interest. Besides two regular calls, BIRAC may also announce need-based additional calls whose terms and conditions would be worked out separately and described in their respective RFPs. 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.
- Company/LLP User Registration is open round the clock.
- Online Proposal Submission can be done only during an active call.

(Advertisement for Call for proposals is released in all national dailies and some biotechnology related magazines. Intimation of an active call is also displayed on the BIRAC website).

- **Call shall remain open only till 17:30 hrs on the last date of submission)**

Please note:

- *The number of ongoing projects at a given point of time must not exceed two as primary applicant and two as collaborator.*
- *The applicant must submit an undertaking at the time of submission of the proposal that there is no duplicate funding from any other funding agency for the same or similar proposal.*

5. Evaluation and Decision Making

- ***Process of Evaluation***

The process of evaluation broadly comprises the following steps:

- Submitted proposals (till call closure) will undergo initial eligibility check after which eligible proposals would be presented to respective Area Review Panels (ARPs) for shortlisting them for presentation.
 - For shortlisted proposals, respective PIs would make presentations in the respective ARPs. Based on the merit of the proposal, the ARP would select the proposal for further consideration.
 - Due diligence of the shortlisted proposals either physically or through online interaction (based on incubation status/ in-house R&D facility and total project cost) would be undertaken. Diligence will include technical, IP and regulatory aspects of the project. Financial Due Diligence (FDD) of recommended projects is also conducted.
 - Evaluation by Technical Expert Committee (TEC), comprising eminent scientists and experts from all over the country, based upon pre-sanction Site Visit report, detailed IP Search, identification of regulatory requirements.
 - Final scrutiny and decision by the Apex Committee comprising Senior Technical Experts from various ministries, academic institutions, industry and Government departments. The Committee is chaired by the Secretary, DBT & Chairman, BIRAC.
- The proposals are evaluated based on following criteria:
 - a. Preliminary data generated
 - b. Technical strength of PoC
 - c. Clarity of strategy
 - d. Potential of creating a technology or product
 - e. National / Social Relevance
 - f. Commercial potential or translational capacity
 - g. Investigators Credentials and/or collaborative team's expertise.

- **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 / online 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 comprises of following 5 levels of reviews:

- 1. Shortlisting by Area Review Panel (ARP)**
- 2. Presentation before Area Review Panel (ARP)**
- 3. Site visit and Due Diligence – (Technical/ Financial/ IP/ regulatory)**
- 4. Review by Technical Expert Committee**
- 5. Final recommendation by Apex Committee**

There are different subject specific “**Area Review Panels**” namely a) Devices & Diagnostics, b) Drugs & Drug delivery, Biosimilar, Stem Cells, Vaccines & Clinical Trials, c) Agriculture, Veterinary Science & Aquaculture and d) Environment, Energy and Secondary Agriculture. Reviewers are senior scientists / experts in the relevant subject area and each reviewer signs a **Confidentiality and No Conflict of Interest** certificate while accepting to be associated with the review process.

