



Biotechnology Industry Partnership Programme (BIPP) (An Advanced Technology Science Scheme)

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

Government of India, in November, 2008 approved the implementation of a Public Private Partnership Scheme for promoting innovation research in the Biotech sector. The Biotechnology Industry Partnership Programme (BIPP) was launched in January, 2009.

1.1. What is BIPP?

1.1.1. The present scheme on Biotechnology Industry Partnership Programme (BIPP) is a government partnership with Industries for public support on a cost sharing basis for:

- Path-breaking research in frontier futuristic technology areas having major economic potential and making Indian industry globally competitive and focused on IP creation with ownerships by Indian industry and where relevant, collaborating scientists.
- The development of appropriate technologies in the context of recognized national priorities in the area of agriculture, health, bioenergy, green manufacturing, when the scale of the problem has serious consequences for social and economic development.

1.1.2. This is an Advanced Technology Scheme only for high risk, transformational technology/process development. No incremental development will be supported under BIPP. **The project submitted under BIPP should end at TRL 7 or above.**

1.1.3. BIPP covers four broad categories (I, II, III & IV) as described below:

Category	Description
I	Areas with major social relevance but uncertain market driven demand
II	High risk, discovery innovation research with relevance for making India globally competitive
III A	Evaluation & validation of already existing products of high national importance promoting local innovation (Clinical Trials)
III B	Evaluation & validation of already existing products of high national importance promoting local innovation (Agriculture Field Trials)
IV	Shared cost major facilities , critical for enabling innovation

1.14. Category-I: Partnership with industry for fulfilling major unmet national technology needs in health, agriculture, energy and environment friendly / green manufacturing area. This is mainly for those areas which are of high national and social relevance with no assured market such as:

- **Agriculture** - New crops against drought, salinity or major disease and orphan crops of regional interest where private interest is usually low.
- Rapid development of vaccines, biomarkers drugs, bio-therapeutic agents against major infectious diseases that occur as large outbreaks or epidemics (HIV, tuberculosis, malaria, influenza, dengue, etc.) and chronic diseases such as diabetes or stroke. The categorization will be based on national disease burden data, emphasizing death and disabling morbidity.
- **Bioenergy sector-** cutting edge technology for second generation Biofuel development- Algal Biofuel, Bioethanol etc.
- Biomedical devices and implants- Indian development of currently imported health devices and equipment that are used on a large scale, (imported ones are in accessible due to cost) and whose use has a lifesaving impact. Minor use products will not be supported.

This would be more of translational research in such cases it is envisaged that public institutes would be useful partners, so that the basic R&D leads can be translated to product development by the industry.

1.15. Category-II: Partnership with industry for increasing global competitiveness of Indian Industry in new and futuristic technology

- Support for high risk, accelerated technology development especially in futuristic technologies.
- Only accelerated technology development through transformational change to be supported. No incremental development to be supported. Support is for complete process/technology development leading to high value product commercialization. Some examples are:
 - Nano science applications in Medicine and Agriculture,
 - Bio-based energy related advanced biotechnologies,
 - Advanced biomaterials,
 - Stem cell biology and tissue engineering,
 - System biology and computational biology,
 - Genomics, proteomics and metabolomics related technologies for futuristic diagnostics
 - Novel manufacturing processes,
 - Micro fluidics,
 - Synthetic biology solutions in plant and energy field.
 - Sustainable chemistry and others.

1.1.6. Category-III: Partnership with Industry for evaluation and validation of already products of high national importance.