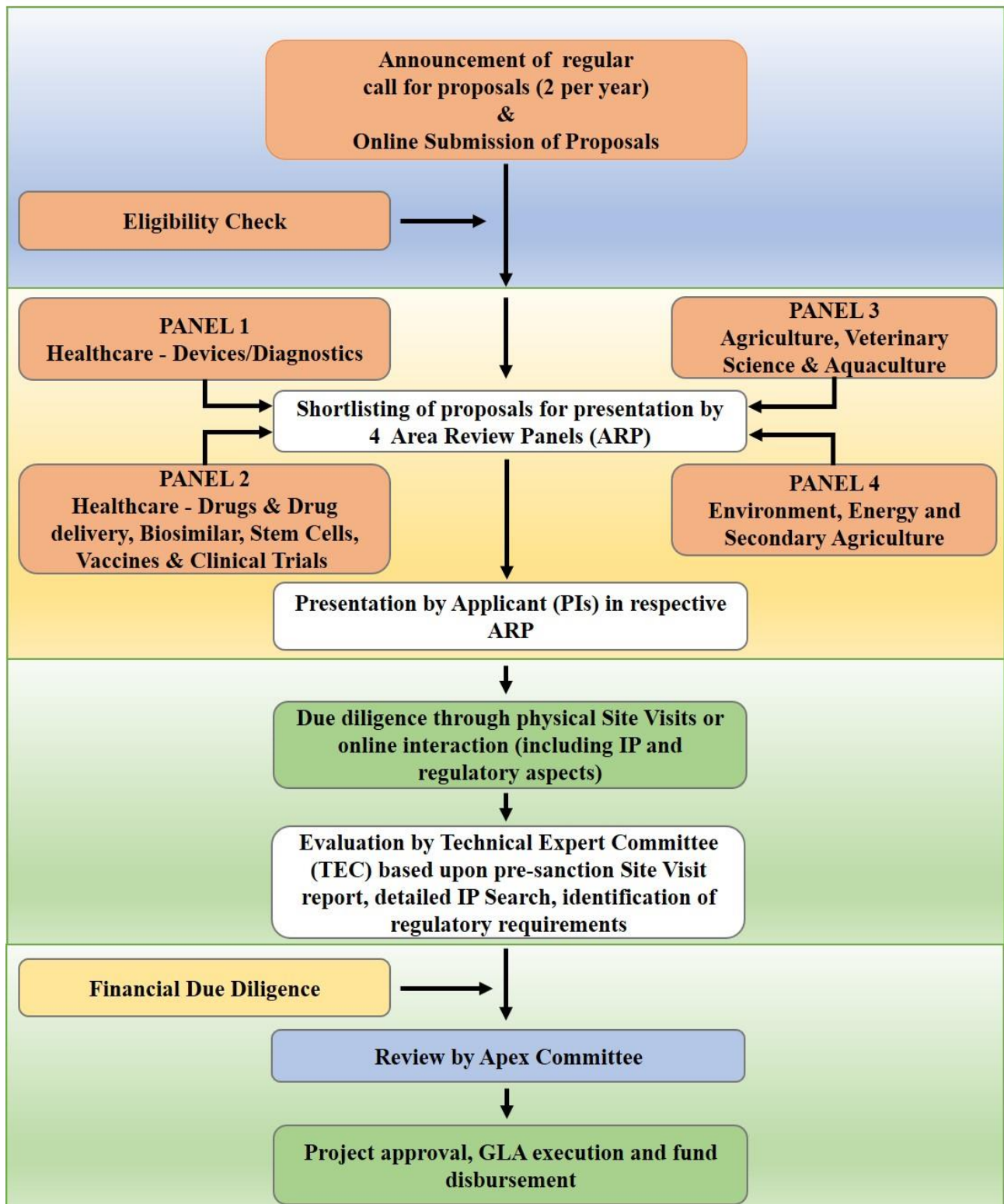
The Reviewers are assigned proposals online along with a brief summary to get a feel of the project and to form an opinion about any conflict of interest. Those experts who have **No conflict of interest** with the applicant and/or the proposals and sign the certificate are then given full access to the proposal.

The proposals are placed before the respective Area Review Panels for evaluating and shortlisting the eligible proposals for presentation

The same ARP then shortlists proposals for next round of screening i.e. Presentation. During the presentation a detailed discussion is made by the applicant and proposals are evaluated for the following:

- Preliminary data generated
- Technical strength of PoC
- Clarity of strategy
- Potential of creating a technology or product
- National / Social Relevance
- Commercial potential or translational capacity
- Investigators Credentials and/or collaborative team’s expertise.

SBIRI Operational Mechanism



**Please note that the decision of the committee at any stage of the evaluation would be final and reconsideration requests would not be entertained. The applicant may reapply in the next call providing clarifications to the committee's comments/recommendations*

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

- (i) There is no ceiling of budget under SBIRI scheme
- (ii) Regardless of the project cost, the applicant LLP/company (ies) shall be required to contribute a minimum of 30% of the total cost
- (iii) The entire cost to the collaborating academic institution (if any) would be borne by BIRAC
- (iv) The fund disbursement will be milestone based i.e., the release of every installment will be subject to successful accomplishment of linked milestone.
- (v) The funds will be disbursed in 3 or 4 installments depending on the duration of the project as detailed below:

Release of funds from BIRAC	Amount (for proposals of more than 12 months duration)	Amount (for proposals of less than 12 months duration)
1 st instalment on signing of contract	40%	50%
2 nd instalment on completion of 1 st technical milestone	30%	40%
3 rd instalment on completion of 2 nd technical milestone	20%	NA
4 th instalment on Submission of Project Completion Report	10%	10%

- (vi) It would be mandatory for the applicant Company to put its contribution prior to the release of every installment by BIRAC
- (vii) The last installment shall be in the form of reimbursement i.e., funds would be released after the completion of the project.