To promote innovation in the Biotech Industry specially the SME's sector, it is important to provide support for product evaluation and validation. There are a number of products which are developed by the industry specially the SME's and to accelerate their commercialization support for product evaluation and validation is essential. In case of the bio-pharma products clinical trials and in case of agriculture products field trials are a critical step in taking the product to the market. Heavy investment is essential to meet increasing stringent global requirement to undertake these activities and the public sector support specially for products of national and societal relevance needs to be provided. Some of the areas where such support is critical are vaccines, public health care diagnostics, bi-therapeutics, implants and devices, transgenic etc. Support would be provided for phase-I, II and III clinical trials of biotechnology based research efforts and for limited and large scale field trials in the case of agriculture products provided there are Indian innovation involved in technology development. SME's as defined by SBIRI (an approved Scheme) would be preferred recipients of support.

Category III is further sub-divided into:

- Category IIIA (Clinical Trials)
- Category IIIB (Field Trials)

1.1.7. Category-IV: Shared major facilities around technology platform as core facilities.

Access to major facilities is an essential requirement for success in futuristic technologies and to lay foundations for discovery and innovation. It is our experience that national facilities, established with good intent lack user friendliness and are underutilized. Public-Private partnership is justified for establishment of core facilities to advance research in futuristic technologies and science. An appropriate model is management in the private hands, access to private sector at commercial rates and to the SME sector and public sector at preferred rates. This type of collaboration is already approved by the government for the infrastructure sector.

Some examples are:

-  Large animal and transgenic facilities
-  Genomic technology centers / facilities
-  Protein engineering science centres / facilities
-  Chemical and molecular libraries
-  Implant and device prototype building labs
-  GMP facilities for cell based product and vaccines

- ✚ Advanced bioinformatics facilities
- ✚ Microbial and pathogenic repositories i. BSL3-4 facilities

1.2. Uniqueness of BIPP

Support for high risk, accelerated technology development especially in futuristic technologies. Only accelerated technology development through transformational change to be supported. **The project submitted under BIPP should end at TRL 7 or above.**

No incremental development to be supported. Support is for complete process/ technology development leading to commercialization and not limited to just specific events in the commercialization chain e.g. Development of a vaccine, transgenic. Improved second / third generation biofuel.

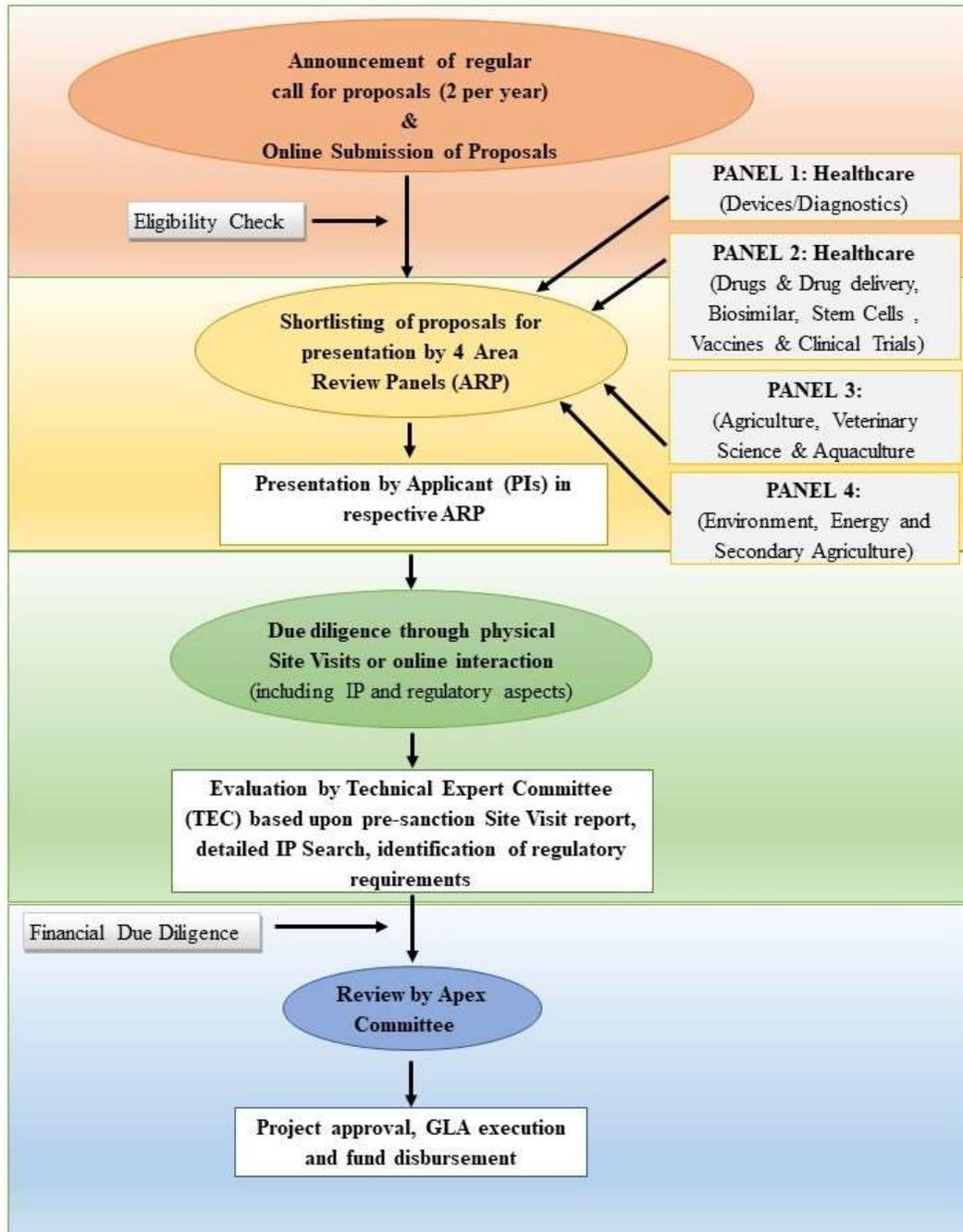
Support for very high risk, nationally and socially relevant areas, with no assured market e.g. Drought resistant rice or wheat, malaria vaccine. This would be more of translational research in such cases it is envisaged that public institutes would be useful partners, so that the basic R&D leads can be translated to product development by the industry.

Provides for product evaluation and validation through support for limited and large scale field trial for agriculture products and clinical trials (Phase I, II, III) for health care products.

Project should necessarily be for novel IP generation. Innovation is the main criteria IP rights belong to industry.

1.3 Operational Mechanism

BIPP 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.*

2. Eligibility

2.1. Who can apply?

1. The proposals can be submitted by following
 - Single or consortia of Company (ies)* incorporated under the Companies Act, 2013 *or*
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

- **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:

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

- **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:

- 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
- 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.

- 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.

2.2. Process of idea generation and eliciting of proposal

2.2.1. Wide ranging consultations are held to generate ideas for cutting edge technologies of national and social relevance and possible solutions, with senior experts, academia and industry. The industry partnership platform established by BIRAC is also used as a knowledge circle for idea generation in partnership with industry. A Technical Screening Committee, which is area specific then works on the concept development based on priority areas identified. This concept is then advertised or if there is limited capacity in the country, the most appropriate companies which meet the required criteria are asked to submit a proposal, along with an academic partner whenever felt necessary.

2.2.2. The specific priority areas identified are widely published and proposals invited. The priority areas could change with the advancing technologies and these would be considered and approved by the Apex Committee.

2.3. How and when to submit proposal?

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 (<http://www.birac.nic.in>)
- If you are a registered user, log-in using the credentials, else you need to register your company/LLP 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 BIPP link.
- Click on the BIPP 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 BIPP 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.*

2.4. Details on How to submit a proposal are available in the **BIPP User Guide (Annexure I)**

2.5. Proforma for Submission of Proposal may be seen at:
<https://www.birac.nic.in/howtoSubmitProposal.php>

3. Evaluation and Decision Making

3.1. 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:
 - ✚ 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.