ROYALTY GUIDELINES- Payment of Royalty

- i. The Company shall pay royalty to BIRAC at the rate of 7% (Seven per cent) on annual Net Sales of the product(s) developed with BIRAC's assistance. Payment of royalty shall fall due beginning with the first sale of the product(s) and the liability to pay royalty will terminate upon the first of any of the following two events to occur: - a) 7% royalty has been paid to BIRAC till the royalty amount paid becomes 1.2 times (1.2X) of the amount of the Grant-In-Aid disbursed and that was not returned to BIRAC as unutilized funds; or (b) in case of Foreclosure or Termination of Project as per the terms of GLA.
- ii. Royalty for each financial year shall be payable to BIRAC within 60 (sixty) days of close of corresponding financial year.
- iii. If the Company gets grant-in-aid assistance for more than one Project that will culminate into the same Product(s), then also the Company shall pay royalty to BIRAC at a cumulative rate of 7%.(seven per cent) on annual Net Sales of the product(s) developed with BIRAC's assistance in the same manner as provided above under sub section (i).
- iv. If the Company gets grant-in-aid assistance for more than one Project that will culminate into the distinct Product(s), then the Company shall pay royalty to BIRAC at the rate of 8 (Eight per cent) on annual Net Sales of each such distinct Product(s) developed with BIRAC's assistance in the same manner as provided above under sub section (i).
- v. If the Company intends to transfer or sell the Product, it shall take prior written permission from BIRAC and BIRAC will recover the Royalty amount or 7% of the resultant income excluding GST tax, as certified by the Chartered Accountant, whichever is less before grant of such permission. Provided, this Project is not determined as a "Nationally Important Project", to be governed through a 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.

8. Nationally Important Projects

If Apex Committee recommends certain Projects as nationally important Projects, then BIRAC will issue a specific “Order” to make the following provisions applicable;

- A. In such cases of national importance BIRAC shall retain a royalty-free, non-exclusive, irrevocable licence to the Product developed with the funding support of BIRAC with right to sub-license for the purposes of public interest/Government of India and/or as decided by the Apex committee. The licensor of such Product will ensure that where the Product has been produced in collaboration with entities not in receipt of BIRAC’s Grant-in-aid, such collaborators will also grant license to BIRAC in the same way.
- B. Nationally Important Projects shall mean such Projects that will serve specific purposes notified by Government of India in public interest.
- C. In cases of national importance, if BIRAC determines that such - (a) Action is necessary because the Fund Recipient or licensee/s has not taken, within the period of four (4) years from the date of completion of the Project, effective steps to commercialize the Product in such field of use; (b) Action is necessary to meet requirements for public use or national interest and such requirements are not reasonably satisfied by the Fund Recipient or licensee/s; Then, March-in- rights are applicable whereby;
 - i. BIRAC along with retainment of royalty-free, non-exclusive, irrevocable licence to the Product 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 transfer the technical know-how of the Product developed under the Project to other entrepreneur(s) and train them, on such terms and conditions as may be mutually agreed among BIRAC, the fund recipient and such other entrepreneur(s). Provided, BIRAC shall reserve its right to require that the Product must be manufactured and sold in India.
 - ii. If the fund recipient (s) does not agree with the terms of above sub section (i), then BIRAC shall require that all rights and interests associated with the Product including Intellectual Property (IP) Rights to be assigned to BIRAC. The Fund Recipient(s) and co-owners of the IP shall undertake all necessary actions to effect the assignment.

9. 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.

10. 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.

11. 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, 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 BIRAC, 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 BIRAC after complying with these provisions.
- ii. The Fund Recipient may, before the completion of the Project, terminate this Agreement by giving **three months' notice** in writing to BIRAC. BIRAC may also terminate this Agreement by written notice in the event of "the Fund Recipient" committing breach of any term of this Agreement and either not rectifying it to the satisfaction of BIRAC or not satisfying BIRAC about its inevitability within a specified period. In the event of termination of the Agreement, no further disbursement shall be made by BIRAC and the Fund Recipient shall be liable to return immediately the amount of grant-in-aid already availed from 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.

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. Terms & Conditions and Requisites for Fund Disbursement

a. Agreement of funding

On announcement of Award, all concerned applicants need to sign the Grant-in-aid Letter Agreement (GLA) with BIRAC. A separate Agreement for governing the terms of Royalty shall be entered into between BIRAC and the Company/LLP.

b. 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:

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

14. 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:

https://www.birac.nic.in/desc_new.php?id=217

Contact Information

Further information can be obtained at

BIRAC Website: www.birac.nic.in

Contact Person for query and feedback:

GM & Head-Investment

Biotechnology Industry Research Assistance Council (BIRAC)
5 th Floor, NSIC Business Park,
NSIC Bhawan, Okhla Industrial Estate,
New Delhi –110 020
Phone : 011 - 29878000

Head - Investment: investment@birac.nic.in

Note: In case of any dispute/ ambiguity/ confusion that may occur in the process of shortlisting/ selection, the decision of BIRAC shall be final and binding on all.