3.2. Role and Responsibility of the Reviewer and Expert Member

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

- Review the project online and give a detailed evaluation based 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/ online visit after detailed interaction with Applicant.
- Recommend proposals for support under BIPP after Technical Expert Committee discussion.
- Assist BIRAC in Monitoring the Project.

3.3. Guidelines for Reviewers and Panel Members

3.3.1. The evaluation process comprises of following 5 levels of reviews:

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

3.3.2. 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.

3.3.3. 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.

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

3.3.5. 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.

3.4. 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.

3.4.1. Confidentiality and Transparency

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

The review panels and technical committees are comprised of senior technical experts and eminent scientists from research institutions, academia and public sector.

Each member signs a confidentiality certificate before having access to any document related to BIPP proposals. Issues related to conflict of interest are specially taken care of and each reviewer declares a no conflict before they can access any documents. The entire process is online.

BIRAC receives applications under BIPP 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, quote, 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 CANNOT reveal the composition of the panel or any of the discussions during the panel meeting or during the entire review processes.

3.4.2. Conflict of Interest: These guidelines are designed to ensure that all such conflicts are:

1. Identified and disclosed;
2. Recorded; and
3. 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 – e.g. as an applicant for funding or as the supervisor of an applicant;
- Membership of a Panel member in an organisation involved in any current submitted application under the programme; or
- ownership of shares by an Advisory Panel member in a company/LLP involved in any current, established or submitted application, or if the future of the company/LLP will be significantly affected by the success of the application.

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.

You must disqualify yourself as a reviewer of an application if you have had any conflict of interest in the project including the following:

- 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)
- 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.

Guidelines for Confidentiality and No Conflict of Interest are at [Annexure II \(https://birac.nic.in/webcontent/1711086756_Confidentiality_agreement_with_conflict_of_interest_draft.pdf\)](https://birac.nic.in/webcontent/1711086756_Confidentiality_agreement_with_conflict_of_interest_draft.pdf)

4. Funding, Cost Sharing & IP Management

- 4.1.** This scheme provides BIRAC contribution up to 50% of project cost as Grant- In-Aid and remaining cost is to be met through the company/LLP's contribution.

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

1 st instalment on signing of GLA	30%
2 nd instalment on completion of 1 st technical milestone	20%
3 rd instalment on completion of 2 nd technical milestone	20%
4 th instalment on completion of 3 rd technical milestone	20%
5 th instalment on Submission of Project Completion Report	10%

- 4.2.** A Detailed Guidelines for Disbursement of funds and Payment of Royalty are as follow (can also be seen at: https://birac.nic.in/webcontent/BIPP_fund_disb_guideline_2016.pdf)

Guidelines for disbursement of funds - Category I, II, III& IV

The Guidelines for disbursement of funds for BIPP as recommended by the Apex Committee are as follows:

- Level of support to be provided by BIRAC will be in terms of grant-in-aid only
 - ✚ The financial support by BIRAC would be 50 % of the approved Project cost to the Company/LLP fund recipient and rest 50% would be borne by the Applicant company/LLP subject to the exemption provided for under 1(iii).
 - ✚ Provided, if the Project proposal has Institute as Academic Collaborator
 - ✚ (s) then the total contribution by BIRAC to the Company/LLP fund recipient will not exceed 50% of Company /LLP component of the approved Project cost as Grant in Aid and the contribution to the Academic Collaborator (s) will be in addition and above to the Grant in- aid of the Company/LLP Fund Recipient
 - ✚ There is no cap on funding in case of Projects falling under Category I, II & III (Projects of national relevance; Projects involving advanced, high- risk technologies; Clinical trials and agriculture field trials respectively). However, costs would be commensurate with activities to be supported.
 - ✚ For conducting phase III clinical trials/ agriculture field trials with high level of innovation and national relevance, the financial support by BIRAC could be up to 75% of the approved Project cost subject to the condition that only the cost of the trial to be conducted within India will be supported. Please note that BIRAC does not intend to become the “Sponsor” in terms of the Rules for the Manufacture, Use, Import, Export & Storage of Hazardous Micro Organisms/ Genetically Engineered Organisms or Cells, 1989, Drugs and Cosmetics Act, 1940 and the Drugs and Cosmetics Rules, 1945 on provision of funding assistance under the scheme. The funding will be subject to the regulatory compliances as prescribed under the law of the land.
- The cost of the Project to be met by BIRAC will be in the form of grant-in- aid having the corresponding obligation of royalty payment (except category IV).
- The approved funds would be released by BIRAC to the participating industry and collaborating partners in instalments, the first on signing of the Agreement and the subsequent instalments on satisfactory progress of the Project in compliance with the agreement as assessed by the Project Monitoring Committee, based on site visit, discussion and Project report.
- Appropriate Grant Award Letter will be issued by BIRAC for the funds disbursed providing for the governing terms and conditions and these will be accepted by the fund recipient(s) within the time period of four (4) weeks from the date of issue.
- The templates having the governing provisions shall be provided to the shortlisted applicants at the time of carrying out the site visit. It is to be noted that except for very specific and case dependent technical aspects, the terms and conditions of the funding shall be uniformly applicable on all fund recipients.

- A separate Royalty Agreement will be entered into between BIRAC and the Company/LLP fund recipient(s) for disclosure of the sale of the Product(s) and ensuing royalty. “Product” for this purpose shall mean products, services, processes, technologies, materials, software or other innovations resulting from this Project which would generate commercial income
- **ROYALTY GUIDELINES- Payment of Royalty**
 - ✚ The Company/LLP shall pay royalty to BIRAC at the rate of 5 (five) 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) 5% royalty has been paid to BIRAC till the royalty amount paid becomes equal to 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.
 - ✚ Royalty for each financial year shall be payable to BIRAC within 60 (sixty) days of close of corresponding financial year.
 - ✚ If the Company/LLP gets grant-in-aid assistance for more than one Project that will culminate into the same Product(s), then 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).
 - ✚ If the Company/LLP gets grant-in-aid assistance for more than one Project that will culminate into the distinct Product(s), then the Company/LLP shall pay royalty to BIRAC at the rate of 5 (five) 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).
 - ✚ If the Company/LLP intends to transfer or sell the Product, it shall take prior written permission from BIRAC and BIRAC will recover the Royalty amount or 5% of the resultant income excluding GST, 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.

- 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 license 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 -
 - ❖ 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;
 - ❖ 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;

- ✚ BIRAC along with retainment of royalty-free, non-exclusive, irrevocable license to the Product BIRAC, after taking into consideration the fund recipient’s 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.
- ✚ 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.

- **Category IV (Infrastructure) Funding**

The funding assistance under Category IV will be in the form of grant-in-aid without the obligation of payment of Royalty

- A. General:
- i. The financial support provided by BIRAC would be subject to a maximum of Rs. 25 crores.
 - ii. In cases where BIPP support is restricted to equipment cost only, the first instalment would be released when 80% of the civil/construction work has been completed.
- B. For Model I & II:
- i. For a public use facility to be set up by a Company/LLP, the Management and Governance Structure should be a well-defined and separate from the Company/LLP.
 - ii. The company/LLP must define the mode of access to the facility by other users.

The funding guidelines have been explained below:

	Model	Investment, cost-sharing and sharing of benefits
I	Government supported – private managed, facility will be located in a National Laboratory and managed by a consortia of industries or a single industry which has no conflict of interest	<ol style="list-style-type: none"> i. 100% grant-in-aid ii. User charge basis <ul style="list-style-type: none"> • To be levied on direct recipient of benefits from the specific public service • To be aimed at improving the efficiency of resources and • Not to be less than the marginal cost of supplying the specific public services iii. Ownership with Government iv. Differential fee for public and private user
II	Public supported in a public institution in partnership with a private investor who has no conflict of interest	<ol style="list-style-type: none"> i. Cost sharing with the industry ii. Upto 50% grant-in-aid iii. Shared profits (that means net profits available after tax for sharing) iv. Ownership will depend on contribution v. Differential fee for public and private user
III	Specialization facility for discovery and innovation to be established, operator and managed by a single private	<ol style="list-style-type: none"> i. Soft loan (Applicable interest rate is 1% per annum if the sanctioned loan amount is upto Rs. 100 lakhs; and 2% per annum if the sanctioned loan amount is above Rs. 100 lakhs)

	industry	ii. User Charge basic iii. Differential fee for public and private iv. Should devote a % of time for education and training of DBT identified trainees for capacitybuilding
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The repayment of the loan component as well as interest by the industry partner will be in 10 equal annual instalments and recovery would commence six months after the completion of the project as per BIRAC guidelines

4.2. INTELLECTUAL PROPERTY GOVERNING FRAMEWORK

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

- 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.

- 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

- The knowledge and information gained from the Project be promptly and broadly disseminated or published.
- Project Developments and/or New IP are made available and accessible at an affordable price to people most in need within developing countries.
- 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.

5. Project Monitoring & Mentoring

5.1. Project Monitoring Committee (PMC)

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

- To monitor the progress of the Project in conformity with the outputs, milestones, targets and objectives as contained in the Agreement.
- To keep track of funding from any other source for the particular Project.
- To assess the global developments impacting the domain of the Project.
- Based on the foregoing, to assess and suggest:
 - ✚ recommend the release of next instalment or part release thereof by the BIRAC.
 - ✚ recommend 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 Company/LLP request involvement of such partner(s), in the overall interest of the Project,
 - ✚ mentor(s) to assist in overcoming any technological problem faced in the Project implementation; and
 - ✚ revision of the financial assistance.
- To advise on issues related to securing of IPR; and
- To advise on any other matter as referred to it by BIRAC/BMA and/or otherwise reasonably necessary for effective discharge of its duties and/or achievement of aims and objectives of BIPP Scheme.

5.2. Reporting of Progress:

5.2.1. On Successful completion of each Milestone the Company/LLP and other Collaborators are required to submit a detailed Milestone Completion Report (MCR) as per prescribed format.

5.2.2. The MCR is assessed by the PMC for its completion. On recommendation of the PMC, the next Milestone budget is released.

5.2.3. The Company/LLP and the Collaborator shall submit UC and SOE duly certified by internal finance personnel/auditor to BIRAC in the format provided on the completion of the respective milestones. Both Company/LLP and BIPP Contribution are to be accounted for.

Format for Milestone Completion Report (MCR), Utilization Certificate and Statement of Expenditure are at:

[https://birac.nic.in/webcontent/1711086842 Format of milestone and project completion report.pdf](https://birac.nic.in/webcontent/1711086842%20Format%20of%20milestone%20and%20project%20completion%20report.pdf) and

[https://birac.nic.in/webcontent/1711086888 Format of UCSOE financial documents company.pdf \(Annexure III and IV\)](https://birac.nic.in/webcontent/1711086888%20Format%20of%20UC%20and%20SOE%20financial%20documents%20company.pdf)

6. Terms & Conditions and Requisites for Fund Disbursement

6.1. 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.

6.2. Other Requisites for Funds Disbursements to Company/LLP

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

6.2.1. A Board Resolution needs to be passed for acceptance of the Grant-in-aid offer by the BIRAC under BIPP

6.2.2. Opening up a No-Lien Account with a scheduled/nationalized Bank in case of a Company/LLP

6.2.3. Letter of Authorization in case of Institute in the prescribed format of BIRAC

7. 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/LLP/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.

8. 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.

9. Contact Information

Further information can be obtained at BIRAC website

Contact Person for query and feedback:

GM & Head – Investment, Email: investment.birac@gov.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.
